
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 20-F

(Mark One)

- REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**
- OR**
- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2022
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
- OR**
- SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report:

For the transition period from _____ to _____

Commission file number: **001-39124**

Centogene N.V.

(Exact name of Registrant as specified in its charter)

The Netherlands

(Jurisdiction of incorporation or organization)

Am Strande 7

18055 Rostock, Germany

(+49) 381 80113 500

(Address of principal executive offices)

Kim Stratton,

Chief Executive Officer

Tel: (+49) 381 80113 500

Email: kim.stratton@centogene.com

Am Strande 7

18055 Rostock, Germany

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares, par value €0.12 per share	CNTG	The Nasdaq Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act.

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None

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Indicate the number of outstanding shares of each of the issuer’s classes of capital or common stock as of the close of the period covered by the annual report.

The number of outstanding common shares as of December 31, 2022 was:

Title of each class	Number of Shares Outstanding as of December 31, 2022
Common shares, par value of €0.12 per share	27,595,835

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes No

Note—Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of “large accelerated filer,” “accelerated filer,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer Accelerated Filer Non-accelerated Filer Emerging growth company

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Yes No

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Yes No

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Yes No

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

- U.S. GAAP
- International Financial Reporting Standards as issued by the International Accounting Standards Board
- Other

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

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If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

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CERTAIN DEFINITIONS

Except otherwise indicated and except where the context otherwise requires, references in this Annual Report on Form 20-F to:

“Centogene”, the “Company”, the “Group”, “we”, “our”, “ours”, “us” or similar terms	are to Centogene N.V. or Centogene N.V. together with its subsidiaries, as the context may require;
“Exchange Act”	are to the United States Securities Exchange Act of 1934, as amended;
“FDA”	are to the United States Food and Drug Administration;
“IASB”	are to International Accounting Standards Board;
“IFRS”	are to International Financial Reporting Standards;
“SEC”	are to the United States Securities and Exchange Commission;
“Securities Act”	are to the Securities Act of 1933, as amended;
“€”, “EUR” and “euro”	are to the European currency euro; and
“\$”, “USD,” “US\$” and “U.S. dollar”	are to the United States dollar.

PRESENTATION OF FINANCIAL INFORMATION

We report under International Financial Reporting Standards (“IFRS”), as issued by the International Accounting Standards Board (the “IASB”). We present our consolidated financial statements in accordance with IFRS. We have made rounding adjustments to some of the figures included in this Annual Report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

Our financial statements included in this Annual Report are presented in euro and, unless otherwise specified, all monetary amounts are in euro. All references in this Annual Report to “\$”, “U.S. dollars” and “dollars” means U.S. dollars and all references to “€”, “EUR” and “euro” mean euro, unless otherwise noted.

In this Annual Report, unless otherwise indicated, some euro amounts as of December 31, 2022, have been translated into U.S. dollars at the official exchange rate quoted by the European Central Bank. For information on the exchange rate used for the Group’s consolidated financial statements as of December 31, 2022, and 2021 and for the three years ended December 31, 2022, 2021 and 2020, included in this Annual Report, please see “Note 5(a)—Foreign currency and currency translations” to such financial statements.

USE OF TRADEMARKS, TRADE NAMES AND SERVICE MARKS

CENTOGENE™ is our main trademark. The trademarks, trade names and service marks appearing in this Annual Report are property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report are referred to without the symbols ® and ™, but such references should not be construed as any indication that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

FORWARD LOOKING STATEMENTS

This Annual Report contains statements that constitute forward-looking statements. All statements other than present and historical facts and conditions contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this Annual Report, the words “anticipate,” “believe,” “can,” “could,” “estimate,” “expect,” “intend,” “is designed to,” “may,” “might,” “plan,” “potential,” “predict,” “objective,” “should,” or the negative of these and similar expressions identify forward-looking statements.

Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under “Item 3. Key Information—D. Risk Factors” in this Annual Report. These risks and uncertainties include factors relating to:

- our ability to generate cash from operations and attract financing;

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- failure to meet covenants in our debt agreements could result in acceleration of our payment obligations, limit our operating and financial flexibility and in an event of default, result in losses to the assets securing our debt obligations;
- our strategic restructuring initiative and the related restructuring cost;
- our ability to effectively manage our future growth and to execute our business strategy;
- our ability to generate sufficient revenue from our relationships with our pharmaceutical partners and clients, and to otherwise maintain our current relationships, or enter into new relationships, with pharmaceutical partners and clients;
- economic, political or social conditions and the effects of these conditions on our pharmaceutical partners' and diagnostics clients' businesses and levels of business activity;
- the effects of pandemics, epidemics, disease outbreaks and other public health crises, such as the COVID-19 pandemic on our business and results of operations;
- our expectations for our products and solutions achieving commercial market acceptance, and our ability to keep pace with the rapidly evolving industry in which we operate;
- our assumptions regarding market size in the rare disease industry and our growth potential;
- our pharmaceutical partners' and clients' need for rare disease information products and solutions and any perceived advantage of our products over those of our competitors;
- our ability to manage our international expansion, including our exposure to new and complex business, regulatory, political, operational, financial, and economic risks, and numerous and conflicting legal and regulatory requirements;
- our continued reliance on our senior management team and other qualified personnel and our ability to retain such personnel;
- our ability to obtain, maintain, protect and enforce sufficient patent and other intellectual property protection for any products or solutions we develop and for our technology;
- the ongoing protection of our trade secrets, know-how, and other confidential and proprietary information;
- our ability to remediate our material weaknesses in internal control over financial reporting;
- general economic, political, demographic and business conditions in North America, the Middle East, Europe and other regions in which we operate;
- changes in government and industry regulation and tax matters;
- other factors that may affect our financial condition, liquidity and results of operations;
- our ability to comply in the future with all of Nasdaq continued listing standards and rules governing the diversity of our board of directors; and
- other risk factors discussed under "Item 3. Key Information—D. Risk Factors."

You should refer to the section of this Annual Report titled “Item 3. Key Information—D. Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

ENFORCEMENT OF JUDGMENTS

We are organized and existing under the laws of the Netherlands, and, as such, under Dutch private international law rules the rights of our shareholders and the civil liability of our directors and executive officers are governed in certain respects by the laws of the Netherlands. The ability of our shareholders in certain countries other than the Netherlands to bring actions against us, our directors and executive officers may be limited under applicable law. In addition, substantially all of our assets are located outside the United States.

As a result, it may not be possible for investors to effect service of process within the United States upon us or our directors and executive officers or to enforce against them or us in United States courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States. In addition, it is not clear whether a Dutch court would impose civil liability on us or any of our directors and executive officers in an original action based solely upon the federal securities laws of the United States brought in a court of competent jurisdiction in the Netherlands.

As of the date of this Annual Report, there is no treaty in effect between the United States and the Netherlands providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. It is noted that, on the date of this Annual Report, the Hague Convention on Choice of Court Agreements of June 30, 2005 has entered into force for the Netherlands, but has not entered into force for the United States. The Hague Convention of July 2, 2019 on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters has not entered into force for either the Netherlands or the United States. Accordingly, a judgment rendered by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized and enforced by the competent Dutch courts. However, if a person has obtained a judgment rendered by a court in the United States that is enforceable under the laws of the United States and files a claim with the competent Dutch court, the Dutch court will in principle give binding effect to such judgment if (i) the jurisdiction of the U.S. court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the U.S. court was rendered in legal proceedings that comply with the Dutch standards of proper administration of justice including sufficient safeguards (*behoorlijke rechtspleging*), (iii) binding effect of such U.S. judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the U.S. court is not incompatible with a decision rendered between the same parties by a Dutch court, or with a previous decision rendered between the same parties by a foreign court in a dispute that concerns the same subject and is based on the same cause, provided that the previous decision qualifies for recognition in the Netherlands. Even if such a U.S. judgment is given binding effect, a claim based thereon may, however, still be rejected if the U.S. judgment is not or no longer formally enforceable. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the number of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*).

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or our directors, representatives or certain experts named herein who are residents of the Netherlands or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

The United States and Germany currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, in civil and commercial matters. Consequently, a final judgment for payment or declaratory judgments given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Germany. German courts may deny the recognition and enforcement of a judgment rendered by a U.S. court if they consider the U.S. court not to be competent or the decision to be in violation of German public policy principles. For example, judgments awarding punitive damages are generally not enforceable in Germany. A German court may reduce the number of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages.

In addition, actions brought in a German court against us, our management board and supervisory board and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions. In particular, German courts generally do not award punitive damages. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. German procedural law does not provide for pre-trial discovery of documents, nor does Germany support pre-trial discovery of documents under the 1970 Hague Evidence Convention. Proceedings in Germany would have to be conducted in the German language and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our management board and supervisory board and the experts named in this Annual Report.

PART ONE

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable

Item 2. Offer Statistics and Expected Timetable

Not applicable

Item 3. Key Information

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable

C. Reason for the Offer and Use of Proceeds

Not applicable

D. Risk Factors

Summary Risk Factors

In the course of conducting our business operations, we are exposed to a variety of risks, some of which are inherent in our industry and others of which are more specific to our own businesses. The discussion below addresses the material factors, of which we are currently aware, that could affect our businesses, results of operations and financial condition and make an investment in the Company speculative or risky.

Some of these risks include:

Certain Factors Relating to Our Business and Strategy

- Our strategic restructuring initiative may not achieve intended benefits and the related restructuring cost could have a material adverse effect on our business and results of operations.
- We may fail to generate sufficient revenue from our relationships with our clients or pharmaceutical partners to achieve and maintain profitability.
- Many events beyond our control, including geopolitical events, may adversely affect our business.
- We may fail to maintain our current relationships with pharmaceutical companies or enter into new relationships on a similar scale.
- Difficulty in successfully identifying patients for our pharmaceutical partners due to relatively small patient populations for rare diseases.
- We may fail to generate sufficient volumes of data from our diagnostic tests for inclusion in our data repository.
- Volatile, negative or uncertain economic, political or social conditions and the effects of these conditions on our pharmaceutical partners' and diagnostics clients' businesses and levels of business activity.
- We derive a large proportion of our revenues and equipment from agreements with a limited number of pharmaceutical partners and suppliers, respectively.
- Restrictions or delays in the receipt of patient samples to our laboratories for diagnostic testing.
- Substantial product liability or professional liability claims that could exceed our resources.
- Challenges to patient consent validity could impede our rare disease information development efforts.
- Interruption of access or damage to our highly specialized laboratory facilities, storage facilities or equipment.
- Pandemics, epidemics, disease outbreaks and other public health crises, such as the COVID-19 pandemic, have disrupted our business and operations, and future outbreaks or reemergence of the COVID-19 pandemic could materially adversely impact our business, financial condition, liquidity, and results of operations.
- Failure in our information technology systems.
- We rely on a limited number of suppliers, or, in some cases, a sole supplier, for some of our laboratory equipment and may not be able to find replacements or immediately transition to alternative suppliers.
- Inability to attract and retain new talent, including members of our senior management team.
- New and complex business, regulatory, political, operational, financial, and economic risks as a result of international business expansion.
- Unanticipated difficulties involved in the implementation of partnership agreements with our pharmaceutical partners.
- Failure to achieve or maintain sales of our products and solutions.
- Failure to manage our future growth effectively, which could make it difficult to execute our business strategy.
- Inability to successfully commercialize new products or solutions on a timely basis or at all.
- Failure to expand our direct sales and marketing force to adequately address our pharmaceutical partners' and clients' needs.
- The knowledge and interpretation-based solutions we provide to our pharmaceutical partners may not achieve significant commercial market acceptance.
- Failure to keep pace with the rapidly evolving industry in which we operate.
- We may fail to successfully respond to increasing demand for our products and solutions.
- Failure to obtain favorable pricing for our products and to meet our profitability expectations.
- Ethical, legal and social concerns related to the use of genomic information could reduce demand for our genetic rare disease knowledge and interpretation-based products and solutions.
- Our resource allocation decisions may lead us to focus on research and development programs that are not commercially viable, and as a result we may be unable to recover the costs incurred under these efforts.
- Failure to compete successfully with competitors, including new entrants in the market.

- If our pharmaceutical partners experience any of a number of possible unforeseen events in connection with their clinical trials, our ability to commercialize future solutions or improvements to existing solutions could be delayed or prevented.
- Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, insider trading, misappropriation of trade secrets and wrongful use or disclosure of confidential information.
- We may lose the support of key thought leaders and fail to establish our products and solutions as a standard of care for patients with rare and neurodegenerative diseases.
- Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- We are subject to significant foreign currency exchange controls in certain countries in which we operate.
- We may acquire assets or other businesses that could negatively affect our operating results, dilute our shareholders' ownership, or increase our debt.
- We may enter into joint ventures with third parties, which may subject us to various risks, including limited decision-making authority, reliance on our joint venture partners' financial condition and the risk of disputes with our joint venture partners, which could adversely affect us.
- Regulatory risks including as a result of conflicting requirements, regulatory changes in the way that the FDA and the European Union regulate laboratory developed tests, non-compliance with FDA and EMA regulatory requirements and with evolving European and other data privacy laws, violations of worldwide anti bribery laws, transactions involving Iran or other sanctioned countries, and our inability to obtain timely regulatory approvals or adhere to regulations regarding our products and solutions.
- We may fail to achieve coverage or adequate reimbursement for our products and solutions by commercial third-party payors or government payors.
- Inspections, reviews, audits and investigations under federal and state government programs and contracts and health insurance providers regarding our billing practices.

Intellectual Property Risks Related to Our Business

- Inability to obtain and maintain patent and other intellectual property protection for any products or solutions we develop and for our technology, allowing our competitors to develop and commercialize products and solutions similar or identical to ours.
- Additional intellectual property risks, including our inability to protect the confidentiality of our trade secrets, know how, and other confidential and proprietary information, the unenforceability of our patents and intellectual property rights, third party claims of intellectual property infringement or commercial rights to inventions we develop, non-compliance with patent agency requirement and dependence on licenses granted to us by others.

Risks Relating to Our Financial Condition and Capital Requirements

- We have a history of losses, and we may incur losses in the future.
- We will require additional funding, which may not be available to us in the desired amount, at the desired time or on acceptable terms, or at all.
- Failure to obtain additional capital to fund, develop and expand our operations.
- We may fail to meet covenants in our debt agreements, which could result in acceleration of our payment obligations under our debt agreements, limit our operating and financial flexibility and in an event of default, result in losses to the assets securing our debt obligations.
- Increasing our financial leverage could affect our operations, profitability, and ability to raise additional capital.
- We may be required to refund grants and subsidies and may fail to meet covenants under loan facilities.
- Our results of operations could be materially adversely affected by fluctuations in foreign currency exchange rates.
- We have identified three material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate our material weaknesses or establish and maintain an effective system of internal control over financial reporting, we may not be able to report our financial results accurately or to prevent fraud, and such failure could cause investors to lose confidence in our reported financial and other public information and have a negative effect on the trading price of our common shares.

Certain Factors Relating to Our Common Shares

- Risks relating to our common shares, including fluctuations in our share price, risk of dilution upon future issuances, multi-jurisdictional tax consequences, impacts of our Dutch public company status (including differing shareholder rights), risks resulting from our emerging growth company and foreign private issuer status, our non-payment of dividends and our broad discretion in the use of our cash on hand.
- We may in the future not comply with all of Nasdaq's continued listing standards and our common shares could be delisted.
- Failure to comply with Nasdaq's rules governing the diversity of our board of directors.
- Although we do not believe that we were a "passive foreign investment company," or a PFIC, for U.S. federal income tax purposes for 2022, there is a significant risk that we may be a PFIC for 2023 or one or more future taxable years. If we are a PFIC for any taxable year, U.S. shareholders may be subject to adverse U.S. federal income tax consequences.

Additional factors discussed below could affect our business, prospects, financial condition, and results of operations. You should carefully consider the following risks and uncertainties and all the other information in this Annual Report before making any investment decision. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common shares could decline, and you could lose all or part of your investment. The risks described below are those that we currently believe may materially affect us. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial.

Certain Factors Relating to Our Business and Strategy

Our strategic restructuring initiative may not achieve intended benefits and the related restructuring cost could have a material adverse effect on our business and results of operations.

In November 2021, our management board and supervisory board approved a restructuring plan to further reduce operating costs and improve profitability. The estimated total restructuring charges, which consist of personnel costs and one-time severance charges, was approximately €640 thousand during 2021 and 2022. In March 2022, the plan finalized and the amount of the incurred costs was approximately €740 thousand. In addition, on February 1, 2022, we announced the resignation of Dr. Andrin Oswald as CEO due to prolonged medical leave of absence and the appointment of Kim Stratton as CEO.

We are pursuing a number of additional restructuring initiatives that could extend our cash runway until our operating cash flows reach break-even. In addition to measures intended to reduce our operating expenditure, we are in active discussions with various counterparties regarding new private equity financing and/or additional debt (which may be convertible debt) financing.

The process to undertake these restructuring initiatives could take more time and be more costly than anticipated, and we may not be able to obtain the anticipated operational improvements within the contemplated timing or at all. The restructuring initiatives could also place substantial demands on our management, which could lead to the diversion of management's attention from other business priorities. Further, the restructuring may yield unintended consequences such as attrition beyond our targeted workforce reduction. The Company's success is dependent on the skills of our key personnel. Our restructuring plan involving workforce reduction may lead to an unintended loss of experienced employees or know-how. The loss of any member of our key personnel and actual or threatened work slowdowns or stoppages could lead to operational delays or cost increases. In addition, if we reduce or eliminate some or all of our research and development programs, this could cause significant delays in our preclinical, clinical and regulatory efforts, which could adversely affect our business prospects. If these incidents occur or if we are unable to attract, retain and maintain productive relations with our employees and key professionals, we might fail to deliver under existing commitments to third parties, which could harm our business and negatively affect our operating results and financial condition.

We may fail to generate sufficient revenue from our relationships with our clients or pharmaceutical partners to achieve and maintain profitability.

We believe our commercial success is dependent upon our ability to successfully market and sell our products and solutions to clients and pharmaceutical partners, to continue to sell our suite of diagnostic tests, to continue to expand our current relationships and to develop new relationships with pharmaceutical partners. The demand for our existing services may decrease or may not continue at historical rates for several reasons, including, among others, the development by competitors of new products or solutions that we are not able to commercialize, and increased competition from companies that offer similar products and solutions. In addition to reducing our revenue, if our pharmaceutical partners or clients decide to decrease or discontinue their partnerships or relationships with us, and their use of our knowledge and interpretation-based solutions, this may reduce our access to research and patient data that facilitates the incorporation of new information about rare or neurodegenerative diseases into our data repository. Our business model and strategy depend on the continued input of new data into our repository, and any such reduction in access to research and patient data could affect our ability to offer the same quality and scope of solutions to our pharmaceutical partners and other clients, which could adversely affect our business, prospects, financial condition, and results of operations. We are currently not profitable. Even if we succeed in increasing adoption of our existing solutions by pharmaceutical partners or tests by our clients or pharmaceutical partners, we may fail to generate sufficient revenue to achieve and maintain profitability.

Many events beyond our control, including geopolitical events, may adversely affect our business.

Many events beyond our control can adversely affect the healthcare industry, with a corresponding negative impact on our business and results of operations. Our operations and those of our third-party suppliers and collaborators could be subject to power shortages, telecommunications failures, water shortages, floods, hurricanes, earthquakes or other extreme weather conditions, medical epidemics, labor disputes, war, or other business interruptions. Although we have limited business interruption insurance policies in place, any interruption could come with high costs for us, as salaries and loan payments would usually continue. Moreover, any interruption could seriously harm our ability to timely proceed with our diagnostics, pharmaceutical collaborations, and research activities.

For example, the ongoing conflict between Russia and Ukraine has significantly disrupted supply chains and international trade. Following Russia's invasion of Ukraine in February 2022, the United States, the United Kingdom, the European Union and other countries and supra-national entities have imposed comprehensive economic sanctions against Russia. The effects of the ongoing conflict between Russia and Ukraine on the Russian and global economy remains uncertain. However, they have resulted in significant volatility in financial markets, as well as an increase in energy and commodity prices globally.

While our business and operations are currently not significantly impacted, it is not possible to predict the broader or longer-term consequences of the Russia-Ukraine conflict. If the armed conflict involving Russia and Ukraine were to spread to other countries in Europe, we may incur significant costs associated with assisting our employees with relocating to neighboring countries or providing other forms of aid. We may also lose clients or experience other disruptions of our business activities in the impacted regions.

Other consequences of the Russia-Ukraine conflict could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and financial markets. Such geopolitical instability and uncertainty could have a negative impact on our ability to conduct ongoing and future Diagnostics activities, Pharmaceutical collaborations, and research programs in certain regions. This could be due to trade restrictions, embargoes and export control law restrictions, and logistics restrictions, which could increase the costs, risks and adverse impacts from supply chain and logistics challenges. There can be no assurance that the Russia-Ukraine conflict, including any resulting sanctions, export controls or other restrictive actions, will not have a material adverse impact on our future operations and results.

In addition, increases in inflation may have an adverse effect on our business. Current and future inflationary effects may be driven by, among other things, supply chain disruptions and governmental stimulus or fiscal policies as well as the ongoing military conflict between Russia and Ukraine. Continuing increases in inflation could impact the overall demand for our products, our costs for labor, material and services, and the margins we are able to realize on our products and services, all of which could have an adverse impact on our business, financial position, results of operations and cash flows.

We may fail to maintain our current relationships with pharmaceutical companies, or enter into new relationships on a similar scale.

Our success in the future depends in part on our ability to maintain relationships and to enter into new relationships with pharmaceutical partners. Partnerships are complex and time-consuming to negotiate and document. Whether we reach a definitive agreement for a partnership will depend on a number of factors, including, among other things, upon our partners' assessment of our industry knowledge, data repository, logistical resources and expertise, the terms and conditions of the proposed partnership, and our partners' evaluation of the potential value added from our rare and neurodegenerative disease knowledge and insights. If we are unable to do so, we may have to curtail our research on a particular rare or neurodegenerative disease or increase our expenditures and undertake research and development activities at our own expense. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners.

Our ability to maintain our current relationships with our pharmaceutical partners, or enter into new relationships, can be difficult due to several factors, including that:

- our products and solutions are focused towards facilitating the development of rare disease treatments which limits our market to pharmaceutical partners active in the rare and neurodegenerative disease space;
- orphan drug development is complex, expensive and time-consuming due to limited identified patient populations and limited industry knowledge of rare diseases;
- our pharmaceutical partners may decide to decrease or discontinue their use of our rare and neurodegenerative disease information platform due to circumstances outside of our control, including changes in their research and development plans, whether they can obtain positive data or regulatory approval in clinical trials or successfully commercialize a treatment, changes in the regulatory environment, or utilization of internal testing resources or genetic or other tests performed by other parties, among others;
- internal and external constraints may be placed on potential pharmaceutical partners that can limit the number and type of relationships with companies like us they can consider and consummate; and
- our pharmaceutical partners may be dissatisfied with our products or solutions or that we may fail to deliver expected benefits from our products or solutions.

Additionally, some of our pharmaceutical partners have contracted with us to provide testing for large numbers of samples or to focus our research on a particular rare or neurodegenerative disease, which could restrict our ability to perform tests for other clients or pharmaceutical partners or limit our ability to expand our data repository outside of a specified patient population or rare disease. If we fail to maintain our current relationships with our pharmaceutical partners, or enter into new partnerships, our business could suffer.

Because the identified patient populations for rare diseases are relatively small, it may be difficult to successfully identify patients for our pharmaceutical partners.

Our inability to identify a sufficient number of patients for our partners' clinical trials could result in significant delays and could require our partners to abandon one or more clinical trials altogether. Enrollment delays in our partners' clinical trials may result in increased development costs for our partners' drug candidates, which would cause the value of the solutions which we offer to our pharmaceutical partners to decline. If we are unable to identify patients with a specified driver of disease or applicable genomic alteration, this could compromise our ability to add value to our partners' clinical trials by accelerating clinical development and regulatory timelines. In addition, our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our partners' existing treatments or drug candidates, are based on our internal estimates derived from data in our repository. These estimates may prove to be incorrect, and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States, European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our partners' drug candidates or may be difficult to identify and access, all of which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We may fail to generate sufficient volumes of data from our diagnostic tests for inclusion in our data repository.

Our business model assumes that we will be able to continue to generate significant diagnostic test volume to maintain the generation of data that feeds into our data repository, which is necessary for the development of new products and solutions for our pharmaceutical partners and clients. We may not succeed in continuing to drive clinical adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic or other data from our tests have only recently become available at relatively affordable prices, the pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic or other data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic or other testing that is specific to one or a few genes. To generate demand for our tests, we will need to continue to make our diagnostics clients, as well as physicians and key opinion leaders, aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic or other data available from which to make treatment decisions. In addition, physicians in other areas of medicine may not adopt genetic or other testing for certain rare diseases as readily as it has been adopted for some more well-known rare diseases and our efforts to sell our tests to physicians outside of a set number of rare diseases may not be successful. A lack of or delay in increased clinical acceptance of our diagnostic tests would negatively impact sales and market acceptance of our tests and limit our ability to expand on the scope and quality of knowledge and interpretation-based solutions offered to our pharmaceutical partners, which could in turn impact our revenue growth and potential profitability.

In addition, genetic or other testing is still relatively expensive, and many potential pharmaceutical partners and clients may be sensitive to pricing concerns. Potential pharmaceutical partners or clients may not adopt our tests if adequate reimbursement is unavailable, or if we are not able to maintain low prices in the future relative to our competitors. If we are not able to generate demand for our tests at sufficient volumes, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition, and results of operations could be materially harmed.

We may be adversely affected by volatile, negative or uncertain economic, political or social conditions and the effects of these conditions on our pharmaceutical partners' and diagnostics clients' businesses and levels of business activity.

Global economic conditions affect our pharmaceutical partners' and diagnostic clients' businesses and the markets they serve, and volatile, negative or uncertain economic conditions may have an adverse effect on our revenue growth and profitability. Volatile, negative or uncertain economic conditions in our significant markets, in particular in our North America, Middle East or European regions, where we generated 42.0% and 13.2%, respectively, of our total revenues for the year ended December 31, 2022, could undermine business confidence, both in those markets and other markets, and cause our pharmaceutical partners or clients to reduce or defer their spending on new technologies or initiatives or terminate existing contracts, which would negatively affect our business. Growth in the markets we serve could be at a slow rate, or could stagnate, for an extended period of time. Differing economic conditions and patterns of economic growth and contraction in the geographical regions in which we operate and the industries we serve may affect demand for our products and solutions. Weakening in these markets as a result of high government deficits, credit downgrades or otherwise could have a material adverse effect on our results of operations. Ongoing economic volatility and uncertainty affects our business in a number of other ways, including making it more difficult to accurately forecast partner demand beyond the short term and effectively build our revenue and resource plans, particularly given the iterative nature of the negotiation of new contracts with our pharmaceutical partners. This could result, for example, in us not having the level of appropriate personnel where they are needed and could have a significant negative impact on our results of operations.

In addition, global capital markets have continued to display increased volatility in response to global events, including the COVID-19 virus pandemic and the Russian invasion of Ukraine. Future crises may be precipitated by any number of causes, including natural disasters, epidemics, geopolitical instability and war, changes to energy prices or sovereign defaults. Any sudden or rapid destabilization of global economic conditions could negatively impact our ability to obtain new equity or debt financing or make other suitable arrangements to finance our operations. If increased levels of volatility continue or in the event of a rapid destabilization of global economic conditions, including as a result of an escalation of the Russia-Ukraine war, it may result in a material adverse effect on the Company and the trading price of the Company's common shares could be adversely affected.

Furthermore, increases in inflation may have an adverse effect on our business. Current and future inflationary effects may be driven by, among other things, supply chain disruptions and governmental stimulus or fiscal policies as well as the ongoing military conflict between Russia and Ukraine. Continuing increases in inflation could impact the overall demand for our products, our costs for labor, material and services, and the margins we are able to realize on our products, all of which could have an adverse impact on our business, financial position, results of operations and cash flows.

Moreover, acts of terrorist violence, political unrest, armed regional and international hostilities and responses to these hostilities, natural disasters, global health risks or pandemics or the threat of or perceived potential for these events could have a negative impact on us. These events could adversely affect our pharmaceutical partners' levels of business activity and precipitate sudden significant changes in regional and global economic conditions and cycles. These events also pose significant risks to our people and to physical facilities and operations around the world, whether the facilities are ours or those of our distributors, pharmaceutical partners or physicians that utilize our diagnostic testing services. By disrupting communications and travel and increasing the difficulty of obtaining and retaining highly skilled and qualified personnel, these events could make it difficult or impossible for us to deliver products and solutions to our clients and pharmaceutical partners. Extended disruptions of electricity, other public utilities or network services at our facilities, as well as system failures at, or security breaches in, our facilities or systems, could also adversely affect our ability to serve our clients and pharmaceutical partners. We might be unable to protect our people, facilities and systems against all such occurrences. We generally do not have insurance for losses and interruptions caused by terrorist attacks, conflicts and wars. If these disruptions prevent us from effectively serving our clients and pharmaceutical partners, our results of operations could be adversely affected.

We derive a large proportion of our revenues from agreements with a limited number of pharmaceutical partners and clients.

We have historically earned a large proportion of our revenue from a limited number of pharmaceutical partners and diagnostic testing clients. In the years ended December 31, 2022 and 2021, our top five pharmaceutical partners, in the aggregate, accounted for 29.8% and 31.2% of our revenues, respectively. The loss of, or material reduction in, revenues from any one of our major pharmaceutical partners or clients could materially reduce our total revenues, harm our reputation in the industry and/or reduce our ability to accurately predict our revenue, net income and cash flow. The loss of, or material reduction, in revenue from any one of our major pharmaceutical partners or clients could also adversely affect our gross profit and utilization as we seek to redeploy resources previously dedicated to that partner. We cannot assure you that revenue from our major pharmaceutical partners or clients will not be significantly reduced in the future. We also may not be able to maintain our relationships with our major pharmaceutical partners or clients on existing or on continued favorable terms and our major pharmaceutical partners or clients may not renew their agreements with us, in which case our business, financial condition and results of operations would be adversely affected.

In particular, during the year ended December 31, 2022, our collaboration with Takeda Pharmaceutical Company Limited, represented 15.5% of our total revenues (2021: 24.8%). We expect that our collaboration with Takeda will continue to account for a material portion of our revenue in 2023. The revenue attributable to Takeda may fluctuate in the future, which could have an adverse effect on our financial condition and results of operations. In addition, changes in the terms of our agreements with Takeda, or a modification or termination of our relationship with Takeda, could result in delays in the receipt of revenue by us, or a temporary or permanent loss of revenue to us. In addition, certain pharmaceutical companies, including those with which we currently have agreements, may choose not to do business with us or may seek out other partners for genetic rare disease information due to our strategic collaboration with Takeda, particularly if they are actual or potential competitors with Takeda. If we are unable to continue to grow our business with other pharmaceutical companies, our business and results of operations would be adversely affected.

Our client concentration may also subject us to perceived or actual leverage that our pharmaceutical partners or clients may have, given their relative size and importance to us. If our pharmaceutical partners or clients seek to negotiate their agreements on terms less favorable to us and we accept such unfavorable terms, this may have a material adverse effect on our business, financial condition and results of operations. Accordingly, unless and until we diversify and expand our client base, our future success will significantly depend upon the timing and volume of business from our largest pharmaceutical partners and clients and the financial and operational success of these pharmaceutical partners and clients.

We may face restrictions or delays in the receipt of patient samples to our laboratories for diagnostic testing.

Our business depends on our ability to receive samples quickly and reliably from physicians. Our proprietary, CE-Marked dried blood spot (DBS) collection kit, CentoCard®, is typically sent from locations worldwide to our laboratory in Rostock, Germany as well as our Cambridge, Massachusetts, United States facility. Disruptions in delivery, whether due to factors beyond our control such as natural disasters, pandemics, terrorist threats, political instability, wars, governmental policies, failures by physicians to properly label or package the samples, failure by postage services, labor disruptions, bad weather or other factors could adversely affect the receipt by us of samples or specimen integrity and could impact our ability to process samples in a timely manner and to provide our services to our clients and pharmaceutical partners. There is a general trend in certain countries, for example in China, Saudi Arabia and certain countries in South America, where policies have been introduced or are under consideration that restrict the processing of genetic or other testing outside the country in which the patient is located. This could disrupt the transportation of samples to our testing facilities in Germany and the United States from such countries and could adversely impact our current business operations or prevent us from expanding into certain new regions.

In addition, the majority of our samples are delivered to us via regular postal services worldwide. If such services are disrupted, or if we are unable to continue to obtain expedited delivery services or specialized delivery services for certain products, such as our prenatal algorithmic test, on commercially reasonable terms, our operating results may be adversely affected.

We may become subject to substantial product liability or professional liability claims that could exceed our resources.

The marketing, sale and use of our products and solutions could lead to the filing of product liability claims if someone were to allege that our products and solutions identified inaccurate or incomplete information regarding the diagnostic information of the disease indication analyzed, reported inaccurate or incomplete information concerning the available treatments for a certain type of rare or neurodegenerative disease or otherwise failed to perform as designed. For example, we have been subject to a claim from a client that our prenatal diagnostic test conducted at their request failed to identify a specific mutation present in a patient. See “Item 4. Information On the Company—B. Business Overview—Legal Proceedings” and “Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Legal Proceedings.” We may also be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Our service and professional liability insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation or cause current clients or pharmaceutical partners to terminate existing agreements and potential clients or pharmaceutical partners to seek other partners, any of which could impact our results of operations.

If the validity of a consent from a patient was challenged, we could be forced to stop using certain data resources, which would impede our rare and neurodegenerative disease information development efforts.

We provide diagnostic testing services to patients of our pharmaceutical partners and diagnostics clients worldwide. We also provide products and solutions, including biomarker development and testing, to our pharmaceutical partners. Such products and solutions involve the aggregation of data obtained from patients in our existing data repository and data obtained from new tests conducted both on patients whose samples remain in our biobank or new patients from whom we collect samples.

To a large extent, we also rely upon our pharmaceutical partners, our clients and, in some cases, third-party laboratories to collect the subjects’ informed consent and comply with applicable local laws and international regulations. Although we maintain policies and procedures designed to monitor the collection of consent by both us and such third parties, we or third parties may not obtain the required consent in a timely manner, or at all. In addition, consent that we have obtained or will obtain may not meet the existing or future standards required by relevant governmental authorities.

The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of consent and the status of genetic material under many different legal systems. In some jurisdictions, samples that contain a person's DNA might irrevocably qualify as personal data, as in theory such samples can never be completely anonymized. Legitimate interests of the donor might cause a "revival" of his or her personal rights in the future and limit our rights of utilization. The subject's consent obtained in any particular country could be withdrawn or challenged in the future, and those consents could prove invalid, unlawful, or otherwise inadequate for our purposes. Furthermore, we may face disputes with patients should their data be used in a manner which they did not expect or if the consent was recorded incorrectly or obtained fraudulently. Any findings against us, or our pharmaceutical partners, clients, or distributors, could deny us access to or force us to stop using certain of our clinical data or samples, which would impede our genetic or other information solution development efforts. We could become involved in legal challenges, which could consume our management and financial resources.

If access to our highly specialized laboratory facilities, storage facilities or equipment is interrupted or damaged, our business could be negatively impacted.

Our diagnostic testing products and pharmaceutical solutions are rendered at our laboratory facilities. We currently run most of our core diagnostic testing at our laboratory in Rostock, Germany, and we also commenced operations at our laboratory in Cambridge, Massachusetts, United States in August 2018. If one or more of our laboratories, and particularly our facility in Rostock, become inoperable or some or all of our key equipment ceases to function even for a short period of time, we may be unable to perform our genetic or other tests or develop solutions in a timely manner or at all, which may result in the loss of clients and pharmaceutical partners or harm to our reputation, and we may be unable to regain those clients and pharmaceutical partners or repair our reputation in the future. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, flood, power loss, communications or internet failure or interruption, or terrorism, which may render it difficult or impossible for us to operate our information platforms or equipment for some period of time.

In particular, the biomaterials that are stored in our biobank are located in our Rostock facility. Should the biomaterials that we store there be damaged or destroyed, we would lose part or all our existing biomaterials and as a result we would not be able to retest this material for future research and development uses.

Furthermore, our facilities and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild any of our facilities or license or transfer our proprietary technology to a third party, particularly considering the licensure and accreditation requirements and specific equipment needed for laboratories like ours. Even in the unlikely event we are able to find a third party with such qualifications to enable us to perform our genetic or other tests or develop our solutions, we may be unable to negotiate commercially reasonable terms with such third parties. Any interruption of our laboratory operations could harm relationships with our clients and pharmaceutical partners or regulatory authorities, which could adversely affect our ability to generate revenue or maintain compliance with regulatory standards.

While we carry insurance for damage to our property and laboratory and the disruption of our business, such insurance may not cover all of the risks associated with damage to our property or laboratory or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses, may be challenged by insurers underwriting the coverage, and may not continue to be available to us on acceptable terms, if at all.

Pandemics, epidemics, disease outbreaks and other public health crises, such as the COVID-19 pandemic, have disrupted our business and operations, and future outbreaks or reemergence of the COVID-19 pandemic could materially adversely impact our business, financial condition, liquidity and results of operations.

Pandemics, epidemics or disease outbreaks either locally or globally, including the COVID-19 pandemic, have disrupted, and may in the future disrupt, our business, which could materially affect our results of operations, financial condition, liquidity and future expectations. The COVID-19 pandemic adversely affected businesses, economies and financial markets worldwide, placed constraints on the operations of businesses, decreased consumer mobility and activity, and caused significant economic volatility in capital markets. Any such events in the future, including a reemergence of COVID-19, may adversely impact our global operations, particularly as it relates to the United States (from where a significant proportion of our sequencing products are sourced) as well other countries in which we operate and from where we receive tests, may result in the loss of our significant client relationships and result in significant volatility of the trading price of our common shares. We may also be subject to enhanced legal risks, including potential litigation related to any future pandemics. Any new pandemic or other public health crisis, or the reemergence of the COVID-19 pandemic, could have a material impact on our business, financial condition and results of operations going forward.

To the extent any pandemics, epidemics, disease outbreaks and other public health crisis adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described under “—We may face restrictions or delays in the receipt of patient samples to our laboratories for diagnostic testing” and “—We may be adversely affected by volatile, negative or uncertain economic, political or social conditions and the effects of these conditions on our pharmaceutical partners’ and diagnostics clients’ businesses and levels of business activity.”

We depend upon our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations, including the CENTOGENE Biodatabank, our CentoPortal® client-facing platform, our laboratory information management system, our third-party datacenter solutions, our broadband connections and our client relationship management system. We have installed several enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial controls and reporting, contract management and other infrastructure operations. These information technology systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities. In addition, our system is backed up by two offsite data centers that offer a disaster recovery system for our database in separate locations near Frankfurt. Any technical problems that may arise in connection with third-party data center hosting facilities could result in interruptions in our service.

Our information technology systems are vulnerable to damage from a variety of sources, including network failures, malicious human acts, and natural disasters. Our business will also be harmed if our laboratory partners and potential laboratory partners believe our service is unreliable. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, malicious computer software (malware), and similar disruptive problems. Failures or significant downtime of our information technology systems, or those used by our third-party service providers, could prevent us from conducting our comprehensive genomic analyses, preparing, and providing reports and data to partners and physicians, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities, and managing the administrative aspects of our business. We may also need to expend significant additional resources to protect against cybersecurity threats or to address actual breaches or to redress problems caused by cybersecurity breaches. Additionally, to the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur significant liability. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

We rely on a limited number of suppliers, or, in some cases, a sole supplier, for some of our laboratory equipment and may not be able to find replacements or immediately transition to alternative suppliers.

We believe that there are only a few equipment manufacturers that are currently capable of supplying and servicing the sequencing equipment necessary for our laboratory operations. For example, we rely on Illumina as a key supplier for certain sequencing equipment used for our processes. We may not be able to obtain acceptable substitute equipment from another supplier on the same basis or at all. Even if we are able to obtain acceptable substitutes from replacement suppliers, their use could require us to significantly alter our laboratory operations. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing or maintaining the proper function of this laboratory equipment. Any such interruption could negatively impact research and development and launches of new products or solutions, and significantly affect our business, financial condition, results of operations, and reputation.

The loss or transition of any member of our senior management team, or our inability to attract and retain new talent, could adversely affect our business.

Our success depends on the skills, experience, and performance of key members of our senior management team. The individual and collective efforts of these employees will be important as we continue to develop the CENTOGENE Biodatabank and additional products and solutions, and as we expand our commercial activities. The loss or incapacity of existing members of our senior management team could adversely affect our operations if we experience difficulties in hiring qualified successors.

The complexity inherent in integrating a new key member of the senior management team with existing senior management may limit the effectiveness of any such successor or otherwise adversely affect our business. Leadership transitions can be inherently difficult to manage and may cause uncertainty or a disruption to our business or may increase the likelihood of turnover of other key officers and employees. Specifically, a leadership transition in the commercial team may cause uncertainty about or a disruption to our commercial organization, which may impact our ability to achieve sales and revenue targets.

Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses globally. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting, or retaining qualified sales people. Recruitment and retention difficulties can limit our ability to support our research and development and sales programs.

International expansion of our business exposes us to new and complex business, regulatory, political, operational, financial, and economic risks.

Our business strategy incorporates plans for significant expansion in the countries in which we currently operate and internationally. Doing business internationally involves several risks, including:

- multiple, conflicting, and changing laws and regulations such as data protection laws, privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements (including requirements related to patient consent, testing of genetic material and reporting the results of such testing) and other governmental approvals, permits, and licenses, or government delays in issuing such approvals, permits, and licenses;
- failure to obtain regulatory approvals for the manufacture and sale of our products and use of our products and solutions in various countries;
- transition and management of our former distribution relationships in various countries;
- potentially relevant third-party intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property rights;
- logistics and regulations associated with preparing, shipping, importing and exporting tissue and blood samples, including infrastructure conditions, transportation delays, and customs;
- limits in our ability to penetrate new geographical regions due to competition;
- logistical issues or increases in costs of transporting tests and samples since our diagnostic tests are conducted primarily in Germany;
- financial risks, such as the impact of local and regional financial crises on demand and payment for our products and solutions, and exposure to foreign currency exchange rate fluctuations;
- risks associated with operations in countries which have experienced, or are currently experiencing, high rates of inflation which increase our costs, inhibit economic growth and could lead to reduced demand for our products and solutions;
- natural disasters, political, and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions; and

- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distribution activities that may fall within the purview of the United States Foreign Corrupt Practices Act (the “FCPA”) or comparable foreign regulations, including its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations. The difference in regulations under the laws of the countries in which we may expand and the laws of the countries in which we currently operate may be significant and, in order to comply with such new laws, we may have to implement global changes to our products and solutions or business practices. Such changes may result in additional expense to us and either reduce or delay development of our products and solutions, commercialization of our biomarkers and other solutions or expansion of our data repository and biobank. In addition, any failure to comply with applicable legal and regulatory obligations could affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our activities in these countries.

Failure to manage these and other risks may have a material adverse effect on our operations in any country and on our business as a whole.

Implementation of partnership agreements with our pharmaceutical partners may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of client relationships and diversion of management’s attention.

The negotiation of our existing partnership agreements, as well as any new partnership agreements that we enter into, take up significant management time and resources. Moreover, in part due to the complex nature of our partnership agreements, which typically provide for research and development collaboration as well as utilization of our patient screening processes, we may need to expend capital and dedicate manpower to meeting the requirements of our pharmaceutical partners. Any partnership agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations with other third parties, or to otherwise provide products and solutions in connection with a particular rare disease indication. As a result of these and other factors, our partnership agreements may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of client relationships and diversion of management’s attention.

Many of these factors will be outside of our control, and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management’s time and energy, which could materially impact our business, financial condition, and results of operations. As a result, we cannot assure you that our relationship with any pharmaceutical partner will result in the realization of the anticipated benefits.

If our products and solutions do not perform as expected, we may fail to achieve or maintain sales of our products and solutions.

Our success depends on the market’s confidence that we can provide accurate diagnostic testing products and reliable, high-quality rare and neurodegenerative disease information solutions. Our partnerships with our pharmaceutical partners and clients are typically designed to provide results in respect of a particular disease, and our preliminary assessments or knowledge about such disease may necessarily be limited by the amount of information currently available. As a result, the work we undertake on behalf of our pharmaceutical partners and clients may not yield the results that our pharmaceutical partners and clients expect or anticipate. We believe that our pharmaceutical partners and clients are likely to be particularly sensitive to solution and testing service defects and errors, including if our products or services fail to detect genomic or other alterations with high accuracy from clinical specimens or if we fail to accurately develop a biomarker.

Moreover, we may fail to maintain the accuracy and reproducibility we have demonstrated to date with our genetic or other testing services, particularly for clinical samples, as our test volume increases. The sequencing process yields that we achieve depend on the design and operation of our sequencing process, which uses several complex and sophisticated biochemical, informatics, optical, and mechanical processes, many of which are highly sensitive to external factors. An operational or technological failure in one of these complex processes or fluctuations in external variables may result in sequencing processing yields that are lower than we anticipate or that vary between sequencing runs. In addition, we are regularly evaluating and refining our sequencing process. These refinements may initially result in unanticipated issues that further reduce our sequencing process yields or increase the variability of our sequencing process yields. Errors, including if our products or solutions fail to detect genomic variants with high accuracy, or mistakes, including if we fail to or incompletely or incorrectly identify the significance of gene variants, could have a significant adverse impact on our business.

Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required to interpret testing results for an individual patient and to develop an appropriate patient report. As a result, we may make errors in our interpretation of testing results, which could impair the results of our tests and adversely impact the quality of our overall knowledge base. The failure of our products or solutions to perform as expected would significantly impair our operating results and our reputation. We may also be subject to legal claims arising from, or loss of business as a result of, any defects or errors in our products and solutions.

We may fail to manage our future growth effectively, which could make it difficult to execute our business strategy.

We anticipate growth in our business operations. This future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service, and sales force management. We may fail to maintain the quality or expected turnaround times of our products and services or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures.

We plan to expand our laboratory and technical operations as our business grows. However, any expansion strategies and any future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales force management. We may not be able to maintain the quality or expected turnaround times of our testing services or satisfy client demand as our business grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and managerial controls, as well as our reporting systems and procedures, and to obtain appropriate regulatory approvals and meet regulatory standards applicable for the operation of our business.

The development of new products and solutions is a complex process, and we may be unable to successfully commercialize new products or solutions on a timely basis or at all.

New diagnostic test products and our interpretation-based solutions, including our biomarkers, take time to develop and commercialize. We may fail to develop and commercialize new diagnostic tests or solutions on a timely basis. Moreover, there can be no assurance that our products or solutions will be capable of meeting the needs of our clients and pharmaceutical partners, or that we will be able to commercialize them at all. Before we can commercialize any new products or solutions, we need to expend significant funds in order to:

- conduct substantial research and development, including epidemiology and validation studies and potentially patient scope analyses;
- further develop our laboratory processes or equipment;
- allocate laboratory space for new solutions or further scale our infrastructure to accommodate research and development or new equipment;
- in the case of products or solutions for which we are seeking regulatory or marketing approval, such as biomarkers, pursue such regulatory approval.

The development of new products and solutions involves risk, and development efforts may fail for many reasons, including the failure of any product or solution to perform as expected, a lack of validation or reference data, failure to demonstrate utility of a test or solution, or, in the case of solutions for which we are seeking or have received the Food and Drug Administration (“FDA”), European Commission and European Medicines Agency (“EMA”), German Federal Institute for Medicinal Products and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*), or comparable authorities’ or agencies’ approval, the inability to obtain such approval or the loss of such approval. In particular, our biomarker development and patent processes are subject to review by regulatory agencies and governing bodies. We cannot predict whether or when we will successfully complete development of each biomarker and if we will receive patent protection on any biomarkers that we develop.

As we develop new products and solutions, we will have to make significant investments in development, marketing, and selling resources. Any failure to develop or deliver adequate products or solutions to our clients and pharmaceutical partners on a timely basis or at all could significantly affect our business, financial condition, results of operations, and reputation.

We have limited experience in marketing and selling our products and solutions and we may fail to expand our direct sales and marketing force to adequately address our pharmaceutical partners' and clients' needs.

We have limited experience in marketing and selling our products and solutions to pharmaceutical partners, and currently rely on a small sales force to sell our products and solutions. We may not be able to market, sell, or distribute our existing products and solutions or other services we may develop effectively enough to support our planned growth.

Our future sales and further business growth will depend in large part on our ability to develop, and expand, our sales force and to increase the scope of our marketing efforts, particularly in the United States. Our target market of pharmaceutical partners and clients is a diverse market with individualized needs. As a result, we believe it is necessary to develop a sales force that includes sales representatives with specific rare and neurodegenerative disease technical backgrounds. We will also need to attract and develop marketing personnel with industry expertise. Competition for such employees is intense. We may not be able to attract and retain personnel or be able to build an efficient and effective sales and marketing force, which could negatively impact sales and market acceptance of our products or solutions and limit our revenue growth and potential profitability. Our expected future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, and integrate additional employees. Our future financial performance will depend in part on our ability to manage this potential future growth effectively, without compromising quality.

If we believe a significant market opportunity for our products or solutions exists in a particular jurisdiction in which we do not have direct access through one of our existing offices, from time to time we may enlist distribution partners and local laboratories to assist with sales, distribution, and client support. We may not be successful in finding, attracting, and retaining distribution partners or laboratories, or we may not be able to enter into such arrangements on favorable terms. Sales practices utilized by our distribution partners that are locally acceptable may not comply with sales practices standards required under German, Dutch, the United States or other laws that apply to us, which could create additional compliance risk. If these additional sales and marketing efforts are not successful, we may not achieve significant market acceptance for our solutions in these markets, which could harm our business.

The knowledge and interpretation-based solutions we provide to our pharmaceutical partners may not achieve significant commercial market acceptance.

Our knowledge and interpretation-based solutions may not gain significant acceptance in the orphan drug development market and, therefore, may not generate substantial revenue or profits for us. Our ability to achieve increased commercial market acceptance for our existing knowledge and interpretation-based solutions will depend on several factors, including:

- our ability to convince the medical and pharmaceutical community of the clinical utility of our solutions and their potential advantages over existing and new solutions;
- the willingness of our pharmaceutical partners, as well as their physicians and patients, to utilize our solutions; and
- the agreement by commercial third-party payors and government payors to reimburse any treatments provided by our pharmaceutical partners, the scope and amount of which will affect a partners' willingness or ability to pay for our solutions and will influence physicians' decisions to recommend our solutions.

We believe that the successful completion of clinical trials by partners that use our solutions, publication of scientific and medical results based on the information gained from our repository in peer-reviewed journals, and presentations at leading conferences are critical to the broad adoption of our solutions. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving our solutions sufficiently novel or worthy of publication.

The failure to be listed in physician guidelines or the failure of our solutions to produce favorable results for our partners or to be published in peer-reviewed journals could limit the adoption of our solutions. Failure to achieve widespread market acceptance of our solutions would materially harm our business, financial condition, and results of operations.

Failure to keep pace with the rapidly evolving industry in which we operate could make us obsolete.

Our business relies on commercial activities in the rare and neurodegenerative disease genetic or other testing and diagnostics field. In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in rare diseases and treatments, including through the development of biomarkers. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards. Our future success will also depend on our ability to keep pace with the evolving needs of our clients and pharmaceutical partners on a timely and cost-effective basis and to pursue new market opportunities that develop because of technological and scientific advances. Our current products and solutions could become obsolete unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in rare diseases and treatments. If we fail to anticipate or respond adequately to technological developments, demand for our products and solutions will not grow and may decline, and our business, revenue, financial condition, and operating results could suffer materially.

Moreover, many companies in this market are offering, or may soon offer, products and solutions that compete with our products and solutions, in some cases at a lower cost than ours. We cannot assure you that research and discoveries by other companies will not render our existing or potential products and solutions uneconomical or result in tests superior to our existing tests and those we may develop. We also cannot assure you that any of our existing products and solutions, or those that we develop in the future, will be preferred by our clients, pharmaceutical partners, physicians or other payors to any existing or newly developed technologies or tests. If we fail to maintain competitive test products, our business, prospects, financial condition and results of operations could be adversely affected.

We may fail to successfully respond to increasing demand for our products and solutions.

As our sales volume grows, we will need to continue to increase our infrastructure for sample intake, customer service, billing and general process improvements, expand our internal quality assurance program, and extend our platform to support comprehensive genomic and other analyses at a larger scale within expected turnaround times. We will need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our products and solutions. Portions of our process cannot be fully automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take a long time to procure, set up, and validate, and increase our software and computing capacity to meet increased demand.

We may fail to successfully implement any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements and we may have inadequate space in our laboratory facilities to accommodate such required expansion.

As additional products and solutions are commercialized, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult or impossible for us to meet market expectations for our products and solutions and could damage our reputation and the prospects for our business.

We may fail to obtain favorable pricing for our products and solutions and to meet our profitability expectations.

If we are not able to obtain favorable pricing for our products and solutions to enable us to meet our profitability expectations, our revenues and profitability could materially suffer. The rates we are able to charge for our products and solutions are affected by a number of factors, including:

- general economic and political conditions in the countries in which we operate;
- the competitive environment in our industry, as described below;
- our clients' and pharmaceutical partners' cost sensitivities;
- our ability to accurately estimate, attain and sustain revenues and royalties, margins, and cash flows over the full partnership period for our solutions, which includes our ability to estimate the impact of inflation and foreign exchange on our margins over long-term contracts; and

- procurement practices of our pharmaceutical partners and clients and their use of third-party advisors.

The competitive environment in our industry affects our ability to obtain favorable pricing in several ways, all of which could have a material negative impact on our results of operations. The less we are able to clearly convey the value of our products and solutions or differentiate our products and solutions, the more risk we have that they will be seen as commodities, with price being the driving factor in selecting us as a partner. Competitors may be willing, at times, to price contracts or products lower than we do to enter the market or increase market share. Further, if competitors develop and implement methodologies that yield greater efficiency or efficacy, they may be able to offer products and solutions like ours at lower prices.

Ethical, legal and social concerns related to the use of genomic or other diagnostic information could reduce demand for our rare and neurodegenerative disease knowledge and interpretation-based products and solutions.

Genomic testing, like that conducted for our pharmaceutical partners and clients using our genetic rare and neurodegenerative disease information platform, has raised ethical, legal, and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use genomic tests even if permissible.

Ethical and social concerns may also influence the United States and foreign patent offices and courts about patent protection for technology relevant to our business. These and other ethical, legal and social concerns may limit market acceptance of our products and solutions or reduce the potential markets for products and solutions enabled by our genetic rare and neurodegenerative disease information platform, either of which could have an adverse effect on our business, financial condition, or results of operations.

We have limited resources to be expended on research and development programs. Our resource allocation decisions may lead us to focus on research and development programs that are not commercially viable, and as a result we may be unable to recover the costs incurred under these efforts.

Because we have limited financial and managerial resources, we focus on research and development programs that we identify for rare and neurodegenerative diseases in collaboration with our pharmaceutical partners or based on our assessment of the market needs. As a result, we may forego or delay pursuit of opportunities with other orphan drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs for specific diseases may not yield any relevant results that are helpful to our existing programs or assist in the creation of any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing, or other royalty arrangements.

If we fail to compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

While personalized genomic diagnostics is a relatively new area of science, we face competition from companies that offer tests or have conducted research to profile genes and gene expression in various rare and neurodegenerative diseases. Our principal competition comes from diagnostic companies that offer diagnostic tests that capture genetic, phenotypic and epidemiological data, as well as laboratories and academic research centers. Many hospitals and academic medical centers may also seek to perform the type of genetic or other testing and knowledge and interpretation-based solutions we offer at their own facilities or using their own research capabilities.

Some of our present and potential competitors may have substantially greater financial, marketing, technical or manufacturing resources than we do. Our competitors may also be able to respond more quickly to new technologies or processes and changes in client demands. They may also be able to devote greater resources towards the development, promotion and sale of their products or solutions for pharmaceutical partners than we can. As competition in our market increases, we may also be subject to increased litigation risk, including in connection with patents as well as our marketing practices and other promotional activities. In addition, our current and potential competitors may make strategic acquisitions or establish cooperative relationships among themselves or with third parties that increase their ability to address the needs of our physicians or partners. If we fail to compete successfully against current or future competitors, our business will be harmed.

Because our genetic or other testing and knowledge and interpretation-based solutions and products have limited patent protection, new and existing companies worldwide could seek to develop genetic or other tests or similar products and solutions that compete with ours. These competitors could have technological, financial, and market access advantages that are not currently available to us and they could develop and commercialize competing products and solutions faster than we are able to do so. Increased competition, including price competition, could have a material adverse impact on our net revenues and profitability.

If our pharmaceutical partners experience any of a number of possible unforeseen events in connection with their clinical trials, our ability to commercialize future solutions or improvements to existing solutions could be delayed or prevented.

Our pharmaceutical partners may experience numerous unforeseen events during, or because of, clinical trials that could delay or prevent their ability to continue or conduct further clinical trials or obtain regulatory approval of or commercialize future orphan drugs. Unforeseen events that could delay or prevent our pharmaceutical partners' ability to conduct or support clinical trials, obtain regulatory approval of, or commercialize future orphan drugs include:

- regulatory authorities or ethical review boards, Institutional Review Boards (IRBs), may not authorize the commencement of a clinical trial or may not accept clinical trial protocols;
- clinical trials may produce negative or inconclusive results, and our pharmaceutical partners may decide, or regulatory authorities may require them, to abandon development programs;
- the number of patients, or amount of data, required for clinical trials may be larger than we or our pharmaceutical partners anticipate, patient enrollment in clinical trials may be slower than we or our pharmaceutical partners anticipate or patients may drop out of these clinical trials at a higher rate than we or our pharmaceutical partners anticipate;
- failure to conduct our clinical trials in accordance with applicable regulatory requirements of the FDA and of the regulatory authorities responsible for authorization or oversight of the conduct of clinical trials in other countries;
- inability to develop companion diagnostic tests for a particular rare disease or to add companion diagnostic claims to existing tests, and/or obtain regulatory approval to market any such test on a timely basis or at all;
- due to a new legislative framework in the EU on the conduct of clinical trials on medicinal products for human use, the Regulation (EU) No. 536/2014 of April 16, 2014 ("CTR"), which results in EU-wide harmonization of the authorization process, approval and monitoring of clinical trials in the EU, there may be delays in initiating new clinical trials in the EU until our pharmaceutical partners become familiar with the new regulatory requirements, in particular the new authorization procedure via the new Clinical Trial Information System database ("CTIS");
- clinical trials of our pharmaceutical partners for which we are developing companion diagnostic tests may suggest or demonstrate that our partners' treatments are not as efficacious and/or as safe as other similar treatments or that our companion diagnostic test is not essential to determine which patients would benefit from these treatments;
- mergers and acquisitions could have an impact on the priorities of our pharmaceutical partners; and
- our pharmaceutical partners may decide, or regulatory authorities or institutional review boards may require them, to suspend or terminate clinical research for various reasons, including cost, adequate end market size, available data, or non-compliance with regulatory requirements.

If our pharmaceutical partners choose not to conduct clinical trials for treatments in the rare or neurodegenerative disease space due to the above factors or otherwise, they may have less need for our products and solutions and may therefore choose not to partner with us. Our ability to continually expand our existing data repository depends on our ability to maintain partnerships with our pharmaceutical clients. Should our partners delay or cancel their ongoing existing trials or choose not to begin new trials for treatments in the disease areas relevant to us, our ability to commercialize future solutions or improvements to existing solutions could be delayed or prevented.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and commercial partners, including our distributors in our diagnostics business and pharmaceutical partners in our pharmaceutical business. Misconduct by these parties could include intentional failures to comply with the regulations of applicable regulatory authorities (including the FDA and the European Commission and EMA), comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, bribery, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, client incentive programs, and other business arrangements. Such misconduct could also involve the improper use of information obtained during clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have an insider trading policy as well as a code of conduct applicable to all of our employees and conduct a background check before entering into any new contracts with third party distributors, but it is not always possible to identify and deter employee or third-party misconduct, and our insider trading policy and code of conduct, due diligence and the other precautions we take to detect and prevent such misconduct may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could have a significant impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these actions or investigations.

We may lose the support of key thought leaders and fail to establish our products and solutions as a standard of care for patients with rare and neurodegenerative diseases, which may limit our revenue growth and ability to achieve future profitability.

We have established relationships with leading rare and neurodegenerative disease thought leaders at premier institutions and disease networks. If we suffer harm to our reputation, whether due to actions outside of our control or otherwise, our relationships with these persons may suffer which could adversely impact our business, including our key pharmaceutical partnerships and diagnostic client relationships. Moreover, if these key thought leaders determine that the CENTOGENE Biodatabank, our existing products or solutions or other new products or solutions that we develop are not useful to our partners' development of treatments for rare and neurodegenerative diseases, that alternative technologies are more effective, or if they elect to use internally developed products or solutions, we could encounter significant difficulty validating our testing platform, driving adoption, or establishing our genetic knowledge and interpretation-based solutions and tests as a standard of care, which would limit our revenue growth and our ability to achieve profitability.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property, and proprietary business information owned or controlled by us or physicians, pharmaceutical partners and other clients. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. We also communicate, and facilitate the exchange of, sensitive patient data to and between ourselves and physicians of the patients for whom we conduct diagnostic tests through an online client-facing portal, CentoPortal®. These applications and related data encompass a wide variety of business-critical information including legally protected health information, personally identifiable information, research and development information, commercial information, and business and financial information. We face a number of key risks related to the protection of this information, including unauthorized access risk, inappropriate or unauthorized disclosure risk, inappropriate modification risk and the risk of being unable to adequately monitor our controls.

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy. Our information technology and infrastructure, and that of our third-party disaster recovery back-up providers, may be vulnerable to attacks by hackers or malicious software or breached due to personnel error, unauthorized access, malfeasance, or other disruptions. Any such breach or interruption could compromise the security or integrity of our networks, and the information stored there could be accessed by unauthorized parties or publicly or incorrectly disclosed, corrupted, lost, or stolen. Any such access, disclosure, corruption, other loss, or theft of information could result in governmental investigations, class action legal claims or proceedings, liability under laws that protect the privacy of personal information, such as but not limited to the Health Insurance Portability and Accountability Act (“HIPAA”), the General Data Protection Regulation (EU 2016/679) (“GDPR”), the United Kingdom’s General Data Protection Regulation (“UK GDPR”) and regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, applications such as our online client-facing portals are currently accessible through public web portals and may, in the future, be accessible through dedicated mobile applications, and there is no guarantee we can absolutely protect our online portals or our mobile applications from breach. Unauthorized access to, or loss or dissemination of, the data embedded in or transferred via these applications could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill our pharmaceutical or other partners, provide client assistance solutions, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and solutions and other pharmaceutical partner and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

We are a “covered entity” as defined under HIPAA, and the United States Office of Civil Rights may impose penalties on a covered entity for a failure to comply with a requirement of HIPAA. Penalties will vary significantly depending on factors such as the date of the violation, whether the covered entity knew or should have known of the failure to comply, or whether the covered entity’s failure to comply was due to willful neglect. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and imprisonment up to one year. The criminal penalties increase to \$100,000 and up to five years’ imprisonment if the wrongful conduct involves false pretenses, and to \$250,000 and up to 10 years’ imprisonment if the wrongful conduct involves the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm. The United States Department of Justice (the “DOJ”) is responsible for criminal prosecutions under HIPAA. Furthermore, in the event of a breach as defined by HIPAA, the covered entity has specific reporting requirements under HIPAA regulations. In the event of a significant breach, the reporting requirements could include notification to the general public.

In addition, the interpretation and application of consumer, health-related, and data protection laws in the United States, Europe, and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Our operations or business practices may not comply with these regulations in each country, and complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

We are subject to significant foreign currency exchange controls in certain countries in which we operate.

We are in some countries, and could become elsewhere, subject to strict restrictions on the movement of cash and the exchange of foreign currencies, which limits our ability to use this cash across our global operations. We also face risks related to the collection of payments due to us from our major pharmaceutical partners or clients that are located in certain geographical regions with foreign currency or international monetary controls. This risk could increase as we continue our geographic expansion. In particular, for the years ended December 31, 2022 and 2021 we derived 42.0% and 8.7% respectively, of our total revenues from our Middle East region. Certain Middle East economies have adopted or been subject to international restrictions on the ability to transfer funds out of the country and convert local currencies into euros. This may increase our costs and limit our ability to convert local currency into euros and transfer funds out of certain countries. Any shortages or restrictions may impede our ability to convert these currencies into euros and to transfer funds, including for the payment of dividends or interest or principal on our outstanding debt.

We may acquire assets or other businesses that could negatively affect our operating results, dilute our shareholders' ownership or increase our debt.

In addition to organic growth, we may pursue growth through the acquisition of assets or other businesses that may enable us to enhance our technologies and capabilities, expand our geographic market, add experienced management personnel or add new or improve our existing products and solutions. We also may pursue strategic alliances and joint ventures that leverage our technical platform and industry knowledge to expand our products and solutions. Negotiating these transactions and the formation of strategic alliances or joint ventures can be time-consuming and expensive and may be subject to third-party approvals as well as approvals from governmental authorities, which are beyond our control. In addition, some third parties may choose not to enter into partnership or collaboration agreements with us because of our existing relationships with other pharmaceutical partners. Consequently, we may not be able to complete any contemplated transactions on favorable terms or at all, and we can make no assurance that such transactions, once undertaken and announced, will close.

An acquisition or investment may result in unforeseen operating difficulties and expenditures, including in integrating businesses, products and solutions, personnel, operations, and financial, accounting, and other controls and systems, and retaining key employees, with the assumption of unknown liabilities or known liabilities that prove greater than anticipated, and in retaining the clients of any acquired business. Any such difficulties could disrupt our ongoing operations or require management resources that we would otherwise focus on developing our existing business. Future acquisitions could result in the use of our available cash and marketable securities, potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities, or impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition. As a result, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, or joint venture. These challenges related to acquisitions or investments could adversely affect our business, results of operations, and financial condition.

We may enter into joint ventures with third parties, which may subject us to various risks, including limited decision-making authority, reliance on our joint venture partners' financial condition and the risk of disputes with our joint venture partners, which could adversely affect us.

We may make investments in assets or enter into agreements with companies that we do not control, including joint venture partnerships, or other structures with third parties. If we enter into any joint ventures, we may have limited decision-making authority and we may face the risk of disputes with our joint venture partners, including without limitation potential deadlocks in making major decisions and restrictions on our ability to exit the joint venture. Any disputes that may arise between us and any joint venture partners may result in litigation or arbitration. We may also face risks associated with any joint venture partners' financial condition, including, among other things, the risk of bankruptcy and/or failure to fund their share of required capital contributions. As a result, we may be exposed to liabilities more than our share of any joint venture. Any joint venture partners may also have business interests or goals that are inconsistent with our business interests or goals and may be able to take actions contrary to our policies or objectives. We may, in specific circumstances, be liable for the actions of any joint venture partners. Any of the foregoing may have a material adverse effect on our business, financial condition, and results of operations.

Certain Factors Relating to Our Industry

Regulatory Risks

Our global operations expose us to numerous and sometimes conflicting legal and regulatory requirements, and violation of these requirements could harm our business.

We are subject to numerous, and sometimes conflicting, legal regimes in the countries in which we operate, including on matters as diverse as health and safety standards, marketing and promotional activities, anticorruption, import/export controls, content requirements, trade restrictions, tariffs, taxation, sanctions, immigration, internal and disclosure control obligations, securities regulation, anti-competition, data privacy and labor relations. This includes in emerging markets where legal systems may be less developed or familiar to us. We strive to abide by and maintain compliance with these laws and regulations. Compliance with diverse legal requirements is costly, time-consuming and requires significant resources. Violations of one or more of these regulations in the conduct of our business could result in significant fines, criminal sanctions against us or our supervisory board or officers, prohibitions on doing business and damage to our reputation. Violations of these regulations in connection with the performance of our obligations to our clients or pharmaceutical partners also could result in liability for significant monetary damages, fines and/or criminal prosecution, unfavorable publicity and other reputational damage, restrictions on our ability to process information and allegations by our clients or pharmaceutical partners that we have not performed our contractual obligations. Due to the varying degrees of development of the legal systems of the countries in which we operate, local laws might be insufficient to protect our rights.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, products and solutions, pricing, reimbursement and marketing of our products and solutions, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. The imposition of new laws or regulations, including potential trade barriers, may increase our operating costs, impose restrictions on our operations or require us to spend additional funds to gain compliance with the new rules, if possible, which could have an adverse impact on our financial condition.

Current and future legislation, in particular legislation related to orphan drugs, may impact overall investment and activity in the rare disease space or our ability to obtain regulatory approvals.

In the United States, the European Union and its member states and some other foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system. These changes could affect our ability to sell profitably any products for which we require approvals. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare.

Specifically, regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the European Union, the European Commission grants orphan drug designation after receiving the opinion of the EMA's Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than one in 2,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). In addition, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug. In the European Union, orphan drug designation entitles a party to financial incentives, such as reduction of fees or fee waivers, and a ten-year market exclusivity once the drug is on the market.

These legislative initiatives have led to an increase in investment and activity in the rare disease drug development space. In 2020, the EU Commission launched a consultation process to revise the existing legal framework for orphan drugs with the aim of adopting a new regulation to increase the development of new products for patients with rare diseases, to provide faster access to corresponding medicines and to establish an efficient evaluation and approval process for these medicines. The consultation process has already ended, but neither an analysis nor a new draft regulation has yet been published. However, the published consultation working paper "Inception Impact Assessment", inter alia, indicates that the EU Commission acknowledges the granting of market exclusivity as the main incentive, but nevertheless considers that the duration of such exclusivity should be variable or shortened under certain criteria yet to be defined.

On April 26, 2023, the EU Commission adopted a proposal for a new Directive and a new Regulation, which, if enacted, would revise and replace the existing general pharmaceutical legislation in the EU (Regulation 726/2004 and Directive 2001/83/EC) and the legislation on medicines for children and for rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC, respectively). The draft provides for significant changes to the existing legal regime. The draft provides, inter alia, for a shortening of the general market exclusivity period for orphan drugs from ten to nine years, but companies can take advantage of additional market exclusivity periods. The Commission proposal is now under review by the EU Parliament and EU Council and may undergo substantial changes during the ongoing legislative procedure (2023/0131/COD).

If these and other legislative initiatives were to change to become less favorable to orphan drug developers and researchers, it could harm our business, results of operations and financial condition.

We may fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business and become subject to severe financial and other consequences.

Our laboratory in the United States is subject to the Clinical Laboratory Improvement Amendments of 1998 ("CLIA"), a United States federal law that regulates all clinical diagnostic laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance, and inspections. Our laboratory facilities located in Rostock, Germany and Cambridge, Massachusetts, United States each have a current certificate of accreditation under CLIA to conduct all genetic and biochemical analyses offered through our accreditation by the College of American Pathologists ("CAP"). To renew the CLIA certificates, we are subject to a survey and inspection every two years. Moreover, CLIA inspectors may make unannounced inspections of our clinical laboratories at any time.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. Most CLIA deficiencies are not classified as "condition-level" deficiencies, and there are no adverse effects upon the laboratory operations if the deficiencies are corrected. Remediation of these deficiencies are routine matters, with corrections occurring within several hours or weeks. More serious CLIA deficiencies could rise to the level of "condition-level" deficiencies, and CMS has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA certified laboratory by any owners or operators of the deficient laboratory. There is an administrative hearing procedure that can be pursued by the laboratory in the event of imposition of such sanctions, during which the sanctions are stayed, but the process can take a number of years to complete. If we were to lose our CLIA certification or CAP accreditation, we would not be able to operate our clinical laboratories and perform our genetic or other tests, which would result in material harm to our business and results of operations.

We are also required to maintain a license for our Cambridge laboratory facility to perform testing in Massachusetts. Massachusetts laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control over and above that required by CLIA. We are also licensed to perform testing in our Cambridge laboratory facility by the states of California, Pennsylvania and Maryland. We are in the process of obtaining a New York State license to perform testing and deliver the related test report for specimens originating from New York.

For samples tested in the U.S., we are also subject to HIPAA, under which the Department of Health and Human Services established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions; certain of our services, including our online client-facing portals for reporting and research, are subject to these standards and requirements. Amendments to HIPAA under the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”), and related regulatory amendments, which strengthen and expand HIPAA privacy and security standards, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification.

We furnish pharmaceutical partners with genomic information that has been de-identified in accordance with HIPAA or anonymized in accordance with GDPR, the UK GDPR and relevant international health information privacy regulations. The laws of certain states and countries may require specific consent from the individual either to retain or utilize certain genetic or other information for research or other purposes even if such information has been de-identified or may require that we obtain a waiver of such consent from an ethical or privacy review board. Even where we furnish pharmaceutical partners and academic researchers’ genomic information that has been de-identified or anonymized in accordance with applicable laws and regulations, pharmaceutical partners or academic researchers may use technology or other methods to link that de-identified or anonymized genomic information to the patient from whom it was obtained in contravention of one or more applicable laws and regulations. Similarly, as we expand our decision support applications and offerings, we may encounter greater regulatory risk, such as compliance with HIPAA, GDPR, the UK GDPR and other regulations governing the use of protected health information and the promotion of FDA approved drugs. A finding that we have failed to comply with any such laws and any remedial activities required to ensure compliance with such laws could cause us to incur substantial costs, to be subject to unfavorable publicity or public opinion, to change our business practices, or to limit the retention or use of genetic or other information in a manner that, individually or collectively, could be adverse to our business.

In the European Union, various regulations apply to genetic or other testing and the use of genomic information. In Germany, the Genetic Diagnosis Act (*Gendiagnostikgesetz*) (the “GenDG”) and guidelines and written opinions on novel genetic screenings developed by the Commission on Genetic Testing, an interdisciplinary independent commission established in 2009 in accordance with the GenDG, apply to such testing. The GenDG prohibits us from communicating results of genetic or other tests directly to a patient located within Germany. Instead, the results may only be provided to a physician who is a qualified genetic counsellor under applicable rules. Moreover, as of May 26, 2022, the new Regulation (EU) 2017/746 of the European Parliament and of the Council of April 5, 2017 on in vitro diagnostic medical devices (the “In Vitro Diagnostic Medical Device Regulation” or “IVDR”) became applicable. The IVDR not only regulates the placing on the market of in vitro diagnostic medical devices (“IVD”) in the European Union, but also provides for stricter requirements in its Art. 6 with regard to the use of IVD in the context of a commercial activity for the provision of diagnostic or therapeutic services offered by means of an information society service. We are subject to the requirements of the IVDR if we provide services to natural or legal persons established in the EU by using products which qualify as IVD within the meaning of Art. 2 para. 1 IVDR, provided we offer these services “through means of information society services”.

In addition to CLIA, GDPR, the UK GDPR, HIPAA, the GenDG and the IVDR, our operations are subject to other extensive federal, state, local, and foreign laws and regulations, all of which are subject to change. Our failure to comply with any such laws and regulations could lead to civil or criminal penalties, exclusion from participation in government healthcare programs, or prohibitions or restrictions on our ability to conduct commercial activities. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. In particular, about the novelties of the IVDR on the provision of services using IVDs, the scope of application of the provisions is unclear and no official practice has yet been established in this regard. If one or more such agencies allege that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties.

We may fail to comply with evolving European and other privacy laws.

On May 25, 2018, Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the “GDPR”) went into effect, and the UK GDPR became effective in January 2021. The GDPR and the UK GDPR impose a broad range of strict requirements on companies subject to the GDPR and the UK GDPR, such as us, including requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such information outside the European Economic Area (the “EEA”), including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data as processor, responding to individuals’ requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR and the UK GDPR increase substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to the higher of 10,000,000 Euros and 2% of our total worldwide annual turnover for the preceding financial year for certain comparatively minor offenses, or up to the higher of 20,000,000 Euros and 4% of our total worldwide annual turnover for the preceding financial year under the GDPR, or 17,500,000 GBP and 4% of our total worldwide annual turnover under the UK GDPR, for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the European Union are still in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the European Union. Also, in the field of handling genetic and health data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. Following Brexit, we are also required to comply with the UK GDPR. The free movement of data between the United Kingdom and the Member States of the European Union is ensured by an Adequacy Decision by the European Commission pursuant to Art. 45 GDPR. However, there are efforts to change data protection law in the United Kingdom. In this context, there is uncertainty as to whether an adequate level of data protection can continue to be maintained, including the free movement of data between the United Kingdom and the European Union. These changes could lead to additional compliance costs and could increase our overall risk.

We must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with European data protection laws. In this regard, the July 2020 ruling by the Court of Justice of the EU (the “CJEU”) in the case referred to as Schrems II is significant. The CJEU held that businesses can use European Commission endorsed standard contractual clauses (“SCCs”), which are widely relied on, for data transfers to jurisdictions outside of the EEA. However, it emphasized the need for due diligence by businesses if they wish to use SCCs and called into question whether businesses can use SCCs to facilitate data transfers to certain jurisdictions with invasive surveillance regimes in a way which complies with the GDPR and the UK GDPR. This is also true for the new set of SCCs adopted by the European Commission in 2021. The CJEU also invalidated the EU-US Privacy Shield for transferring personal data from the EEA to the US. Under Clause 14 of the new SCC, data exporters must conduct a “data transfer impact assessment” (“DTIA”) to ensure that the data importer can actually contractually guarantee adequate data protection standards under the SCC. Such DTIA are both costly and time consuming. In addition, there is great uncertainty about how the DTIA is to be carried out in individual cases and how the national regulations in the country of the data importer are to be considered. As for data transfers to the United States, on October 7, 2022, U.S. President Joe Biden signed an Executive Order implementing the long-awaited EU-U.S. Data Privacy Framework. The European Commission concurrently announced that it will launch its adequacy determination procedure for EU personal data transferred to the United States under the arrangement. It is expected that a new Adequacy Decision by the European Commission will be available from the middle of 2023, on which basis personal data can then again be transferred to the United States without restrictions.

We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multinational clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR and the UK GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

We could be adversely affected by violations of worldwide anti-bribery laws, including the U.S. Foreign Corrupt Practices Act.

We are subject to a variety of anti-bribery and anti-corruption laws in the jurisdictions in which we operate. In particular, we are subject to Germany's Anti-Bribery Act of 2015 (*Gesetz zur Bekämpfung der Korruption im Gesundheitswesen*), which implements EU anti-corruption laws and the European legislation and the Criminal Law Convention on Corruption of the Council of Europe into German law, and the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-United States government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery.

We use third-party collaborators, strategic partners, law firms and other representatives for patent registration and other purposes in a variety of countries, including those that are known to present a high corruption risk. We also use third-party distributors worldwide as part of our diagnostics business. Our reliance on third parties to sell our products and solutions internationally demands a high degree of vigilance because we can be held liable for the corrupt or other illegal activities of these third-party collaborators, or their or our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. In addition, although we have implemented policies and procedures to ensure compliance with anti-corruption and related laws and maintain a code of conduct, there can be no assurance that all of our employees, representatives, contractors, partners, or agents will comply with these laws at all times. Other United States companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals.

These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws, any changes in these laws, or the interpretation thereof. Non-compliance with these and other relevant laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and debarment from contracting with certain governments or other persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations, and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Enforcement actions and sanctions could further harm our business, results of operations, and financial condition.

Transactions involving Iran or other countries or parties that are targets of U.S. or other economic sanctions could expose us to certain risks and may lead some potential customers and investors to avoid doing business with us or investing in our securities.

U.S. law generally prohibits U.S. persons, and in some cases non-U.S. entities owned or controlled by U.S. persons, from doing business with countries, territories, individuals and entities that are the target of sanctions administered by the U.S. Department of the Treasury's Office of Foreign Assets Control, including Iran. Other countries also maintain certain economic sanctions targeting certain countries, territories and parties. The United States has also implemented certain sanctions targeting non-U.S. persons for activities conducted outside the United States "secondary sanctions" that involve specific sanctions targets or certain activities, including, among other things, certain transactions related to Iran. Further, certain countries maintain and enforce export controls regulating trade in items that originate in, incorporate content from, or are produced on the basis of technology developed in such country "export controls."

Centogene GmbH, which is not a U.S. person and is not owned or controlled by U.S. persons provided diagnostic tests to a pathology and genetic center in Iran during the year ended December 31, 2022, through which it provides diagnostic tests to patients in Iran. To our knowledge, neither we nor our customer have entered into any arrangements with or sold any products to persons included on the Specially Designated Nationals and Blocked Persons List maintained by the U.S. Department of the Treasury's Office of Foreign Asset Control. During the years ended December 31, 2022, 2021 and 2020, revenues from Iran amounted to zero, €1 thousand and €13 thousand, respectively. Our net assets receivable from or attributable to our contacts in Iran as of December 31, 2022, 2021 and 2020 amounted to zero, zero and €1 thousand, respectively. We had no liabilities due from or attributable to our contacts in Iran for these periods. Centogene believes that its business with Iranian parties is conducted in compliance with all applicable sanctions and export controls and that such activities, which involve providing genetic or other testing services to patients, are not sanctionable under U.S. secondary sanctions targeting Iran. However, U.S. sanctions are subject to change and if we were then determined to have engaged in activities targeted by certain U.S. sanctions, we could be exposed to the possible imposition of sanctions on us. We may also face reputational damage due to our sales to Iran. The above circumstances could have an adverse effect on our business or results of operations.

We may fail to adhere to regulations of promotional claims and activities regarding our products and solutions.

Once a patient has been identified and diagnosed through our diagnostics testing, we provide each patient's physician with a diagnostic report. If a positive diagnosis is confirmed, we provide the physician with information on relevant treatment options, although the physician is responsible for ultimately making clinically relevant decisions for the treatment of his or her patient.

In the United States, the FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drugs and devices. In particular, a device may not be promoted for uses or indications beyond those contained in the device's approved labeling, or "off-label" uses. Similar laws and regulations exist in other jurisdictions where we promote our products. If the FDA determines that we have promoted our products for off-label use, it could request that we modify those promotional materials or take regulatory or enforcement actions, including the issuance of an untitled letter, warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities may take action if they consider our promotional or training materials to constitute promotion of an unapproved use. If not successfully defended, enforcement actions related to off-label promotion could result in significant fines or penalties. The U.S. government has levied large civil and criminal fines against companies for alleged improper promotion and has entered into corporate integrity agreements and deferred prosecution agreements with companies that engaged in off-label promotion. The FDA has also requested that such companies enter into consent decrees and has taken other enforcement action. If the DOJ or FDA determines that we have engaged in off-label promotion in our test reports, we may be subject to civil or criminal fines. Although our policy is to refrain from statements that could be considered off-label promotion of third parties, the regulatory standards regarding off-label promotion are ambiguous, and the FDA or another regulatory agency could conclude that we have engaged in off-label promotion.

In addition to promoting our devices in a manner consistent with their approved indications, we must have adequate substantiation for the claims we make for our products or solutions. If any of our claims are determined to be false, misleading or deceptive, our products or solutions could be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act (the "FDC Act") or to violate the Federal Trade Commission Act. We could also face lawsuits from our competitors under the Lanham Act, alleging that our marketing materials are false or misleading. Such lawsuits, whether with or without merit, are typically time-consuming, costly to defend, and could harm our reputation.

Federal and state legislation regulate interactions between medical device manufacturers and healthcare professionals. We are subject to federal and state laws targeting fraud and abuse in healthcare, including anti-kickback laws, false claims laws, and other laws constraining or otherwise related to financial arrangements manufacturers may enter into with healthcare professionals. For example, the Physician Payments Sunshine Act requires device manufacturers to report and disclose payments or other transfers of value made to physicians and teaching hospitals. Violations of these laws can result in criminal or civil sanctions, including fines, imprisonment, and exclusion from government reimbursement programs, all of which could materially harm our business.

In addition, incentives exist under applicable laws that encourage competitors, employees, and physicians to report violations of law governing promotional activities for pharmaceutical products and solutions. These incentives could lead to so-called whistleblower lawsuits as part of which such persons seek to collect a portion of monies allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products and solutions beyond labeled claims. These incentives could also lead to lawsuits that claim we have mischaracterized a competitor's service in the marketplace and, as a result, we could be sued for alleged damages to our competitors. Such lawsuits, whether with or without merit, are typically time-consuming and costly to defend. Such lawsuits may also result in related shareholder lawsuits, which may also be costly to defend.

Changes in the way that the FDA and the European Union regulate laboratory developed tests, manufactured, validated, and performed by laboratories like ours could result in additional expense in offering our current and any future products and solutions or even possibly delay or suspend development, manufacture, or commercialization of such products and solutions.

The FDA does not currently regulate most laboratory developed tests (“LDTs”). We believe that the tests we currently offer meet the definition of LDTs, as they have been designed, developed and validated for use in a single CLIA-certified laboratory. If our tests are qualified as LDTs, they are currently not subject to FDA regulation as medical devices. Since the early 1990s, the FDA has taken the position that, although LDTs are medical devices, it would exercise enforcement discretion by not requiring compliance with the FDC Act, or its regulations for LDTs. That remains the guidance of the FDA today. However, the FDA has taken certain actions in the past that, if renewed by the FDA, could result in a new regulatory approach for LDTs. In October 2014, the FDA published two draft guidance documents that, if finalized, would implement a regulatory approach for most LDTs. The draft guidance documents proposed to impose a risk-based, phased-in approach for LDTs similar to the existing framework for IVD devices. In January 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining an updated possible approach to regulation of LDTs. Although the discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents, it proposes a risk-based framework that would require most LDTs to comply with most of the FDA’s regulatory requirements for medical devices. In March 2017, a discussion draft of the Diagnostic Accuracy and Innovation Act (“DAIA”) was circulated, which, if enacted, would implement a regulatory scheme for all diagnostic tests, including both in vitro diagnostic devices and LDTs. Under DAIA, CMS would have jurisdiction over laboratory operations under an amended CLIA, and the FDA would regulate the design, development and validation of diagnostic tests under an amended FDC Act. We cannot predict whether this bill or any other any other legislative proposal will be enacted into law or the impact such new legal requirements would have on our business. We also cannot predict whether the FDA will take action to regulate LDTs or what approach the FDA will seek to take.

In addition, in November 2013, the FDA finalized guidance regarding the sale and use of products labeled for research or investigational use only. Among other things, the guidance states that the FDA continues to be concerned about distribution of research- or investigational-use only products intended for clinical diagnostic use. The guidance states that the FDA will assess whether a manufacturer of such research- or investigational-use only products intends that its products be used for clinical diagnostic purposes by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support such as assistance performing clinical validation, surrounding the distribution of the product in question. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research- or investigational-use only, the device could be deemed misbranded and adulterated within the meaning of the FDC Act. If the FDA were to undertake enforcement actions, some of our suppliers may cease selling research-use only (“RUO”) products to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

In the European Union LDTs are similarly exempt from certain regulations that govern medical devices and IVD under certain conditions. As of May 26, 2022, when the new IVDR became applicable, the general safety and performance requirements set out in Annex I of the IVDR are applicable also to IVD manufactured and used only within health institutions. Overall, the exemptions for LDTs are narrowed, as even in relation to LDTs, health institutions, among others, have to provide information upon request on the use of such devices to their competent authority and each health institution will have to draw up a declaration, which it will make publicly available. If these conditions are not met and/or diagnostic tests are manufactured and used only within health institutions but “on an industrial scale”, or if the health institution cannot justify in its documentation that the target patient group’s specific needs cannot be met (including at the appropriate level of performance) by an equivalent device already available on the market, from May 26, 2028, such tests will qualify as IVDs with the full applicability of the IVDR. If we were not able to qualify for an exemption, we would be subject to all legal requirements of the IVDR. We also cannot predict whether the EU will amend or implement new laws which may impact our current operations.

For tests that are subject to FDA or EU regulation, we may not be able to obtain timely approvals for our tests or for modifications to our tests, which could delay or prevent us from commercializing our tests and harm our business.

The diagnostic tests we currently offer might meet the definition of LDTs, as they have been designed, developed and validated for use in a single CLIA-certified laboratory. If our tests are LDTs, they are currently not subject to FDA as an IVD. As of 2022, when the new IVDR came into force in the European Union, a qualification of our diagnostic tests as IVD becomes more likely as the manufacturing of diagnostic tests “on an industrial scale” might not qualify as LDTs. The IVDR itself does not provide for a definition of the term “industrial scale”. According to the guidance document MDCG-2023-01 published by the Medical Devices Coordination Group (“MDCG”), this new concept for LDTs involves many factors to be considered on a case-by-case basis, including e.g., volume of production, commercial aspects and manufacturing process. Moreover, the facilitations applicable to LDT as laid down in Art. 5 IVDR should only be applicable to devices that are produced by a health institution in order to meet the patient group’s specific needs, and therefore, no more than the estimated number of required devices should be produced. If the FDA takes action to finalize and implement a regulatory system for LDTs, or if legislation is enacted that subjects LDTs to FDA regulation, we would need to comply with the FDA regulatory requirements for our LDTs. If the FDA takes action to regulate LDTs as devices, we believe that our LDTs would likely be regulated as Class II devices.

In the EU, genetic or other tests on humans and prenatal tests for genetically caused disorders are regulated as Class C devices under the IVD Regulation. If our LDTs are subject to the IVD Regulation, our tests that qualify as Class C devices will be subject to conformity assessments performed by a notified body.

If services that are currently marketed as LDTs become subject to FDA requirements for in-vitro-diagnostics or are qualified as being subject to the European Union regulations on in vitro diagnostic medical devices, including requirements for premarket clearance or approval, we may not be able to obtain such clearance or approvals on a timely basis, or at all. Our business could be negatively impacted if we are required to stop selling genetic rare disease knowledge and interpretation-based products and solutions pending their clearance or approval, or the launch of any new products and solutions that we develop could be delayed. Likewise, for tests that are regulated as medical devices, we may not be able to obtain clearance or approval of new devices or modifications to marketed devices on a timely basis, or at all, which could delay or prevent us from commercializing our tests and harm our business.

Class II medical devices must obtain FDA clearance of a premarket notification, or 510(k), prior to marketing, unless the FDA has exempted the device from this requirement. Under the 510(k) process, we must demonstrate that our test is substantially equivalent in technological characteristics and intended use to a legally marketed predicate device. The FDA’s review and clearance of a 510(k) usually takes from four to twelve months, but it can take longer. Any modifications to an FDA-cleared device that could significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or, if the modified device is not substantially equivalent, possibly a de novo classification request or a premarket approval application (“PMA”).

If we are unable to identify an appropriate predicate that is substantially equivalent to our device, we would be required to submit a PMA application or a de novo reclassification request, because devices that have not been classified are automatically categorized as Class III. Under the de novo process, we may request that the FDA classify a new low or moderate risk device that lacks an appropriate predicate as a Class I or Class II device. The de novo process typically requires the development of clinical data and usually takes between six to twelve months from the time of submission of the de novo application, but it can take longer.

For tests that are subject to FDA or EU regulation, if we do not comply with FDA or EMA regulatory requirements, we may be subject to enforcement action, with severe consequences for our business.

After approval, devices subject to FDA or EMA regulation are required to comply with post-market requirements. Among the requirements, we and our suppliers must comply with the FDA’s Quality System Regulations (“QSRs”), which set forth requirements for the design and manufacture of devices, including the methods and documentation for the design, control testing, quality assurance, labeling, packaging, storage, and shipping of our devices. Our limited experience in complying with these requirements may lead to operational challenges as we increase the scale of our QSR-compliant operations in the United States and develop and refine our policies and procedures for evaluating and mitigating issues we encounter with our processes. Further, if there are any modifications made to the manufacturing of our PMA-approved marketed solutions, a PMA supplement may be required to be submitted to, and approved by, the FDA before the modified device may be marketed.

Other post-market requirements include the reporting of adverse events and malfunctions of which we become aware within the prescribed time frame to the FDA, post-approval studies, establishment registration and device listing, and restrictions on advertising and promotion. We may fail to meet these requirements, which could subject our business to further regulatory risks and costs.

The FDA enforces the post-market requirements of the FDC Act through announced and unannounced inspections. Failure to comply with applicable regulatory requirements could require us to expend time and resources to respond to the FDA's observations and to implement corrective and preventive actions, as appropriate. If we cannot resolve such issues to the satisfaction of the FDA, we may be subject to enforcement actions, including untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future solutions, operating restrictions, a partial suspension, or a total shutdown of service. Any such enforcement action would have a material adverse effect on our business, financial condition, and results of operations.

We face inspections, reviews, audits and investigations under federal and state government programs and contracts and health insurance providers regarding our billing practices.

We may be subject to inspections, reviews, audits and investigations regarding our billing practices to verify our compliance with federal and state government program requirements and contracts and applicable laws and regulations. Other third-party payors, including private health insurance providers, may also reserve the right to conduct audits. An adverse result of an inspection, review, audit or investigation could result in:

- denial of claims or recoupment or refunding of amounts we have been paid pursuant to the Medicare or Medicaid programs or from other payors;
- state or federal agencies imposing fines, penalties or other sanctions on us, including under the federal U.S. False Claims Act;
- temporary suspension of payments;
- revocation of billing privileges or exclusion from participation in the Medicare or Medicaid programs or one or more payor networks;
- self-disclosure of violations to applicable regulatory authorities;
- damage to our reputation;
- criminal penalties;
- revision or restatements of historical financial statements, including derecognition of revenue for claims we were not entitled to; and
- loss of certain rights under, or termination of, our contracts with payors.

We have in the past and may in the future be required to refund amounts we have been paid and/or pay fines and penalties as a result of these inspections, reviews, audits and investigations, in particular if our documentation, billing and other practices do not comply with applicable government program or other payor requirements.

We are currently responding to an asserted overpayment following an audit of claims for diagnostic tests we submitted to the U.S. government Medicare program previously recognized. In addition, we have refunded payments received from a private health insurance company relating to reimbursement claims submitted for COVID-19 testing services between November 2020 and November 2021 and recognized in 2021. As a result of the foregoing requests, we have recognized in our consolidated financial statements as of December 31, 2022, €1,060 thousand of other liabilities to be refunded back to Medicare for overpayments made between 2019 and 2022.

In the future, we may fail to achieve coverage or adequate reimbursement for our products and solutions by commercial third-party payors or government payors.

As we expand our operations globally, and in particular to the United States, sales of our existing and any future products and solutions we develop, in particular our diagnostic testing services, in the future may depend upon the availability of adequate reimbursement from third-party payors. These third-party payors include government healthcare programs and/or statutory health insurance schemes in various markets, such as Medicare and Medicaid in the United States and statutory health funds in Germany (the “GKV”), managed care providers, accountable care organizations, private health insurers, and other organizations. We believe that obtaining a positive Medicare Local Coverage Determination, or National Coverage Determination and a favorable Medicare reimbursement rate and obtaining the agreement of established commercial third-party payors to provide coverage and adequate payment, for each of our existing diagnostic testing services, and any future products and solutions we develop, will be an important element in achieving material commercial success in the United States. Physicians may not order our products and solutions unless commercial third-party payors and government payors authorize coverage and pay for all, or a substantial portion, of the rates established for our products and solutions.

Commercial third-party payors and government payors internationally increasingly attempt to contain healthcare costs by lowering reimbursement rates, limiting coverage of diagnostic test services, and creating conditions of reimbursement, such as requiring participation in clinical evidence development involving research studies and the collection of physician decision impact and patient outcomes data. As a result of these cost-containment trends, commercial third-party payors and government payors that currently provide, or in the future may provide, reimbursement for one or more of our services may propose and/or actually reduce, suspend, revoke, or discontinue payments or coverage at any time. Payors may also create conditions for coverage or may contract with third-party vendors to manage laboratory benefits, in both cases creating administrative hurdles for ordering physicians and patients that may make our products and solutions more difficult to sell. The percentage of submitted claims that are ultimately paid, the length of time to receive payment on claims, and the average reimbursement of those paid claims is likely to vary from period to period.

There is significant uncertainty surrounding whether the use of diagnostic tests that incorporate new technology will be eligible for coverage by commercial third-party payors and government payors or, if eligible for coverage, what the reimbursement rates will be for these services. In Germany, the majority of patients are insured via the GKV. The benefit catalogue defining which services in medical care are reimbursed by the GKV is specified by the directives of the Federal Joint Committee as the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. The fact that a diagnostic test has been approved for reimbursement in the past, has received approval from the FDA or has been certified by a notified body, or has obtained coverage for any particular rare disease indication or in any particular jurisdiction, does not guarantee that such diagnostic service will remain covered and/or reimbursed or that similar or additional diagnostic tests and/or related rare disease types will be covered and/or reimbursed in the future.

As a result, if adequate third-party coverage and reimbursement are unavailable, we may not be able to maintain volume and price levels sufficient to realize an appropriate return on investment in our diagnostic testing services or to advance our research and development solutions for our pharmaceutical partners.

We cannot predict what future healthcare initiatives will be introduced or implemented in the jurisdictions in which we operate, or how any future legislation or regulation may affect us. Any taxes imposed by legislation, as well as changes to the reimbursement amounts paid by payors for our existing and future products and solutions, could have a material adverse effect on our business, financial condition and results of operations.

Intellectual Property Risks Related to Our Business

If we are unable to obtain and maintain patent and other intellectual property protection for any products or solutions we develop and for our technology, or if the scope of intellectual property protection obtained is not sufficient, our competitors could develop and commercialize products and solutions similar or identical to ours, and our ability to successfully commercialize any products or solutions we may develop may be adversely affected.

Our success depends on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries for our biomarkers and other products and solutions. Patent law relating to the scope of claims in the fields in which we operate is complex and uncertain, so we cannot make any assurances that we will be able to obtain or maintain patent or other intellectual property rights, or that the patent and other intellectual property rights we may obtain will be valuable, provide an effective barrier to competitors or otherwise provide competitive advantages. In particular, our Lyso-Gb3 biomarker, which we use to support the diagnosis of Fabry disease, is not protected by any patents or included in any pending patent applications, and its successful commercialization by one of our competitors or by other third parties, which, in all probability, we would not be able to prevent, could materially harm our business or results of operations. Moreover, patent applications that we have made in the past have been subject to comment and revision by the relevant patent offices, which have resulted in our withdrawal of certain patent applications. If we are unable to obtain or maintain patent or other intellectual property protection with respect to our proprietary products and solutions, our business, financial condition, results of operations, and prospects could be materially harmed.

The scope of patent protection is uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Parties who have access to confidential or patentable aspects of our research and development output, such as our management and employees, advisors, and other third parties, and who are subject to non-disclosure and confidentiality agreements with us, may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection, or might themselves file respective IP rights. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of companies in our industry generally is unsettled, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our products or solutions or which effectively prevent others from commercializing competitive products and solutions.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold may be challenged, narrowed, circumvented, or invalidated by third parties. In particular, for more information regarding U.S. patent law decisions that negatively impact the patentability of biomarkers, diagnostic products and diagnostic methods, and the validity of granted U.S. patents covering such subject matter, see “—Developments in patent law could have a negative impact on our business” below. Consequently, we do not know whether any of our biomarkers or other products and solutions will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products and solutions in a non-infringing manner. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, know-how, and other confidential and proprietary information, our business and competitive position would be harmed.

In addition to seeking patent protection for our products and solutions, we also rely upon trade secret protection and non-disclosure agreements and invention assignment agreements with our management and employees, consultants and other third parties to protect our unpatented know-how, technology, and other confidential or proprietary information. For example, significant elements of our proprietary platform and some of our tests, including aspects of sample preparation, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets and know-how that to our knowledge are not publicly disclosed. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not provide adequate protection for our proprietary information; for example, in the case of misappropriation of intellectual rights by a member of management, an employee, consultant, or other third party with authorized access. We also cannot rule out the possibility that third parties specifically try to obtain our know-how, trade secrets or other confidential and proprietary information.

Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable non-disclosure agreements and invention assignment agreements with our management and employees, consultants and other third parties who have had access to our trade secrets or other proprietary information. Our security and contractual measures may not prevent a member of management, an employee, consultant, or other third party from misappropriating our trade secrets and providing them to a competitor, other third parties or to the public, and any recourse we take against such misconduct, including litigation, may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated intellectual property can be difficult, expensive, and time-consuming, and the outcome is unpredictable. Due to variations in the degree of protection afforded to intellectual property of this nature under the laws and regulations applicable to different international markets where our services are sold, our ability to pursue and obtain an adequate remedy may depend significantly on the jurisdiction in which the misconduct takes place and our ability to enforce a favorable judgment against the offending party in a jurisdiction in which such party has substantial assets. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information were independently developed by a competitor, our competitive position could be harmed.

Patents covering our products or solutions could be found invalid or unenforceable if challenged

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Others have filed, and in the future are likely to file, patent applications or related intellectual property rights that are similar or identical to ours. To determine the priority of inventions, demonstrate that we did not derive our invention from another individual or entity, or defend third-party challenges or reservations of the granting authorities to the validity or enforceability of our patent rights, we may have to participate in opposition, derivation, revocation, reexamination, entitlement, post-grant and *inter partes* review (“IPR”), or interference proceedings at the U.S. Patent and Trademark Office (the “USPTO”) or similar offices or respective courts in Europe or other jurisdictions. For example, we are aware of an opposition proceeding filed at the European Patent Office (“EPO”) by Sanofi against EP Patent No. 2 718 725 B1 (the “725 Patent”), a European patent that we (i.e. Centogene GmbH) own relating to our biomarker for Gaucher disease. The EPO opposition proceeding challenges the patentability of the ‘725 Patent in its entirety. The EPO rejected the opposition in the first instance in the hearing held on February 4, 2020. Sanofi filed an appeal against the opposition decision to the Board of Appeal at the EPO and the ‘725 Patent may still be revoked or maintained in amended form, in whole or in part, if the Board of Appeal does not uphold the opposition decision. The Board of Appeal scheduled oral appeal proceedings for September 26, 2023. Revocation or limitation of the ‘725 Patent may limit our ability to stop others from using or commercializing similar or identical products and solutions to ours or limit the duration of the patent protection of our products and solutions. We are also aware of an opposition proceeding filed at the European Patent Office (“EPO”) by Sanofi against EP Patent No. 3 318 881 B1 (the “881 Patent”) on April 15, 2021, another European patent that we (i.e. Centogene GmbH) own relating to our biomarker for Gaucher disease. The EPO opposition proceeding challenges the patentability of the ‘881 Patent in its entirety. Oral proceedings concerning the European patent took place before the opposition division of the EPO on May 04, 2022. The ‘881 Patent was maintained in limited form. We and Sanofi appealed the opposition decision. While we claim in our appeal that the opposition decision is reversed and the 881 Patent is maintained based on the set of claims as granted, Sanofi claims that the ‘881 Patent is revoked in its entirety. The outcome of the appeal is unclear. The ‘881 Patent may be revoked or maintained in amended, also further limited form, in whole or in part, which could materially harm our business. Revoking or maintaining the ‘881 Patent in amended form may limit our ability to stop others from using or commercializing similar or identical products and solutions to ours or limit the duration of the patent protection of our products and solutions. See “Item 4. Information On The Company—B. Business Overview—Legal Proceedings” and “Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Legal Proceedings.” Sanofi or other third parties may file future oppositions or other challenges, in Europe or other jurisdictions, against other patents that we own and may also challenge or attack the validity of the national parts of the ‘725 Patent and/or the ‘881 Patent before national patent courts in parallel or after the proceedings before the EPO. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our products or solutions and compete directly with us, without payment to us.

As of June 1, 2023, actions will most likely also be possible before the new European Unified Patent Court. If we do not actively exclude our existing (European patent applications as well as granted) European patents from this system (“opt-out”), they will become part of this new court system and it will be possible for third parties to challenge these patents before the courts of the Unified Patent Court system, with the consequence that these patents can then be restricted or revoked for the territory of all EU Member States participating in the Unitary Patent Court system (at the time of February 2023, these are Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia and Sweden; other countries may be added in the future, in particular Cyprus, Czech Republic, Greece, Hungary, Ireland, Romania and Slovakia) for which the European patent has effect. The same applies for future European patents and patent applications that are not opted out of the Unified Patent Court system, which is possible for a period of seven years after the date of entry into force of the Agreement on a Unified Patent Court unless an action has already been brought before the Unified Patent Court system in respect of the European patent or patent application. For future European patent applications, it also has to be decided whether a request for unitary effect is submitted with the consequence that the patent if grantable will be granted as Unitary Patent and can therefore be challenged before the Unified Patent Court and be restricted or revoked for the territory of all EU Member States participating in the Unitary Patent Court system.

Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office or nullity or entitlement proceedings, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patents being cancelled, narrowed, amended, invalidated, revoked, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and solutions, or limit the duration of the patent protection of our products and solutions. Such proceedings could also result in substantial costs in legal fees and require significant time from our management and employees, even if the eventual outcome is favorable to us. In the event of entitlement proceedings, purported co-inventors may bring claims for ownership, co-ownership, compensation and/or damages. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products or solutions, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In other jurisdictions, defendants have and/or may have comparable grounds for defending against such claims, especially with regard to claims that a patent is invalid. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution or that a court or office dealing with the invalidity will judge prior art known to us to be detrimental to novelty in a manner deviating from our opinion and/or the opinion of the granting authority, or will consider the invention to be obvious and thus not protectable on the basis of such prior art. Such challenges could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer sufficiently cover our products and solutions. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or solutions. Such a loss of patent protection would materially harm our business, prospects, financial condition and results of operations.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products and solutions and/or impact our share price.

Our commercial success depends upon our ability to develop and commercialize products and solutions and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. We could become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any products or solutions we may develop, including interference proceedings, post-grant review, IPR, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as oppositions before the EPO or nullity or entitlement proceedings. Third parties may assert infringement and other claims against us based on existing patents or patents that may be granted in the future, regardless of their merit, and we may assert infringement and other claims against third parties. As we continue to commercialize our genetic rare and neurogenerative disease information solutions (including our biomarkers), launch new solutions and enter new markets, we expect that competitors will claim that our products or solutions infringe or otherwise violate their intellectual property rights, including as part of business strategies designed to impede our successful commercialization and entry into new markets. Third parties may have obtained, and may in the future obtain, patents under which such third parties may claim that the use of our technologies constitutes patent infringement. Third parties have in the past asserted and may in the future assert that we are employing their proprietary technology without authorization, and we occasionally receive letters from third parties inviting us to take licenses under, or alleging that we infringe, their patents. Depending upon the circumstances, we may elect to remove a particular biomarker from one of our products or solutions.

Even if we believe that third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products or solutions we may develop or have developed. In order to successfully challenge the validity of any such U.S. patent in federal court or in courts in other jurisdictions, we would need to overcome a presumption of validity. As this burden is a high one, requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. The same applies to other jurisdictions and patents. Even if we were to find prior art that could justify the invalidation of the intellectual property right under which we are attacked, because of the bifurcated system dealing with infringement and validity before different courts in some jurisdictions (e.g., Germany), we may first be enjoined for infringement of the intellectual property right, which may be corrected only after subsequent invalidation of the intellectual property right. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue commercializing our products or solutions. However, we may not be able to obtain any required license on commercially reasonable terms, or at all and therefore may be unable to develop, sell or otherwise commercialize our products or solutions. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing, royalty, and other payments. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize, and sell our products and solutions, and could result in the award of substantial damages against us. In the event of a successful claim of infringement, misappropriation, or other intellectual property violation against us, we may be required to render account for and pay damages and attorneys' fees, recall or destroy stocks and obtain one or more licenses from third parties, or be prohibited from developing, commercializing and selling certain products or solutions. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right.

The new European Unified Patent Court system, which is expected to start on June 1, 2023, will allow the patent owner to obtain injunctive relief with unitary effect with a single decision of the courts of the Unified Patent Court system, i.e. within all the territories of the EU Member States participating in the Agreement on a Unified Patent Court including e.g. claims for damages, compensation, recall, destruction and information with regard to its Unitary Patents. For European patents not taken out of the Unified Patent Court system by "opt-out" and future European patents for which no request for unitary effect was submitted, decisions of the courts of the Unified Patent Court system cover the territory of the EU Member States participating in the Agreement on a Unified Patent Court for which the European patent has effect. This may result in the loss of significant market opportunities and substantial adverse effects of a judgement.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. We also could incur substantial costs and divert the attention of our management and other employees in participating in litigation or proceedings of this nature, and an adverse ruling or perception of an adverse ruling could have a material adverse impact on our cash position and share price. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees and various other governmental fees associated with patents and patent applications due in several stages over the lifetime of patents and patent applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forego patent protection or allow a patent application or patent or other intellectual property right to lapse purposefully or inadvertently, our competitive position could suffer. In such an event, potential competitors might be able to enter the market with similar or identical products and solutions. If we fail to obtain, maintain, protect or enforce our intellectual property rights successfully, our competitive position could suffer. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

Our rights to develop and commercialize our technology, products and solutions may in the future be subject, in part, to the terms and conditions of licenses granted to us by others.

In connection with the development of new products and solutions we may license intellectual property from third parties in the future or may deem it necessary to do so in order to commercialize our products or solutions. We may be unable to obtain these licenses at a reasonable cost, or at all. We could, therefore, incur substantial costs related to royalty payments or other payments for licenses obtained from third parties. We may also be unable to obtain exclusive rights to use such intellectual property or technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our products and solutions in the future and, as a result, we may not be able to prevent competitors from developing and commercializing competitive products or solutions. Moreover, we could encounter delays in introducing new products or solutions while we attempt to develop alternative products and solutions, and the defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing our products and solutions, which would materially affect our ability to grow.

Our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and solutions covered by such agreements. License agreements could also be time-limited or terminated, when possible, thereby removing our ability to develop and commercialize products and solutions covered by such agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors might have the freedom to market competing products and solutions identical or similar to ours. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues; as well as the effectiveness of the license agreement in general;
- whether our products and solutions infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the payment of royalties;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners, including the question of bearing the costs; and
- the priority of invention of patented technology.

In addition, agreements under which we license intellectual property or technology from third parties could be complex and turn out to be invalid in whole or in part. Certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement. Moreover, if disputes over intellectual property or technology that we have licensed prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, defending our position could materially harm our business, prospects, financial condition and results of operations.

With regard to the expected start of the Unified Patent Court on June 1, 2023, it should be noted that this is a completely new court system, whose procedural and adjudicative methods as well as the mutual effects between the national European patent jurisdictions and the jurisdiction of the new system are practically impossible to assess at present. This creates an uncertainty that may harm our business, prospects, financial condition and results of operations because decisions may be issued, and case law may develop that is disadvantageous for us.

Developments in patent law could have a negative impact on our business.

Changes in either the patent laws or interpretation of patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. From time to time, the United States Supreme Court (the “Supreme Court”), other federal courts, the U.S. Congress, the USPTO, or other foreign patent offices, courts or legislators may change the standards of patentability and any such changes could have a negative impact on our business. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the “America Invents Act”), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, IPR, and derivation proceedings. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in our industry are particularly uncertain. U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For example, diagnostic method claims and “gene patents” were considered in two landmark Supreme Court cases, *Mayo Collaborative v. Prometheus Laboratories* (“Prometheus”), and *Association for Molecular Pathology v. Myriad Genetics* (“Myriad”). In Prometheus, a case involving patent claims over a medical testing method directed to optimizing the amount of drug administered to a specific patient, Prometheus’ claims failed to incorporate sufficient inventive content above and beyond merely describing underlying natural correlations to allow the claimed processes to qualify as patent-eligible processes that apply natural laws. In Myriad, a case brought by multiple plaintiffs challenging the validity of patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2, the court held that isolated genomic DNA that exists in nature, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patentable subject matter, but that cDNA, which is an artificial construct created from RNA transcripts of genes, may be patent eligible. The Federal Circuit has begun to apply the holdings in Prometheus and Myriad. In 2015, the Federal Circuit, in *Ariosa v. Sequenom*, applying Prometheus, found claims to a prenatal diagnostic method that relied on a natural product to be patent ineligible, and clarified that the absence of preemption of a natural phenomenon was not sufficient to demonstrate patent eligibility.

In response to the Supreme Court decisions in Prometheus, Myriad, and *Alice Corporation Pty. Ltd. v. CLS Bank International* (“Alice Corp.”), and others, the USPTO has updated the Manual of Patent Examination Procedure to provide guidance to USPTO personnel in determining the eligibility of patent claims reciting judicially recognized exceptions to patentable subject matter, including laws of nature, natural phenomena, or abstract ideas, for patent eligibility. The USPTO guidance indicates that claims reciting a judicial exception to patent-eligible subject matter must amount to significantly more than the judicial exception itself in order to be patent-eligible subject matter. We cannot assure you that our efforts to seek patent protection for our products and solutions will not be negatively impacted by this interim guidance issued by the USPTO, the decisions described above, rulings in other cases, or changes in guidance or procedures issued by the USPTO.

We cannot fully predict what impact the Supreme Court's decisions in *Prometheus*, *Myriad*, *Alice Corp.*, and other decisions may have on our ability or the ability of companies or other entities to obtain or enforce patents relating to DNA, genes, or genomic-related discoveries in the future. Despite the USPTO's interim guidance and Federal Circuit cases described above, the contours of when claims reciting laws of nature, natural phenomena, or abstract ideas may meet the patent eligibility requirements are not clear and may take years to develop via interpretation at the USPTO and in the courts. There are many previously issued patents claiming nucleic acids and diagnostic methods based on natural correlations that issued before the recent Supreme Court decisions discussed, and although many of these patents may be invalid under the standards set forth in the Supreme Court's recent decisions, until successfully challenged, these patents are presumed valid and enforceable, and certain third parties could allege that we infringe, or request that we obtain a license to, these patents. Whether based on patents issued prior to or after these Supreme Court decisions, we might have to defend ourselves against claims of patent infringement, or choose to license rights, if available, under patents claiming such methods. In particular, although the Supreme Court has held in *Myriad* that isolated genomic DNA is not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other classes of gene-related patent claims, and we could have to defend ourselves against these claims by asserting non-infringement and/or invalidity positions or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter in question if we are unable to obtain a license on reasonable terms or at all. Such outcomes could materially affect our ability to offer our products and solutions and have a material adverse impact on our business. Even if we are able to obtain a license or successfully defend against claims of patent infringement, the cost and distraction associated with the defense or settlement of these claims could have a material adverse impact on our business. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

We may not be able to enforce our intellectual property rights throughout the world.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. Accordingly, we may face an increased risk in these jurisdictions that unauthorized parties may attempt to copy or otherwise obtain or use our patented technology, trademarks, formulations or other intellectual property. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of Germany or the United States. Specifically, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents or other intellectual property rights and to prevent third parties from selling or importing products made using our inventions in and to the United States, Germany or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent or other protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in Germany or the United States. These products may compete with our products and solutions, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, the use of our patents and/or other intellectual property rights may be permitted in individual cases because, for example, prior use rights or other privileges exist, e.g. use of the patents for experimental or research purposes. Additionally, many countries have compulsory licensing laws under which a patent owner must grant licenses to third parties or limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Monitoring infringement and misappropriation of intellectual property can be difficult and expensive, and we may not be able to detect every instance of infringement or misappropriation of our proprietary rights. Even if we do detect infringement or misappropriation of our proprietary rights, proceedings to enforce our intellectual property rights could result in substantial costs, divert the efforts and attention of our employees and management from other aspects of our business, put our patents at risk of being invalidated or construed narrowly or provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop. In addition, changes in the law and legal decisions by courts in Germany, the United States and other jurisdictions, in particular, the newly formed European Unified Patent Court, may affect our ability to obtain adequate protection for our products and solutions and to enforce our intellectual property rights. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. For example, we rely on certain third parties to provide us with biological materials that we use to conduct our genomic analyses. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to clearly address the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims that our agreements with our management, employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. We cannot exclude the possibility that third parties may claim to have made contributions to our inventions and accordingly claim co-inventor shares in inventions that we believe were made without the participation of third parties. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property and may even face damages and/or compensation claims of the third party for our use of the intellectual property. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

Most of our employees and inventions are subject to German law.

Most of our personnel, including many of our directors, work in Germany and are subject to German employment law. Inventions which may be the subject of a patent or of protection as a utility model and which are or were made by personnel working in Germany (except for legal representatives of our respective legal entities, for example managing directors) are subject to the provisions of the German Act on Employees' Inventions (*Gesetz über Arbeitnehmererfindungen*) (the "German Inventions Act"), which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes may occur between us and our current or past employees pertaining to the sufficiency of compensation paid by us, allocation of rights to inventions under this Act or alleged non-adherence to the provisions of this Act, any of which may be costly to resolve and take up our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Inventions Act, certain employees retain rights to patents and/or utility models they invented or co-invented and disclosed to us prior to October 1, 2009. If we do not manage to have the respective third-party interests transferred to us or are unable to obtain an exclusive license to any such third-party co-owners' or owners' interest in such patents and/or utility models, such co-owners or owners may be able to transfer or license their rights to other third parties, including our competitors. In addition, we may need the cooperation of any such co-owners or owners to enforce any such patents and/or utility models against third parties, or to conclude license agreements regarding such patents and/or utility models with third parties, and such cooperation may not be provided to us. While we believe that all our current and past German employee inventors have subsequently assigned to us their interest in inventions, patents and/or utility models they invented or co-invented, there can be no assurance that all such assignments are fully effective, which can lead to unexpected costs or economic disadvantages. Even if we lawfully own all inventions created by our employees who are subject to the German Inventions Act, we are required under German law to reasonably compensate such employees for the use of the inventions and intellectual property rights related thereto. If we are required to pay compensation or face other disputes under the German Inventions Act, our results of operations could be adversely affected. Legal representatives of legal entities, for example managing directors, whose contractual relationships with the respective entity are subject to German law and that are not subject to the German Inventions Act as well as consultants must assign and transfer their interest in inventions, patents and/or utility models they invent or co-invent to us in order for us to have any rights to such inventions, patents and/or utility models. While we believe that all assignments have been made, there can be no assurance that all such assignments are fully effective, which may harm our business, prospects, financial condition and results of operations.

If any of our current or past employees, legal representatives of our legal entities or consultants obtain or retain ownership or co-ownership of any inventions or related intellectual property rights that we believe we own, we may lose valuable intellectual property rights and be required to acquire the respective third-party interests or to obtain and maintain licenses from such employees, legal representatives of legal entities or consultants to such inventions or intellectual property rights, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to acquire the respective third-party interests or to obtain and maintain a license to any such employee's, legal representatives of legal entities' or consultant's interest in such inventions or intellectual property rights, we may need to cease the development, manufacture, and commercialization of one or more of the products or solutions we may develop or may have developed. In addition, any loss of exclusivity of our intellectual property rights could limit our ability to stop others from using or commercializing similar or identical products and solutions. We may also face entitlement, compensation and/or damages claims from our current or past employees, legal representatives of our legal entities or consultants owning or co-owning any inventions or related intellectual property rights that we believe we own. Any of the foregoing events could materially harm our business, prospects, financial condition and results of operations.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

Many of our employees (including our management) and consultants are currently or were previously employed at universities or other diagnostic or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a current or former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees and/or consultants. Such claims could materially harm our business, prospects, financial condition and result of operations.

In addition, while it is our policy to require our employees (including our management) and consultants who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could materially harm our business, prospects, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products or solutions that are similar to any products or solutions we develop or commercialize or utilize similar technology but that are not covered by the claims of our patents or patents that we might own or license in the future;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may own or license in the future, and this may result for example in possible rights to use the invention for the one who first made the invention; and in the invalidity of our patents;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;

- our issued patents or patents for which we hold or will hold licenses may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- courts might find our patents not infringed by products of third parties;
- our customers or competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products or solutions for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could materially harm our business, prospects, financial condition and results of operations.

Risks Relating to Our Financial Condition and Capital Requirements

We have a history of losses and we may incur losses in the future.

We have historically incurred losses, including total comprehensive losses of €31,917 thousand, €45,703 thousand, and €22,034 thousand in the years ended December 31, 2022, 2021 and 2020, respectively. We expect our losses to continue as a result of ongoing research and development expenses and increased selling and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and shareholders' equity. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.

We will require additional funding to continue as a going concern.

We incurred net losses for the year ended December 31, 2022. Our continued operations and the development of our business will require additional capital. Based on our current and anticipated level of operations, we do not believe that our cash and cash equivalents, together with anticipated revenues from operations, will be sufficient to meet our anticipated operating expenses, liabilities and obligations for at least 12 months from the date of this Annual Report. We will require additional funds to sustain operations, satisfy our obligations and liabilities, fund our ongoing operations, or for other purposes. In addition to sales of our products, we have historically relied upon sales of our equity or debt securities to fund our operations.

For example, on January 31, 2022, we entered into a securities purchase agreement and a warrant agreement, each signed with certain investors, under which we received EUR 15.0 million as consideration for the issuance by us of an aggregate of 4,479,088 common shares at a price per share of USD 3.73 and warrants initially exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares at an initial exercise price per common share of USD 7.72. The warrants are exercisable immediately as of the date of issuance and will expire on December 31, 2026.

On January 31, 2022, the Company and certain of its subsidiaries entered into a loan and security agreement with Oxford Finance LLC ("Oxford") in the total amount of up to USD 45.0 million (as amended from time to time, the "Loan and Security Agreement"). The Loan and Security Agreement contains customary affirmative covenants, negative covenants and events of default, including covenants and restrictions that, among other things, require the Company to satisfy a financial covenant, restrict the Company's ability to transfer cash to its subsidiaries and, in certain circumstances, restrict the Company's ability to incur liens, incur additional indebtedness, engage in mergers and acquisitions, make distributions or make asset sales without the prior written consent of the lenders thereunder. Additional debt financing, if available, would further increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

On July 28, 2022, we amended the Loan and Security Agreement to expand the scope of Permitted Indebtedness and Permitted Liens (each, as defined therein). On April 30, 2023, we amended the Loan and Security Agreement for a second time (the “Second Amendment”) to permit (i) the delivery of our audited consolidated financial statements for the fiscal year ended December 31, 2022 thirty days later than is otherwise required and (ii) the listing of our common shares on NASDAQ Capital Market.

The Second Amendment introduced new requirements that (i) we prepay any outstanding loans under the Loan and Security Agreement in an amount of \$5.0 million (plus fees, interest and expenses, in each case, pursuant to the terms of the Loan and Security Agreement) upon the first new business development or financing transaction we enter and (ii) we maintain at least €9.1 million in unrestricted cash on deposit in collateral accounts subject to Oxford’s perfected security interest granted under the Loan and Security Agreement.

Management plans to complete a significant financing primarily through private equity financing and/or convertible debt financing. The convertible debt financing discussions are at a progressed stage and aim to, not only, obtain a significant cash injection but also a long-term strategic collaboration in one of our key commercial regions. In parallel, management is in discussion with several private equity parties aiming to materialize a significant capital injection also with a suitable strategic fit for the company. Management has a reasonable level of confidence that one or more of the mentioned transactions should materialize in the next months improving the overall cash position and the mid-long-term sustainability of the Company.

The requirement for additional financing represents a material uncertainty that raises significant doubt about our ability to continue as a going concern. Without such funding considered, our current cash and cash equivalents will not be sufficient to fund our operations and meet all of our obligations as they fall due for at least one year from the date of the issuance of these consolidated financial statements. We do not know whether additional funding will be available in the desired amount, at the desired time, or on acceptable terms, or at all. Our ability to obtain required debt or equity financing or funds from other transactions will be subject to a number of factors, including without limitation market conditions, our capitalization, our operating performance and investor sentiment. We cannot assure you that we will be able to secure the funding required to allow us to continue as a going concern.

We may need to raise additional capital to fund our existing operations, develop our genetic information platform, commercialize new products and solutions and expand our operations.

If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products or solutions as a result of other risks described herein, we may seek to sell common or preferred equity or convertible debt securities, enter into another credit facility or another form of third-party funding, or seek other debt financing.

Our ongoing efforts to expand our business will require substantial cash resources. We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of our products and solutions and address competitive developments;
- fund development and marketing efforts of any future products and solutions;
- further expand our laboratory operations;
- expand our technologies into other types of diseases;
- obtain, maintain, protect and enforce existing or new intellectual property rights;
- acquire, license or invest in technologies, including information technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.
- Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products and solutions;
- our rate of progress in, and cost of research and development activities associated with, products and solutions in research and early development;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in research and development as a result of any regulatory oversight applicable to our products and solutions.

If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common shares. The terms of debt securities issued or borrowings pursuant to a credit or similar agreement could impose significant restrictions on our operations. Such financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If additional funds are raised by issuing equity securities through the sale of common shares or securities convertible or exchangeable into common shares, the ownership interest of our shareholders may be further diluted, and the terms of any securities may include liquidation or other preferences that materially adversely affect the rights of our common shareholders. In addition, if we were to issue equity securities at a low share price and low market valuation, it might be difficult for us to raise sufficient additional funds due to the significant dilution to current shareholders.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or drug candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Additional equity or debt financing might not be available on reasonable terms or at all. Because of our potential long-term capital requirements, we may access the public or private equity or debt markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us. Lastly, if we are unable to obtain the requisite amount of financing needed to fund our planned operations, our business could be jeopardized, and we may not be able to continue our operations or pursue our strategic plans. If we are forced to scale down or limit or cease operations, our shareholders could lose all of their investment in our Company.

Increasing our financial leverage could affect our operations, profitability and ability to raise additional capital.

Following disbursement of the second tranche of USD 20.0 million loan of our Loan and Security Agreement, our leverage has increased further. Our leverage may materially affect the availability of additional capital resources as well as our operations in several ways, including higher levels of interest expense to service or maintain our outstanding debt, the unavailability of additional borrowings in the future to repay our indebtedness when it comes due, less attractive economic or legal terms on which capital may be available to us and the possible diversion of liquidity from other uses.

Failure to meet covenants in our debt agreements could result in acceleration of our payment obligations thereunder, and we may not be able to find alternative financing.

Under the Loan and Security Agreement among Centogene N.V., Centogene GmbH, CentoSafe B.V. and Centogene US, LLC, as well as Oxford Finance LLC, we are required to maintain a specified amount of consolidated gross product revenue from our diagnostics and pharmaceutical services segments as of the end of each fiscal quarter on a trailing twelve-month basis, as specified in the Loan and Security Agreement. Our ability to comply with this covenant may be affected by factors beyond our control.

On July 28, 2022, we amended the Loan and Security Agreement to expand the scope of Permitted Indebtedness and Permitted Liens (each, as defined therein). On April 30, 2023, we amended the Loan and Security Agreement for a second time to permit (i) the delivery of our audited consolidated financial statements for the fiscal year ended December 31, 2022 thirty days later than is otherwise required and (ii) the listing of our common shares on NASDAQ Capital Market.

The Second Amendment introduced new requirements that (i) we prepay any outstanding loans under the Loan and Security Agreement in an amount of \$5.0 million (plus fees, interest and expenses, in each case, pursuant to the terms of the Loan and Security Agreement) upon the first new business development or financing transaction we enter and (ii) we maintain at least €9.1 million in unrestricted cash on deposit in collateral accounts subject to Oxford's perfected security interest granted under the Loan and Security Agreement.

If we fail to comply with the covenants contained in the Loan and Security Agreement or the amendments thereto, it could result in an event of default under the Loan and Security Agreement, which would permit or, in certain events, require Oxford to declare all amounts outstanding thereunder to be immediately due and payable. There can be no assurances that we will be able to repay all such amounts or able to find alternative financing in an event of a default. Even if alternative financing is available in an event of a default under the Loan and Security Agreement, it may be on unfavorable terms, and the interest rate charged on any new borrowings could be substantially higher than the interest rate under the Loan and Security Agreement, thus adversely affecting cash flows, results of operations, and ultimately, our ability to meet operating cash flow requirements.

The restrictive covenants in the Loan and Security Agreement and the Borrower's obligation to make debt payments under the Loan and Security Agreement may limit our operating and financial flexibility and may adversely affect our business, financial condition and results of operations.

The Loan and Security Agreement imposes operating and financial restrictions and covenants, which may limit or prohibit our ability to, among other things:

- incur additional indebtedness;
- make investments, including acquisitions;
- make payments on debt subordinated to the creditors under the Loan and Security Agreement;
- create liens on our property;
- make dividends, distributions or other restricted payments;
- effect affiliate transactions;
- enter into mergers, divisions, consolidations or sales of substantially all of our or our subsidiaries' assets;
- change business activities; or
- sell or otherwise dispose of property (without using the proceeds thereof to repay the obligations under the Loan and Security Agreement).

In addition, we are required to comply with certain financial covenants under the Loan and Security Agreement as described above.

Such restrictive covenants in the Loan and Security Agreement and our repayment obligations under the Loan and Security Agreement could have adverse consequences to us, including:

- limiting our ability to use cash;
- requiring us to prepay any outstanding loans under the Loan and Security Agreement in an amount of \$5.0 million (plus fees, interest and expenses, in each case, pursuant to the terms of the Loan and Security Agreement) upon the first new business development or financing transaction we enter;
- limiting our flexibility in operating our business and planning for, or reacting to, changes in our business and our industry;

- requiring the dedication of a substantial portion of any cash flow from operations to the payment of principal of, and interest on, our indebtedness, as well as to maintain at least €9.1 million in unrestricted cash in collateral accounts subject to Oxford's perfected security interest granted under the Loan and Security Agreement, thereby reducing the availability of such cash flow to fund our operations, working capital, capital expenditures, future business opportunities and other general corporate purposes;
- restricting us from making strategic acquisitions or causing us to make non-strategic divestitures;
- limiting our ability to obtain additional financing;
- limiting our ability to adjust to changing market conditions; and
- placing us at a competitive disadvantage relative to our competitors who are less leveraged.

If we fail to comply with the terms of the Loan and Security Agreement and there is an event of default, the creditors may foreclose upon the assets securing our obligations thereunder.

To secure the performance of our obligations under the Loan and Security Agreement, we granted Oxford security interests in substantially all of the assets of the Borrower. On April 30, 2023, we amended the Loan and Security Agreement to permit (i) the delivery of our audited consolidated financial statements for the fiscal year ended December 31, 2022 thirty days later than is otherwise required and (ii) the listing of our common shares on NASDAQ Capital Market.

The Second Amendment introduced new requirements that (i) we prepay any outstanding loans under the Loan and Security Agreement in an amount of \$5.0 million (plus fees, interest and expenses, in each case, pursuant to the terms of the Loan and Security Agreement) upon the first new business development or financing transaction we enter and (ii) we maintain at least €9.1 million in unrestricted cash on deposit in collateral accounts subject to Oxford's perfected security interest granted under the Loan and Security Agreement.

Our failure to comply with the terms of the Loan and Security Agreement and the amendments thereto could result in an event of default thereunder. In that event, Oxford will have the option to (and, in certain circumstances, will have the obligation to) foreclose on the assets of the Borrower pledged as collateral under the Loan and Security Agreement or the other documents executed in connection with the Loan and Security Agreement. The foreclosure on our assets could severely and negatively impact our business, financial condition and results of operations.

We may be required to refund grants and subsidies.

We have received various grants and subsidies to fund our research and development programs from various funding organizations. However, the Company continues to engage in efforts to secure further grants and subsidies for the next development steps of its product candidates. Some of these grants and subsidies provide for certain requirements in respect of the utilization of proceeds generated because of the publicly sponsored projects. For example, we received grants from the European Regional Development Fund to fund our Rostock facility, which grants are limited in purpose to development and innovation in the state of Mecklenburg-Western Pomerania, Germany. Other grants which we obtain may impose restrictions on our operations, and if we are in noncompliance with the restrictions and conditions of any grant or subsidy program, a partly or complete repayment cannot be excluded. This may also apply to grants and subsidies we may apply for in the future. If we are required to refund grants or subsidies, this could have a material adverse effect on our liquidity and cash flow position and may negatively affect our business, prospects, and financial conditions. In the year ended December 31, 2022, we have received a total of €506 thousand in grants for our activities.

We incur significant costs as a result of operating as a public company and our management needs to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, accounting, and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act, as well as rules implemented by the SEC, and the Nasdaq Global Market (“Nasdaq”). The SEC and other regulatory authorities have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”) was enacted. There are significant corporate governance- and executive compensation-related provisions in the Dodd-Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, and the way we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance programs and the monitoring of public company reporting obligations, and as a result of the new corporate governance- and executive compensation-related rules, regulations, and guidelines prompted by the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such rules and regulations. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make certain activities more time-consuming and costly.

To comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls, other procedures and internal control over financial reporting that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate, and additional material weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in the periodic reports we file with the SEC under Section 404 of the Sarbanes-Oxley Act, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. For example, we identified some errors in our consolidated financial statements for the three months ended March 31, 2022, for the six months ended June 30, 2022, for the years ended December 31, 2021, December 31, 2020 and December 31, 2019, which we corrected and restated in the subsequent filings. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our common shares could decline.

We are required to comply with certain of the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting, commencing with this, our second annual report. This assessment includes the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting or if we are unable to complete our evaluation, testing, and any required remediation in a timely fashion, we will be unable to assert that our internal control over financial reporting is effective. For further details, see “Item 15 – Controls and Procedures”.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company” as defined in the JOBS Act. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on the price of our common shares.

We will no longer qualify as an emerging growth company on November 6, 2024. As a result, we will be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act for the year ending December 31, 2024, and we will no longer be able to take advantage of the exemptions from reporting available to emerging growth companies absent other exemptions or relief available from the SEC. We will incur additional expenses in connection with compliance to these regulations and our management will need to devote additional time and effort to implement and comply with such requirements. For example, we have already hired an IT specialist for the implementation of IT general controls (ITGCs) and application controls, however, due to a two-year delay caused by the COVID-19 pandemic, we are currently significantly behind in establishing robust ITGCs. As such, it might take us longer than expected and we might have to incur additional costs to be fully compliant with the requirements of the Sarbanes-Oxley Act. In addition, a failure to have ITGCs in place may also result in undetected material weaknesses in our internal control over financial reporting and could lead to financial statement restatements and require us to incur the expenses of remediation.

If we fail to implement effective internal controls over financial reporting, such failure could result in material misstatements in our financial statements, cause investors to lose confidence in our reported financial and other public information and have a negative effect on the trading price of our common shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Section 404 of the Sarbanes-Oxley Act of 2002 requires management of public companies to develop and implement internal controls over financial reporting and evaluate the effectiveness thereof. If we fail to design and operate effective internal controls or remediate our existing material weaknesses, it could result in material misstatements in our financial statements, impair our ability to raise revenue, result in the loss of investor confidence in the reliability of our financial statements and subject us to regulatory scrutiny and sanctions, which in turn could harm the market value of our common shares.

We will be required to disclose changes made in our internal controls and procedures and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We will cease to qualify as an emerging growth company on November 6, 2024. As result, we will be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act for the year ending December 31, 2024. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We have identified three material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate our material weaknesses or if we fail to establish and maintain an effective system of internal control over financial reporting, we may not be able to report our financial results accurately or to prevent fraud.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Section 404 of the Sarbanes-Oxley Act of 2002 requires management of public companies to develop and implement internal controls over financial reporting and evaluate the effectiveness thereof. A material weakness is a deficiency or a combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

In connection with the preparation of our unaudited interim condensed consolidated financial statements as of and for the nine-month period ended September 30, 2018, we identified a material weakness in our internal controls as of December 31, 2017, related to the lack of effectively designed review controls over judgmental and complex areas of the financial statement close process and a lack of effectively designed routine financial statement close process controls. The material weakness was not fully remediated as of December 31, 2022 and now relates to a lack of effectively designed review and monitoring financial statement close process controls over routine and non-routine transactions, including the inability of our business to timely and appropriately communicate non-routine transactions to the finance function, together with the lack of accounting policies to enable timely and appropriate technical assessment of the related accounting implications of non-routine transactions; and a lack of an effectively designed and operating general IT controls framework (including system interfaces). In connection with the preparation of our unaudited financial results for the second quarter ended June 30, 2022, we identified a material weakness in our internal controls as of December 31,

2021, December 31, 2020 and December 31, 2019, for the information processed and reported by third parties in the US Dx business revenue recognition cycle, related to a lack of oversight and controls over the work performed. Further, as part of our close process material adjustments were identified due to a lack of review over the work products of a third-party supplier in relation to the valuation of financial instruments.

In response to the first two material weaknesses, management hired additional senior accounting and financial professionals with the experience and knowledge necessary to supervise the financial statement closing process and review the accounting records and necessary adjustments. An additional experienced professional was also engaged to begin establishing and implementing relevant internal control procedures to address the material weaknesses identified. Management also updated its remediation plan specific to the business areas impacted that includes additional reviews by management to exercise preventive control over the business and their third-party suppliers, the appointment of a co-manager from outside of the sales team to ensure appropriate communication between relevant departments. In relation to the second material weakness, we completed an optimization of our accounting system, and we commenced automation of certain control activities and report functionality during 2022. For the third material weakness that was identified during 2022, we implemented contracting guidelines for the selection of third-party suppliers in addition to the remediation efforts related to the first material weakness above.

During 2021 and 2022, we performed risk assessments to identify relevant financial risks and significant business processes and are designing and implementing a formalized SOX based framework for internal control. We designed and formalized policies and procedures to ensure routine transactions and complex areas of the financial statement close process are sufficiently analyzed and assessed against the requirements of IFRS and our corporate governance standards. In the year ending December 31, 2023, we intend to finalize the design and implementation of our internal control framework, including trainings to improve the technical abilities of our team to identify and properly address the requirements of IFRS. Although we are working to remediate the material weaknesses as quickly and efficiently as possible, we cannot reliably estimate the duration that will be required to effectively remediate the material weaknesses.

If we are unable to successfully remediate our identified material weaknesses, if we discover additional material weaknesses or if we otherwise are unable to report our financial statements accurately or in a timely manner, we would be required to continue disclosing such material weaknesses in future filings with the SEC, which could adversely affect our business, investor confidence in our company and the market price of our common shares and could subject us to litigation or regulatory enforcement actions. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the market value of our common shares.

Our results of operations could be materially adversely affected by fluctuations in foreign currency exchange rates.

Although we report our results of operations in euro, not all of our net revenues are denominated in the euro. Unfavorable fluctuations in foreign currency exchange rates could have a material adverse effect on our results of operations.

Because our consolidated financial statements are presented in euro, we must translate revenues, expenses and income, as well as assets and liabilities, into euros at exchange rates in effect during or at the end of each reporting period. Therefore, changes in the value of the euro against other currencies will affect our net revenues, operating income and the value of balance-sheet items originally denominated in other currencies. These changes cause our growth in consolidated earnings stated in euro to be higher or lower than our growth in local currency when compared against other periods.

As we continue to leverage our global delivery model, more of our expenses are incurred in currencies other than those in which we bill for the related services. An increase in the value of certain currencies against the euro could increase costs for delivery of services at off-shore sites by increasing labor and other costs that are denominated in local currency. There can be no assurance that our contractual provisions will offset their impacts. We also face risks that extreme economic conditions, political instability or hostilities or disasters of the type described below could impact our underlying exposures, perhaps eliminating them. Such an event could lead to losses being recognized on the currency hedges then in place, not offset by anticipated changes in the underlying hedge exposure.

Certain Factors Relating to Our Common Shares

Sales of substantial amounts of our common shares in the public market, or the perception that these sales may occur, could cause the market price of our common shares to decline.

Sales of substantial amounts of our common shares in the public market, or the perception that these sales may occur, could cause a decline in the market price of our common shares. This could also impair our ability to raise additional capital through the sale of our equity securities. Under our articles of association, we are authorized to issue up to 79,000,000 common shares, of which 27,595,835 common shares were outstanding as of December 31, 2022. If our existing shareholders sell substantial amounts of common shares in the public market, or the market perceives that such sales may occur, the market price of our common shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

Moreover, we have entered into a registration rights agreement entitling certain of our existing shareholders to rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. In addition, we have registered on a Form S-8 registration statement all common shares that we may issue under our long new term equity incentive plan.

As a result, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common shares could decline.

Our ordinary shares may be thinly traded and you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.

Our common shares may be “thinly-traded” meaning that the number of persons interested in purchasing our common shares at or near bid prices at any given time may be relatively small. This situation may be attributable to a number of factors, including the fact that we are relatively unknown to most stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and might be reluctant to follow a younger company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. A broad or active public trading market for our common shares may not develop or be sustained.

We have broad discretion in the use of our cash on hand and may invest or spend it in ways with which you do not agree and in ways that may not yield a return on your investment.

As of December 31, 2022, we had €36.0 million in cash and cash equivalents. Our management will have broad discretion in the use of such cash and could spend it in ways that do not improve our results of operations or enhance the value of our common shares. You will not have the opportunity to influence our decisions on how to use our cash on hand. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our common shares to decline and delay the development of our product candidates. Pending its use, we may invest our cash on hand in a manner that does not produce income or that loses value.

We may in the future not be compliant with all of Nasdaq’s continued listing standards and our common shares could be delisted.

Our common shares are currently listed for trading on the Nasdaq Global Market. Remaining listed for trading on Nasdaq requires us to remain compliant with Nasdaq’s current continued listing requirements, which include maintaining minimum levels of shareholders’ equity, assets and revenues (depending on the compliance standard being used to demonstrate compliance), and other quantitative standards such as minimum market value of publicly held shares, \$1.00 minimum closing bid price, and number of market makers.

On December 12, 2022, we received notification from the Nasdaq Stock Market LLC Listing Qualifications Department (“Nasdaq’s Listing Department”) that our Company was not in compliance with the minimum bid price requirement set forth in Nasdaq Rule 5450(a)(1) since the closing bid price for the Company’s common shares listed on Nasdaq was below US\$1.00 for 30 consecutive business days. Nasdaq Rule 5450(a)(1) requires the shares to maintain a minimum bid price of US\$1.00 per share, and Nasdaq Rule

5810(c)(3)(A) provides that failure to meet such a requirement exists when the bid price of the shares is below US\$1.00 for a period of 30 consecutive business days. On February 6, 2023, we received confirmation from Nasdaq that our Company has regained compliance with the minimum bid price requirement for continued listing under Nasdaq Rule 5450(a)(1), because the closing bid price of our common shares had been at \$1.00 per share or greater for the last 10 consecutive business days, from January 23 through February 3, 2023.

Subsequently, on April 24, 2023, we received a new notification from Nasdaq's Listing Department, indicating that our Company was again not in compliance with the minimum bid price requirement set forth in Rule 5450(a)(1) of the Nasdaq Listing Rules since the closing bid price for the Company's common shares listed on Nasdaq was below US\$1.00 for 30 consecutive business days (from March 10 through April 21, 2023). In accordance with Listing Rule 5810(c)(3)(A) of the Nasdaq Listing Rules, we have a period of 180 calendar days from the date of notification, or until October 23, 2023, to regain compliance with the minimum bid price requirement. If at any time during the 180-calendar day period, the bid price of our common shares closes at or above US\$1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the minimum bid price requirement and will consider such deficiency matter closed. In the event we do not regain compliance by October 23, 2023, subject to the determination by the staff of Nasdaq, we may be eligible for an additional 180 calendar days compliance period if we meet the continued listing requirements for market value of publicly held shares and all other initial listing standards, with the exception of bid price requirement, of the Nasdaq Capital Market, and provide written notice to Nasdaq of our intention to cure the deficiency.

We intend to actively monitor the bid price for our common shares and will evaluate all available options to resolve the deficiency and regain compliance with Nasdaq Rule 5450(a)(1). In addition to our deficiency regarding the minimum bid price requirement, concurrently with the filing of this Annual Report, we expect to also no longer be in compliance with the shareholder's equity requirement of Nasdaq Global Market, for which we expect to receive an additional delinquency letter. While we could transfer our listing venue to the Nasdaq Capital Market, we cannot rule out that in the future we will be able to satisfy all of the continued listing standards of the Nasdaq Capital Market.

If we are not able to meet any of Nasdaq's continued listing standards, we could be subject to suspension and delisting proceedings. A delisting of our common shares and our inability to list on another national securities market could negatively impact us by: (i) reducing the liquidity and market price of our common shares; (ii) reducing the number of investors willing to hold or acquire our common shares, which could negatively impact our ability to raise equity financing; (iii) limiting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing us from accessing the public capital markets; and (iv) impairing our ability to provide equity incentives to our employees.

If we fail to comply with Nasdaq rules governing the diversity of our board of directors, we could be exposed to financial penalties and suffer reputational harm.

In August 2021, the SEC announced that it had approved Nasdaq's proposed rule change to advance board diversity and enhance transparency of board diversity statistics through new listing requirements. Under these new listing rules, we are now required to annually disclose diversity statistics regarding our directors' voluntary self-identified characteristics and to have at least one diverse director by the later of August 7, 2023, or the date on which we file our annual report in 2023 (or explain why we do not have one such director) and two diverse directors, including one who self-identifies as female and one who self-identifies as either an underrepresented minority or LGBTQ+, by August 6, 2025, or the date on which we file our annual report in 2025 (or explain why we do not have two such directors). Failure to achieve designated minimum gender and diversity levels in a timely manner exposes us to financial penalties and reputational harm.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we are taking advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." For example, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We will cease to qualify as an emerging growth company on November 6, 2024. As result, we will be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act for the year ending December 31, 2024, and we will no longer be able to take advantage of the exemptions from reporting available to emerging growth companies absent other exemptions or relief available from the SEC. We cannot determine if investors find our common shares less attractive because we are relying on

these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (ii) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. If in the future we are not a foreign private issuer as of the last day of the second fiscal quarter in any fiscal year, we would be required to comply with all of the periodic disclosure, current reporting requirements and proxy solicitation rules of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our managing directors, supervisory board members and executive officers may not be United States citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we were to lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the costs we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. These rules and regulations could also make it more difficult for us to attract and retain qualified directors.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we follow certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are a foreign private issuer. As a result, in accordance with the listing requirements of Nasdaq, we are relying on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice will vary from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice varies from the requirement of Nasdaq Listing Rule 5620(b). As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of (i) Nasdaq Listing Rule 5605(d), which requires, among other things, an issuer to have a compensation committee that consists entirely of independent directors and makes determinations regarding the independence of any compensation consultants, (ii) Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations, and (iii) Nasdaq Listing Rule 5605(b), which requires an issuer to have a majority of independent directors on its board. In addition, we have opted out of shareholder approval requirements, as included in the Nasdaq Listing Rules, for the issuance of securities in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of the Company and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq rules.

Insiders continue to have substantial control over us and could limit your ability to influence the outcome of key transactions, including a change of control.

Our principal shareholders, including certain of our managing directors, supervisory board members and executive officers and entities affiliated with them, in the aggregate, continue to beneficially own approximately 57.6% of outstanding common shares as at December 31, 2022. For further information, please refer to note 21 of our consolidated financial statements as of and for the year ended December 31, 2022. As a result, these shareholders, if acting together, are able to influence or control matters requiring approval by our general meeting of shareholders, including the election of managing directors and supervisory board members, changes to our articles of association and the approval of mergers or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree, and which may be averse to your interests. The concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our shareholders of an opportunity to receive a premium for their common shares as part of a sale of our company and might ultimately affect the market price of our common shares.

We do not anticipate paying any cash dividends in the foreseeable future.

We currently intend to retain our future earnings, if any, for the foreseeable future, to repay indebtedness and to fund the development and growth of our business. We do not intend to pay any dividends to holders of our common shares. As a result, capital appreciation in the price of our common shares, if any, will be your only source of gain on an investment in our common shares.

If we do pay dividends, we may need to withhold tax on such dividends payable to holders of our shares in both Germany and the Netherlands.

We do not intend to pay any dividends to holders of our common shares. However, if we do pay dividends, we may need to withhold tax on such dividends both in Germany and the Netherlands. As an entity incorporated under Dutch law, any dividends distributed by us are subject to Dutch dividend withholding tax on the basis of Dutch domestic law. However, on the basis of the 2012 Convention between the Federal Republic of Germany and the Kingdom of the Netherlands for the avoidance of double taxation with respect to taxes on income (the “double tax treaty between Germany and the Netherlands”), the Netherlands will be restricted in imposing these taxes if we continue to be a tax resident of Germany and our place of effective management is located in Germany. See “Item 3. Key Information—D. Risk Factors—We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us.” However, Dutch dividend withholding tax is still required to be withheld from dividends if and when paid to Dutch resident holders of our common shares (and non-Dutch resident holders of our common shares that have a permanent establishment in the Netherlands to which their shareholding is attributable). As a result, upon a payment of dividends, we will be required to identify our shareholders in order to assess whether there are Dutch residents (or non-Dutch residents with a permanent establishment in the Netherlands to which the common shares are attributable) in respect of which Dutch dividend tax has to be withheld. Such identification may not always be possible in practice. If the identity of our shareholders cannot be determined, withholding of both German and Dutch dividend tax may occur upon a payment of dividends.

Furthermore, the withholding tax restriction referred to above is subject to the applicability of the Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting (the “MLI”). While Germany has enacted the MLI with effect as of April 1, 2021, it has, so far, refrained from initiating a notification procedure vis-à-vis the Netherlands as necessary under the rules of the MLI to set into force the rules of the MLI, and neither has the Netherlands notified the applicability of the MLI towards Germany. Only if Germany decides to change its reservation with respect to the tie-breaker provision (the “MLI Tie-Breaker Reservation”) included in Article 4(3) of the 2012 Convention between the Federal Republic of Germany and the Kingdom of the Netherlands for the avoidance of double taxation with respect to taxes on income, and only if the applicability of the MLI has been mutually notified by Germany and the Netherlands, we may no longer be entitled anymore to any benefits of the double tax treaty between Germany and the Netherlands, including the withholding tax restriction, provided that Germany and the Netherlands do not reach an agreement on our tax residency for purposes of the double tax treaty between Germany and the Netherlands, except to the extent and in such manner as may be agreed upon by the authorities. As a result, any dividends distributed by us may be subject to withholding tax both in Germany and the Netherlands.

In addition, a proposed law is currently pending before the Dutch parliament, namely the Emergency act conditional exit dividend tax (Spoedwet conditionele eindafrekening dividendbelasting) which would, if enacted, impose, possibly with retroactive effect, a dividend withholding (exit) tax on certain deemed distributions if we cease to be a Dutch tax resident and become a tax resident of a jurisdiction that is not a member of the EU or the EEA, when such jurisdiction does not satisfy certain conditions. In some cases, we would have a right to recover the amount of tax from our shareholders when such shareholder is not entitled to an exemption.

We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us.

Since our incorporation we have had, on a continuous basis, our place of “effective management” in Germany. Therefore, we believe that we qualify as a tax resident of Germany based on German domestic law. As an entity incorporated under Dutch law, however, we also qualify as a tax resident of the Netherlands based on Dutch domestic law. However, based on our current management structure and the current tax laws of Germany and the Netherlands, as well as applicable income tax treaties, and current interpretations thereof, we believe that we are a tax resident solely in Germany for the purposes of the double tax treaty between Germany and the Netherlands due to the “effective management” tie-breaker. The test of “effective management” is largely a question of fact and degree based on all the circumstances, rather than a question of law. Nevertheless, the relevant case law and OECD guidance suggest that the Company is likely to be regarded as having become a German tax resident from incorporation and remaining so if, as the Company intends, (i) most meetings of its management board are held in Germany (and none are held in the Netherlands) with a majority of directors present in Germany for those meetings; (ii) at those meetings there are full discussions of, and decisions are made regarding, the key strategic issues affecting the Company and its subsidiaries; (iii) those meetings are properly minuted; (iv) at least some of the directors of the Company, together with supporting staff, are based in Germany; and (v) the Company has permanent staffed office premises in Germany. We may, however, become subject to limited income tax liability in other countries with regard to the income generated in the respective other country, for example, due to the existence of a permanent establishment or a permanent representative in such other country.

Our sole tax residency in Germany for purposes of the above-mentioned tax treaty is subject to the application of the provisions on tax residency as stipulated in such tax treaty as amended from time to time. The MLI, Germany and the Netherlands entered into, among other countries, should not, as of this date, affect such tax treaty's rules regarding tax residency.

The applicable tax laws, tax treaties or interpretations thereof may change. Furthermore, whether we have our place of effective management in Germany and are as such tax resident in Germany is largely a question of fact and degree based on all the circumstances, rather than only a question of law, which facts and degree may also change. Changes to applicable tax laws, tax treaties or interpretations thereof and changes to applicable facts and circumstances (for example, a change of board members or the place where board meetings take place), or changes in the applicable tax treaties, including a change to the MLI, may result in us also becoming a tax resident of the Netherlands or another jurisdiction (other than Germany), potentially also triggering an exit liability in Germany. Therefore, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, results of operations, financial condition and prospects, which could cause our share price and trading volume to decline. However, if there is a double tax treaty between Germany and the respective other country, the double taxation of income may be reduced or avoided entirely.

Shareholders may not be able to exercise preemptive rights and, as a result, may experience substantial dilution upon future issuances of common shares

In the event of an issuance of common shares, subject to certain exceptions, each shareholder will have a pro rata preemptive right in proportion to the aggregate nominal value of the common shares held by such holder. These preemptive rights may be restricted or excluded by a resolution of the general meeting of shareholders or by another corporate body designated by the general meeting of shareholders. Our management board is authorized, until June 22, 2027, to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time and to limit or exclude preemptive rights in connection therewith. This could cause existing shareholders to experience substantial dilution of their interest in us.

If equity and industry research analysts publish negative evaluations of or downgrade our common shares, the price of our common shares could decline.

The trading market for our common shares relies in part on the research and reports that equity and industry research analysts publish about us or our business. We do not control these analysts. If one or more of the analysts covering our business downgrade their evaluations of our common shares, the price of our common shares could decline. If one or more of these analysts cease to cover our common shares, we could lose visibility in the market for our common shares, which in turn could cause our common shares price to decline.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

Our ability to utilize our net operating losses ("NOLs") is currently limited, and may be limited further, under Section 8c of the German Corporation Income Tax Act (*Körperschaftsteuergesetz*, the "KStG") and Section 10a of the German Trade Tax Act (*Gewerbesteuergesetz*, the "GewStG"). These limitations apply if a qualified ownership change, as defined by Section 8c KStG, occurs subject to certain exemptions, as described below.

Under current tax laws, tax loss carryforwards can generally be used for an unlimited period of time but any change of control in the Company – including as a result of a capital increase – could result in the expiry of such tax loss carryforwards and of any current year losses if, subject to further prerequisites, more than 50% of the subscribed capital or voting rights of the Company will be, directly or indirectly, transferred to an acquirer (including parties related to the acquirer constituting a group of acquirers with aligned interests) within five years or a comparable acquisition occurs. However, tax loss carryforwards and unused current losses taxable in Germany will not expire to the extent that they are covered by built-in gains of the Company that are taxable in Germany at the time of such acquisition (Stille-Reserven-Klausel, the “Hidden-Reserves Clause”). Further, any share transfer that would otherwise be subject to the loss forfeiture rule above does not result upon application in forfeiture of tax loss carryforwards and interest carryforwards resulting from current business operations of the Company, if the current business operations of the Company remained the same (i) from the time of its establishment; or (ii) during the last three business years prior to the share transfer and such business operations are maintained after the transfer (fortführungsgebundener Verlustvortrag). The determination of whether the business operations have been maintained is assessed on the basis of qualitative factors, such as the produced goods and services, target markets, customer and supplier bases, etc. However, the tax loss carryforwards will be forfeited in any circumstance if, after the share transfer, the business operations of the Company become dormant, are modified or substantially restructured, the Company becomes a partner in an operating partnership (Mitunternehmerschaft), the Company becomes a fiscal unity parent, or assets are transferred from the Company and recognized at a value lower than the fair market value. This requirement is monitored until the retained tax loss carryforwards have been fully utilized.

According to another appeal filed by the fiscal court of Hamburg dated August 29, 2017, Section 8c, paragraph 1, sentence 1 KStG is not in line with the German constitution. The appeal is still pending. It is unclear when the Federal Constitutional Court will decide this case. According to statements in German legal literature, there are good reasons to believe that the Federal Constitutional Court may come to the conclusion that Section 8, paragraph 1, sentence 1 KStG is not in line with the German constitution.

As of December 31, 2022, we estimate unrecognized NOL carryforwards for German tax purposes of €133.5 million available which have not yet been assessed. However, we have not recognized a deferred tax asset for tax losses carried forward in our consolidated financial statements, see “Item 10. Financial Statements—Notes to the consolidated financial statements as of December 31, 2022 and 2021 and for the three years ended December 31, 2022, 2021 and 2020”. Future changes in share ownership may also trigger an ownership change and, consequently, a Section 8c KStG or a Section 10a GewStG limitation. Any limitation may result in the expiration of a portion or the complete tax operating loss carryforwards before they can be utilized. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to reduce German income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

Although we do not believe that we were a “passive foreign investment company,” or a PFIC, for U.S. federal income tax purposes for 2022, there is a significant risk that we may be a PFIC for 2023 or one or more future taxable years. If we are a PFIC for any taxable year, U.S. shareholders may be subject to adverse U.S. federal income tax consequences.

Under the Internal Revenue Code of 1986, as amended (the “Code”), we will be a PFIC for any taxable year in which, after the application of certain “look-through” rules with respect to our subsidiaries, either (i) 75% or more of our gross income consists of passive income or (ii) 50% or more of the average value of our assets (generally determined on a quarterly basis) consists of assets that produce, or are held for the production of, “passive income.” For purposes of the above calculations, we will be treated as if we hold our proportionate share of the assets of, and receive directly our proportionate share of the income of, any other corporation in which we directly or indirectly own at least 25%, by value, of the shares of such corporation. Passive income includes, among other things, dividends, interest, certain non-active rents and royalties, and investment gains. For these purposes cash is generally a passive asset. Goodwill is generally an active asset to the extent associated with business activities that produce active income.

Based on our current operations and composition of our income and assets, and certain estimates as to the value of our assets, we do not believe that we were a PFIC for our 2022 taxable year. However, there can be no assurance that the Internal Revenue Service (the “IRS”) will agree with our conclusion. In addition, whether we will be a PFIC in 2023 or any future taxable year is uncertain because, among other things, (i) we currently own, and expect to continue to own, a substantial amount of passive assets, including cash, (ii) the value of our assets that generate non-passive income for PFIC purposes, including our goodwill and other intangible assets, is uncertain and may vary substantially over time (and may be determined, in part, by reference to our market capitalization, which has been, and may continue to be, volatile) and (iii) the composition of our income may vary substantially over time. Accordingly, there can be no assurance that we will not be a PFIC for any taxable year. For example, if we raise additional cash, or if our market capitalization continues to decline or fluctuate (and the value of our assets were determined in part by reference to our market capitalization), then there is a significant risk that we could be a PFIC for 2023, depending on the composition and average value of our assets for 2023 (which cannot be determined until after 2023).

If we are a PFIC for any taxable year during which a U.S. investor holds our common shares, we will continue to be treated as a PFIC with respect to that U.S. investor for all succeeding years during which the U.S. investor holds our common shares, even if we cease to meet the threshold requirements for PFIC status, unless certain exceptions apply. Such a U.S. investor may be subject to adverse U.S. federal income tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) an additional tax liability representing deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements. We do not intend to provide the information that would enable investors to make a qualified electing fund election (a “QEF Election”) that would result in alternative U.S. federal income tax treatment if we are a PFIC for a taxable year.

For further discussion, see “Item 10. Additional Information—E. Taxation—Material U.S. Federal Income Tax Considerations for U.S. Holders.”

If a U.S. person is treated as owning 10% or more of our stock by vote or value, such person may be subject to adverse U.S. federal income tax consequences.

If a U.S. person is treated as owning (directly, indirectly or constructively) 10% or more of our stock by value or voting power, such person generally will be treated as a “United States shareholder” with respect to each “controlled foreign corporation” (a “CFC”) in our group. A CFC is a non-U.S. corporation more than 50% of the stock (by voting power or value) of which is owned (directly, indirectly, or constructively) by “United States shareholders.” We have not determined whether we are a CFC. However, even if we are not a CFC, under certain ownership attribution rules our non-U.S. subsidiaries could be treated as owned by our U.S. subsidiary and thus may be treated as CFCs. A United States shareholder of a CFC that owns directly or indirectly the CFC’s stock may be subject to additional U.S. federal income tax liabilities and reporting requirements. We do not intend to furnish to any information that may be necessary for United States shareholders, if any, to comply with the CFC rules. U.S. investors that may be treated for purposes of the CFC rules as owning 10% of our stock by voting power or value should consult their tax advisers regarding the potential application of these rules in their particular circumstances.

We are a Dutch public company. The rights of our shareholders are different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions and may not protect investors in a similar fashion afforded by incorporation in a U.S. jurisdiction.

We are a Dutch public company (*naamloze vennootschap*) organized under the laws of the Netherlands. Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in the Netherlands. However, there can be no assurance that Dutch law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the United States, which could adversely affect the rights of investors.

The rights of shareholders and the responsibilities of managing directors and supervisory board members may be different from the rights and obligations of shareholders and board members in companies governed by the laws of U.S. jurisdictions. In the performance of their duties, our managing directors and supervisory directors are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder.

Provisions of our articles of association or Dutch corporate law might deter acquisition bids for us that might be considered favorable and prevent, delay or frustrate any attempt to replace or remove the members of our management board or supervisory board.

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. In this respect, certain provisions of our articles of association may make it more difficult for a third party to acquire control of us or effect a change in our management board and supervisory board. These include:

- a provision that our managing directors and supervisory directors are appointed on the basis of a binding nomination prepared by our supervisory board which can only be overruled by a two-thirds majority of votes cast representing more than 50% of our issued share capital;

- a provision that our managing directors and supervisory directors may only be dismissed by the general meeting of shareholders by a two-thirds majority of votes cast representing more than 50% of our issued share capital, unless the dismissal is proposed by the supervisory board in which case a simple majority of the votes would be sufficient;
- a provision allowing, among other matters, the former chairperson of our supervisory board to manage the supervision of our affairs if all of our supervisory directors are dismissed and to appoint others to be charged with the supervision of our affairs, including the preparation of a binding nomination for our managing directors and supervisory directors as discussed above, until new supervisory directors are appointed by the general meeting on the basis of such binding nomination); and
- a requirement that certain matters, including an amendment of our articles of association, may only be brought to our shareholders for a vote upon a proposal by our management board with the approval of our supervisory board.

Dutch law also allows for staggered multi-year terms of our managing directors and supervisory directors and as a result, only part of our managing directors and supervisory directors may be subject to appointment or re-appointment in any given year.

Furthermore, in accordance with the Dutch Corporate Governance Code, or DCGC, shareholders who have the right to put an item on the agenda for our general meeting or to request the convening of a general meeting shall not exercise such rights until after they have consulted our management board. If exercising such rights may result in a change in our strategy (for example, through the dismissal of one or more of our managing directors or supervisory directors), our management board must be given the opportunity to invoke a reasonable period of up to 180 days to respond to the shareholders' intentions. If invoked, our management board must use such response period for further deliberation and constructive consultation, in any event with the shareholder(s) concerned and exploring alternatives. At the end of the response time, our management board, supervised by our supervisory board, shall report on this consultation and the exploration of alternatives to our general meeting. The response period may be invoked only once for any given general meeting and shall not apply (i) in respect of a matter for which a response period has been previously invoked or (ii) if a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid.

Moreover, our management board, with the approval of our supervisory board, can invoke a cooling-off period of up to 250 days when shareholders, using their right to have items added to the agenda for a general meeting or their right to request a general meeting, propose an agenda item for our general meeting to dismiss, suspend or appoint one or more managing directors or supervisory directors (or to amend any provision in our articles of association dealing with those matters) or when a public offer for our company is made or announced without our support, provided, in each case, that our management board believes that such proposal or offer materially conflicts with the interests of our company and its business. During a cooling-off period, our general meeting cannot dismiss, suspend or appoint managing directors and supervisory directors (or amend the provisions in our articles of association dealing with those matters) except at the proposal of our management board. During a cooling-off period, our management board must gather all relevant information necessary for a careful decision-making process and at least consult with shareholders representing 3% or more of our issued share capital at the time the cooling-off period was invoked, as well as with our Dutch works council (if we or, under certain circumstances, any of our subsidiaries would have one). Formal statements expressed by these stakeholders during such consultations must be published on our website to the extent these stakeholders have approved that publication. Ultimately, one week following the last day of the cooling-off period, our management board must publish a report in respect of its policy and conduct of affairs during the cooling-off period on our website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at our office and must be tabled for discussion at the next general meeting. Shareholders representing at least 3% of our issued share capital may request the Enterprise Chamber of the Amsterdam Court of Appeal, or the Enterprise Chamber (*Ondernemingskamer*), for early termination of the cooling-off period. The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that:

- our management board, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have concluded that the relevant proposal or hostile offer constituted a material conflict with the interests of our company and its business;
- our management board cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making; or
- other defensive measures, having the same purpose, nature and scope as the cooling-off period, have been activated during the cooling-off period and have not since been terminated or suspended within a reasonable period at the relevant shareholders' request (i.e., no 'stacking' of defensive measures).

We are not obligated to, and do not, comply with all best practice provisions of the Dutch Corporate Governance Code.

As a Dutch public company, we are subject to the DCGC. The DCGC contains both principles and best practice provisions on corporate governance that regulate relations between the management board, the supervisory board and the shareholders and matters in respect of financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC is based on a “comply or explain” principle. Accordingly, companies are required to disclose in their annual reports, filed in the Netherlands, whether they comply with the provisions of the DCGC. If a company does not comply with those provisions (for example, because of a conflicting Nasdaq requirement), that company is required to give the reasons for such non-compliance. The DCGC applies to Dutch companies listed on a government-recognized stock exchange, whether in the Netherlands or elsewhere, including Nasdaq. We do not comply with all best practice provisions of the DCGC. This may affect your rights as a shareholder, and you may not have the same level of protection as a shareholder in a Dutch company that fully complies with the DCGC.

Our share price might fluctuate, and as a result, you could lose a significant part of your investment.

The market price of our common shares may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- financial analysts ceasing to cover our common shares or changes in financial estimates by analysts;
- actual or anticipated variations in our operating results;
- changes in financial estimates by financial analysts, or any failure by us to meet or exceed any of these estimates, or changes in the recommendations of any financial analysts that elect to follow our common shares or the shares of our competitors;
- announcements by us or our competitors of significant contracts or acquisitions;
- future sales of our shares; and
- investor perceptions of us and the industries in which we operate.

In addition, the stock market in general has experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors may materially harm the market price of our common shares, regardless of our operating performance. In the past, following periods of volatility in the market price of certain companies’ securities, securities class action litigation has been instituted against these companies. This litigation, if instituted against us, could adversely affect our financial condition or results of operations.

U.S. investors may have difficulty enforcing civil liabilities against us or the members of our management board and supervisory board.

We are organized and existing under the laws of the Netherlands, and, as such, under Dutch private international law rules the rights of our shareholders and the civil liability of our directors and executive officers are governed in certain respects by the laws of the Netherlands. The ability of our shareholders in certain countries other than the Netherlands to bring actions against us, our directors and executive officers may be limited under applicable law. In addition, substantially all of our assets are located outside the United States.

As a result, it may not be possible for investors to effect service of process within the United States upon us or our directors and executive officers or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States. In addition, it is not clear whether a Dutch court would impose civil liability on us or any of our directors and executive officers in an original action based solely upon the federal securities laws of the United States brought in a court of competent jurisdiction in the Netherlands.

As of the date of this Annual Report, there is no treaty between the United States and the Netherlands providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. It is noted, on the date of this Annual Report, that the Hague Convention on Choice of Court Agreements of 30 June 2005 has entered into force for the Netherlands, but has not entered into force for the United States. The Hague Convention of 2 July 2019 on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters has not entered into force for either the Netherlands or the United States. Accordingly, a judgment rendered by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized and enforced by the competent Dutch courts. However, if a person has obtained a judgment rendered by a court in the United States that is enforceable under the laws of the United States and files a claim with the competent Dutch court, the Dutch court will in principle give binding effect to a foreign judgment if (i) the jurisdiction of the U.S. court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the U.S. court was rendered in legal proceedings that comply with the Dutch standards of proper administration of justice including sufficient safeguards (*behoorlijke rechtspleging*), (iii) binding effect of such U.S. judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the U.S. court is not incompatible with a decision rendered between the same parties by a Dutch court, or with a previous decision rendered between the same parties by a foreign court in a dispute that concerns the same subject and is based on the same cause, provided that the previous decision qualifies for recognition in the Netherlands. Even if such a U.S. judgment is given binding effect, a claim based thereon may, however, still be rejected if the U.S. judgment is not or no longer formally enforceable. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the number of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*).

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or our directors, representatives or certain experts named herein who are residents of the Netherlands or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

The United States and Germany currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, in civil and commercial matters. Consequently, a final judgment for payment or declaratory judgments given by a court in the United States, whether predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Germany. German courts may deny the recognition and enforcement of a judgment rendered by a U.S. court if they consider the U.S. court not to be competent or the decision to be in violation of German public policy principles. For example, judgments awarding punitive damages are generally not enforceable in Germany. A German court may reduce the number of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages.

In addition, actions brought in a German court against us, our managing directors, our supervisory board members, our senior management and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions. German courts generally do not award punitive damages. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. German procedural law does not provide for pre-trial discovery of documents, nor does Germany support pre-trial discovery of documents under the 1970 Hague Evidence Convention. Proceedings in Germany would have to be conducted in the German language and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our managing directors, our supervisory board members, our senior management and the experts named in this Annual Report.

Based on the foregoing, there can be no assurance that U.S. investors will be able to enforce against us or management board members, supervisory board members and executive officers or certain experts named herein who are residents of or possessing assets in the Netherlands, Germany, or other countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities.

Item 4. Information on the Company

A. History and Development of the Company

Centogene was founded by our former CEO, Prof. Arndt Rolfs, in 2006 in Rostock, Germany. In connection with our initial public offering (“IPO”), which closed on November 12, 2019, we executed a corporate reorganization whereby Centogene B.V., which was incorporated on October 11, 2018, was converted into Centogene N.V. and Centogene N.V. became the holding company for Centogene AG, which remains our principal operating subsidiary. Centogene N.V. is a Dutch public company (*naamloze vennootschap*) organized under the laws of the Netherlands and our legal and commercial name is Centogene N.V.

In July 2020, we completed a follow-on public offering of 3,500,000 common shares of the Company (the “Follow-on Equity Offering”), consisting of 2,000,000 common shares offered by the Company and 1,500,000 common shares offered by selling shareholders at a price to the public of \$14.00 per common share (i.e., €12.71 per share). Aggregate offering proceeds, net of underwriting discounts, commissions and transaction costs, to the Company were €22 million. On March 5, 2020, the Company resolved that Centogene AG shall be converted into a German limited liability company and renamed Centogene GmbH. Such conversion became effective upon the registration in the German commercial register on June 29, 2020, and was therefore completed in the financial year ending December 31, 2020. On January 31, 2022, pursuant to a securities purchase agreement and a warrant agreement, each signed with certain investors, we received €15.0 million as consideration for the issuance by us of an aggregate of 4,479,088 common shares at a price per share of \$3.73 and warrants initially exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares at an initial exercise price per common share of \$7.72. The warrants are exercisable immediately as of the date of issuance and will expire on December 31, 2026.

Our principal executive offices are located at Am Strande 7, 18055 Rostock, Germany and our additional offices are in Berlin (Germany), Cambridge (Massachusetts, United States), Vienna (Austria), Dubai (United Arab Emirates), Delhi (India), and Zug (Switzerland). The office located in Vienna (Austria) is expected to be closed in 2023. Since November 7, 2019, our common shares have traded on Nasdaq under the symbol “CNTG.” Our agent for service of process in the United States is Cogency Global, located at 10 East 40th Street, 10th Floor, New York, NY 10016.

We are an emerging growth company and as such, we are eligible to, and intend to, take advantage, for up to five years, of certain exemptions from various reporting requirements applicable to other public companies that are not Emerging Growth Companies, such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We will cease to qualify as an emerging growth company on November 6, 2024. As a result, we will be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act for the year ending December 31, 2024, and we will no longer be able to take advantage of the exemptions from reporting available to emerging growth companies absent other exemptions or relief available from the SEC.

We will remain an emerging growth company until the earliest of: (i) the last day of our fiscal year during which we have total annual gross revenues of at least \$1.235 billion; (ii) the last day of our fiscal year following the fifth anniversary of the closing of our IPO; (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt; (iv) the date on which we are deemed to be a Large Accelerated Filer under the Exchange Act, with at least \$700 million of equity securities held by non-affiliates.

Our capital expenditures for 2022, 2021 and 2020 amounted to €2,094 thousand, €5,702 thousand and €16,547 thousand, respectively. These expenditures were primarily for property, plant and equipment and intangible assets. For further details see Item 4B below.

The SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov. Our website can be found at www.centogene.com. The information on our website is not incorporated by reference into this Annual Report, and you should not consider information contained on our website or any websites mentioned in this Annual Report to be part of this Annual Report.

B. Business Overview

We provide data-driven answers to patients, physicians, and pharmaceutical companies for rare and neurodegenerative diseases. We integrate multiomic technologies with the CENTOGENE Biodatabank – enabling a comprehensive analysis to guide precision medicine. Our unique approach enables rapid and reliable diagnosis for patients, supports a more precise physician understanding of disease states, and accelerates and de-risks targeted pharmaceutical drug discovery, development, and commercialization.

Since our founding in 2006, Centogene has been offering rapid and reliable diagnosis – building a network of approximately 30,000 active physicians. Our ISO, CAP, and CLIA certified multiomic reference laboratories in Germany utilize phenomic, genomic, transcriptomic, epigenomic, proteomic, and metabolomic datasets. This data is captured in our CENTOGENE Biodatabank, with approximately 750,000 patients represented from over 120 highly diverse countries, over 70% of whom are of non-European descent. To date, we have diagnosed over 2,500 different rare diseases and the CENTOGENE Biodatabank has contributed to generating novel insights for 277 peer-reviewed publications.

By translating our data and expertise into tangible insights, we have already supported 41 collaborations with pharmaceutical partners, as of December 31, 2022. Together, we accelerate and de-risk drug discovery, development, and commercialization in target and drug screening, clinical development, market access and expansion, as well as offering CENTOGENE Biodatabank Licenses and Insight Reports to enable a world healed of all rare and neurodegenerative diseases.

A rare disease, by definition in the United States, is a disease that affects 200,000 or fewer people. However, with over 7,000 currently identified rare diseases, they in aggregate affect more than 350 million people globally. Rare diseases can be severe and on average, it takes six to eight years for a patient with a rare disease to be diagnosed. This underscores the significant unmet need for high-quality genetic or other information in the rare disease space for the early identification and effective treatment of patients. Despite legislative initiatives and continued investment in rare disease drug development, significant unmet needs still exist. Of the 7,000 identified rare diseases, it is estimated that 80%, or 5,600, have a genetic origin, and of these rare hereditary diseases, less than 5%, have an FDA approved treatment. The introduction of new treatments and development of cost-effective drugs are constrained by a number of factors, including a lack of high-quality information regarding the clinical heterogeneity of medical symptoms, lack of comprehensive and curated medical data, difficulties in the early identification of patients, lack of biomarkers, and difficulties in understanding market size and epidemiology.

Our business is comprised of solutions for both physicians and their patients, as well as biopharma/pharmaceutical companies, including via collaborations with Contract Research Organizations (“CROs”). Our diagnostic solutions typically start with specialist physicians requesting diagnostic information to identify or confirm a rare disease by sending us their patients’ blood samples on our proprietary, CE-marked DBS collection kit, CentoCard, or other biological samples, such as ethylenediaminetetraacetic acid (EDTA) blood, buccal swabs, saliva, ready-to-use DNA, formalin-fixed paraffin-embedded (FFPE) tissue specimens, and cell-free DNA (cfDNA). With highly advanced technology, the CENTOGENE Biodatabank, and our team of medical experts, we then deliver reports back to the physicians that contain what we believe is critical information containing genetic and/or multiomic information, depending on what is most salient for each case. We also input this data into the CENTOGENE Biodatabank, which contributes to improved diagnostics and health outcomes, as well as enables the development of treatments.

For our pharmaceutical partners, we are able to provide various valuable information using our platform. For instance, with the access to the data in our repository and biomaterials in the CENTOGENE Biodatabank, we have successfully developed biomarkers by applying highly sophisticated tools, including mass spectrometry technologies, together with artificial intelligence (“AI”) capabilities in an efficient and cost-effective manner. Biomarkers are important in orphan drug development as well as post commercialization monitoring by demonstrating the efficacy of existing and new drugs, performing longitudinal monitoring, and informing necessary titration for individual rare disease patients. Newly identified biomarkers may also have the potential to become validated disease modifiers – opening up opportunities for new therapeutic approaches. As of December 31, 2022, we have developed and capitalized six biomarkers covering three diseases (aromatic l-amino acid decarboxylase (AADC) deficiency, Gaucher disease, and amyloid transthyretin (ATTR) amyloidosis). We have also commercialized many biomarkers as laboratory developed tests.

In December 2018, the FDA issued a statement that supports the use of real-world evidence to accelerate drug development and to monitor the safety of drugs after they have been commercialized. Moreover, in February 2019, the FDA also issued a revised draft guidance for drug discovery in rare diseases, including a discussion of the benefits of using biomarkers as surrogate endpoints (the outcomes of which can be measured against therapy effectiveness in clinical trials). We believe that this guidance from the FDA, acknowledging the benefits of the use of both real-world evidence and biomarkers, further validates the value of our global proprietary rare disease platform and our biomarkers.

We historically have offered solutions to our customers through two business segments. In addition, the COVID-19 pandemic, which began in December 2019, resulted in our recognizing, as of the beginning of Q3 2020, a separate reportable segment comprising our COVID-19 business. Our historical business segments – Pharmaceutical and Diagnostics – are our core business segments. Our Pharmaceutical segment provides a variety of products and services to our pharmaceutical partners, including target and drug screening, clinical development, market access and expansion, as well as CENTOGENE Biodatabank Licenses and Insight Reports. Our information platforms, access to rare and neurodegenerative disease patients and their biomaterials, and our ability to develop proprietary technologies, such as biomarkers, enable us to provide services to our pharmaceutical partners in all phases of the drug development process as well as post commercialization. Revenues in our Pharmaceutical segment are generated primarily from collaboration agreements with our pharmaceutical partners, which are structured on a fee per analysis basis, milestone basis, fixed fee basis, royalty basis, or a combination of these. For the year ended December 31, 2022, €16,115 thousand, or 33.9%, of our total revenues were derived from our Pharmaceutical segment. For the year ended December 31, 2021, €16,951 thousand, or 44.1%, of our total revenues were derived from our Pharmaceutical segment.

Our Diagnostics segment provides targeted genetic sequencing and diagnostic services to patients through our distribution partners and clients, who are typically physicians, labs, or hospitals. Since our inception in 2006, we have been spearheading advanced diagnostic solutions using enhanced technologies and techniques applied across multiple analysis. As of December 31, 2022, we believe we offer the broadest diagnostic testing portfolio for rare diseases, covering over 19,000 genes using approximately 5,000 different tests, the latter reflecting the portfolio simplification Centogene implemented within 2022.

In 2022, we launched our commercially available multiomic testing portfolio, CENTOGENE MOx – a portfolio of single-step multiomic solutions that enable early diagnosis, improved prognosis, and precision medicine. Within the portfolio, there are three key products, CentoGenome MOx, CentoXome MOx, and CentoMetabolic MOx, which integrate biochemical testing into the foundation of our core sequencing offerings.

In January 2022, we launched CentoCloud, our cloud-based Software as a Service (SaaS) platform that enables laboratories around the world to analyze, interpret, and report genomic variants for rare disease diagnostics. Generating medical reports of diagnostic analyses is resource intensive – requiring an extensive amount of bioinformatic expertise, a sizeable databank of patient samples, and a streamlined recording system. Furthermore, as a trend, an increasing number of laboratories around the world are responding to regional requirements for increasing the amount of genetic sequencing being performed locally. This modular dry lab solution, powered by proven bioinformatic pipelines and the CENTOGENE Biodatabank, helps overcome these obstacles to make rare disease diagnostics accessible around the world. In May 2022, CentoCloud was CE-marked under the In Vitro Diagnostics Directive (98/79/EC). CE-marking is required for all in vitro diagnostic (IVD) devices to be placed in the European Economic Area (EEA) countries, as well as Iceland, Norway, and Liechtenstein, and indicates that the device may be legally commercialized in this area. CentoCloud is one of the world's only CE-marked IVD software for genomic diagnostics.

Revenues from our Diagnostics segment are typically generated by set fees per diagnostic test or per bundle of diagnostic tests under contracts with our clients. For the year ended December 31, 2022, €31,358 thousand, or 66.1%, of our total revenues were derived from our diagnostics segment. For the year ended December 31, 2021, €26,593 thousand, or 63.0%, of our total revenues were derived from our diagnostics segment.

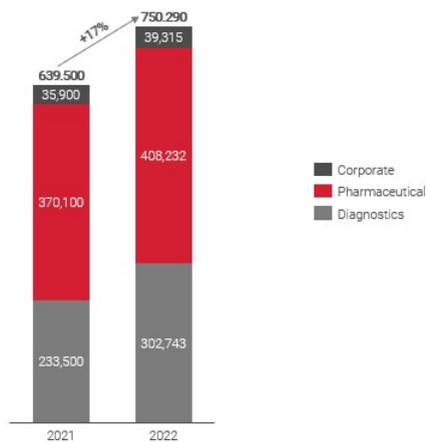
We continuously work on expanding our medical and genetic knowledge of rare and neurodegenerative genetic diseases. We work with renowned international scientific and academic institutions on a variety of groundbreaking research projects involving a significant number of patients.

The test requests that we receive from our customers in our Pharmaceutical segment, our Diagnostics segment, as well as from research projects yield a rich collection of genetic and biochemical data, which is used to map out phenotype-genotype correlations and continuously enrich and improve the quality of the CENTOGENE Biodatabank.

For the year ended December 31, 2022, we received over 110,790 test requests in total for both our Pharmaceutical and Diagnostics segments, as well as for our internal research projects – bringing the total number of test requests received in the period from January 1, 2021, to December 31, 2022, to approximately 230,380. Compared to the total number of patients in the CENTOGENE Biodatabank as of December 31, 2022, this shows that approximately 31% of our data and biomaterials came from the last two years, which is an important factor when it comes to recruiting patients for clinical trials and clinical studies, considering the often shorter average life expectancy of rare disease patients.

The graphic below shows the cumulative test requests for the Diagnostic and Pharmaceutical segments, as well as test requests received for our internal research projects during the period from January 1, 2021 to December 31, 2022. The testing expenses relating to requests received for our internal research projects were included in Corporate as they did not generate any revenue and cannot be allocated to either of our business segments.

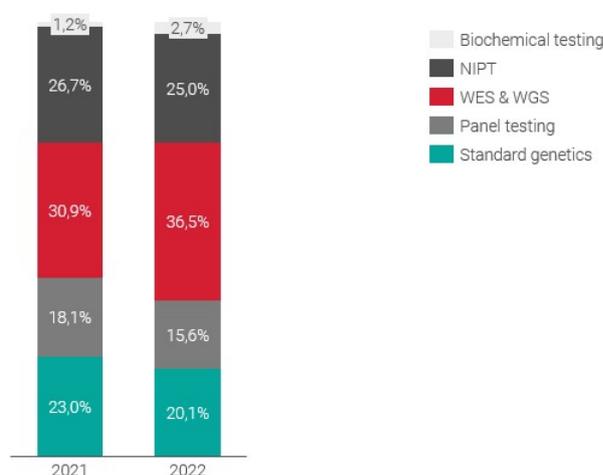
Cumulative order intakes: Jan 1, 2021, to Dec 31, 2022



For the portion of the Pharmaceutical, Diagnostics, and Corporate tests, for which we have optional research consent from the patients in the CENTOGENE Biodatabank, we are able to re-test their biomaterials.

The graphic below shows the cumulative 126,298 test requests received from our Diagnostics segment in the period from January 1, 2021 to December 31, 2022, split by different type of analysis.

Diagnostic # orders split by type: Jan 1, 2021, to Dec 31, 2022



“Standard genetic” testing includes our single gene, CNV, and mutation quantification products.

From our inception in 2006, Centogene has been focused on delivering data-driven solutions to rare and neurodegenerative disease patients. Our laboratory at our headquarters in Rostock, Germany, as well as our Cambridge, Massachusetts, United States facility, are equipped with the most advanced technologies from thirteen different diagnostic platforms, and as of December 31, 2022, together employ more than 460 highly qualified personnel (including consultants) from over 55 nationalities. In addition to our laboratories, we have sales and administrative offices located in Berlin (Germany), Cambridge (Massachusetts, United States), Vienna (Austria), Dubai (United Arab Emirates), Delhi (India), and Zug (Switzerland), allowing us to further expand our international footprint. The administrative office located in Vienna (Austria) is expected to be closed in 2023.

Strategy

Our strategic objective is to be the essential life science partner for data-driven answers in rare and neurodegenerative diseases. We aim to translate our data and expertise into tangible insights to establish rapid and reliable diagnostics and accelerate and de-risk drug discovery, development, and commercialization in target and drug screening, clinical development, and market access and expansion.

To achieve this objective, our strategy is to:

- **Transform the rare and neurodegenerative disease landscape by applying precision medicine more comprehensively.** Rare and neurodegenerative diseases affect patients of all ages and ethnicities across the world. We are focused on creating broader awareness of the challenges these patients and their families face, including the lack of accurate and up-to-date diagnostic solutions and effective therapies. We leverage our global network to access patient populations of varying demographics and continue to expand our existing data repository. We believe this central source of knowledge will allow us to apply precision medicine more comprehensively, which will enable more accurate diagnosis as well as support the more efficient discovery and development of new treatment solutions for rare and neurodegenerative disease patients.

- **Further our leadership position in rare and neurodegenerative diseases and continue to build upon our data in the CENTOGENE Biodatabank.** Since our Company's founding in 2006, we have been focused on collecting clinical, phenotypic and genomic data for patients with rare hereditary diseases. We plan to continue growing this repository of information and biological samples through the identification of additional patients by expanding our clinical network, which will facilitate more effective drug development. This synergistic model will allow us to maintain our competitive advantage of having what we believe is the world's largest real-world integrated multiomic data repository in rare and neurodegenerative diseases.
- **Accelerate drug discovery, development, and commercialization for new and existing pharmaceutical partners.** We believe we are uniquely positioned to support pharmaceutical partners along every stage of the pipeline, from target and drug screening to clinical development to market access and expansion. By leveraging insights generated from the CENTOGENE Biodatabank, multiomic technologies, and deep rare disease expertise, we are shifting the paradigm to transform data into tangible solutions – bringing speed and efficiency to our pharmaceutical partners' drug discovery, development, and commercialization. We also offer CENTOGENE Biodatabank Licenses and Insight Reports, a portfolio of customizable data-driven solutions to enable partners to securely access unique real-world data sets and tailored data analysis reports. We believe this accelerates bringing life-changing treatment solutions to rare and neurodegenerative disease patients. In the most attractive areas, we may establish and pursue our own discovery programs or co-invest into partnered programs. This includes the building of digital representations of diseases.

Rare Disease Overview

Overview

The Rare Diseases Act of 2002 defines a rare disease as having a prevalence of fewer than 200,000 affected individuals in the United States. In the European Union, orphan drug designation is intended to promote the development of drugs for the diagnosis, prevention, or treatment of life-threatening or chronically debilitating conditions affecting not more than one in 2,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected).

The National Institutes of Health lists more than 7,000 disorders that qualify as rare diseases. A wide range of conditions qualify as a rare disease and include, but are not limited to:

- Lysosomal storage disorders, such as Gaucher disease, Fabry disease, Pompe disease, mucopolysaccharidosis disorders, Farber disease, Niemann-Pick disease, and metachromatic leukodystrophy;
- Neurologic and neuromuscular disorders, such as Huntington's disease, spinal muscular atrophy, Duchenne muscular dystrophy, and neuronal ceroid-lipofuscinosis type 2; and
- Non-malignant hematological disorders, such as paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome, hemophilia, and hemoglobinopathies, such as sickle cell disease and β -thalassemia.

According to research published in the *European Journal of Human Genetics* in September 2019, a conservative, evidence-based estimate for the population prevalence of rare diseases is 3.5-5.9%, which equates to 263 to 446 million people affected globally at any point in time. According to the International Rare Diseases Research Consortium, there were over 800 new rare diseases identified between 2010 and 2019.

Causes of Rare Diseases

While there are many causes of rare diseases, approximately 5,600 are due to genetic mutations which are hereditary. To date, there are estimated to be approximately 4,700 rare genetic diseases that can be diagnosed by diagnostic sequencing tools. Despite these advancements in science and availability of Next Generation Sequencing ("NGS") technologies, rare diseases are complex and an underlying genetic cause for approximately 1,400 rare diseases is still unknown.

In addition, new genetic mutations associated with identified rare diseases are discovered every year, and as a result, rare genetic diseases that can be diagnosed need to be continuously updated with the new information, otherwise the diagnosis provided becomes inaccurate over time. Furthermore, capabilities to deeply characterize patients with rare genetic variants, including RNA (transcriptomic) analysis, peptide and protein (proteomic) analysis, and functional assays and metabolite (metabolomic) analysis help significantly to delineate mechanisms of disease, and thereby characterize molecular markers of disease beyond the “naked” disease-causing variants which are captured through DNA sequencing.

Manifestation and Diagnosis of Rare Diseases

Because of phenotypic heterogeneity, rare disease manifestations vary in onset and severity, and many rare diseases exhibit a number of variations or sub-types. Almost 70% of the rare genetic diseases are pediatric onset, which means symptoms may be observed at birth or in childhood, as is usually the case with spinal muscular atrophy, neurofibromatosis, and chondrodysplasia. The remaining rare genetic diseases manifest symptoms during adulthood. Given the delayed onset and large variance in the symptoms that can manifest, the vast majority of these patients are misdiagnosed.

As rare diseases have a multifaceted genetic and phenotypical nature and often only a small number of patients are affected, diagnosis is complex and requires specialist knowledge – making it difficult for rare disease patients to receive an accurate diagnosis. This delay in diagnosis can be significant for many patients and may lead to irreversible progression of the patient’s condition. For example, in the United Kingdom and the United States, the average time to obtain a correct diagnosis for a rare disease is five to seven years, and throughout this period, patients experience two to three misdiagnoses. Pediatric rare disease patients can experience an even more significant delay in diagnosis. Across both pediatric and adult patient populations, approximately 90% of rare disease patients are typically undiagnosed. For example, the National Institutes of Health estimate that there are approximately 50,000 Fabry disease patients in the United States, whereas only 4,000 to 5,000 are currently diagnosed. As a result of incorrect and delayed diagnosis, unnecessary tests and treatments are often carried out, and in some cases, treatment windows are missed entirely.

Overlap Between Rare and Neurodegenerative Diseases

Genetic factors can significantly contribute to neurodegenerative diseases, with considerable heritability estimates. However, there is a large gap in the understanding of how genetics influence the manifestation of neurodegenerative diseases. Due to the hereditary nature of both rare and neurodegenerative diseases, there are clinical and pathological overlaps.

Leveraging the CENTOGENE Biodatabank and unparalleled insights into unique disease-causing variants, we have been able to demonstrate the genetic overlap between rare and neurodegenerative diseases, including more common conditions, such as Parkinson’s disease, as well as rare neurodegenerative diseases, including frontotemporal dementia and amyotrophic lateral sclerosis.

Regulatory Environment and Current Market

The COVID-19 pandemic, which began in December 2019 in China and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny, and other measures. We have taken a series of actions aimed at safeguarding our employees and business associates, including implementing a work-from-home policy for employees, except for those related to our laboratory operations. These disruptions could result in increased costs of execution of operational plans or may negatively impact our business due to its negative impact on the global economy.

For more information on the impact of the COVID-19 outbreak on our business and financial results, please see “Item 3. Key Information—D. Risk Factors— Pandemics, epidemics, disease outbreaks and other public health crises, such as the COVID-19 pandemic, have disrupted our business and operations, and future outbreaks or reemergence of the COVID-19 pandemic could materially adversely impact our business, financial condition, liquidity, and results of operations.”

Orphan drug legislation in the United States has made significant improvements in encouraging the development of new drugs to treat rare diseases. Since the passage of the Orphan Drug Act and subsequent amendments to the orphan drug regulations, the FDA has granted over 6,000 orphan drug designations. Moreover, the FDA’s Center for Drug Evaluation and Research (“CDER”) approved 37 novel drugs in 2022, among which 20, or 54%, of these were for rare or “orphan” diseases (diseases that affect fewer than 200,000 people in the United States).

In the United States, orphan drug designation allows the drug sponsor to benefit from incentives for the development of these products up to marketing approval. The measures apply to all stages of drug development and include tax credits for qualified clinical trials, waiver of user fees, and potential marketing exclusivity for seven years. In addition, more than US\$420 million was provided by the FDA's Orphan Products Clinical Trials Grants Program over the last three decades and led to 70 marketing approvals for the treatment of rare diseases. In the European Union, financial incentives, including fee reductions or waivers, are available and market exclusivity is granted for up to 10 years. In 2020, the EU Commission launched a consultation process to revise the existing legal framework for orphan drugs with the aim of adopting a new regulation to increase the development of new products for patients with rare diseases, to provide faster access to corresponding medicines and to establish an efficient evaluation and approval process for these medicines. The consultation process has already ended, but neither an analysis (announced for Q4 2022) nor a new draft regulation has been published yet. However, the published consultation working paper "Inception Impact Assessment", inter alia, indicates that the EU Commission acknowledges the granting of market exclusivity as the main incentive, but nevertheless considers that the duration of such exclusivity should be variable or shortened under certain criteria yet to be defined.

On April 26, 2023, the EU Commission adopted a proposal for a new Directive and a new Regulation, which, if enacted, would revise and replace the existing general pharmaceutical legislation in the EU (Regulation 726/2004 and Directive 2001/83/EC) and the legislation on medicines for children and for rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC, respectively). The draft provides for significant changes to the existing legal regime. The draft provides, inter alia, for a shortening of the general market exclusivity period for orphan drugs from ten to nine years, but companies can take advantage of additional market exclusivity periods. The Commission proposal is now under review by the EU Parliament and EU Council and may undergo substantial changes during the ongoing legislative procedure (2023/0131/COD).

Due to these legislative initiatives, there has been an increase in investment and activity in the rare disease drug development space. According to a report by Global Genes, a leading rare disease advocacy organization, investment in rare diseases is gaining momentum. In 2021, drug developers invested a total of US\$22.9 billion for research on rare disorders, an increase of 28% compared to 2020. It is estimated that Orphan invoice spending has been increasing at a rate of over 14% for the last five years, and faster than other specialty or traditional drugs for the past four years. These investments are expected to lead to the approval of new rare disease drugs, which, according to market research, are expected to grow at a CAGR of 12% from 2021 to 2026 to US\$273 billion, capturing approximately 20% of worldwide prescription sales.

Key Challenges in Rare Disease Drug Development

Despite the legislative initiatives to encourage orphan drug development and the consequent increase in investment and activity in the rare disease drug development space, significant unmet needs still exist. Of the 5,600 rare hereditary diseases, very few rare hereditary diseases have an FDA approved treatment. The limited number of treatments available for rare diseases is the greatest challenge for patient care and is based on the lack of research on rare diseases and barriers in developing and commercializing treatments.

We believe the following summarizes the key challenges clinicians and the pharmaceutical industry are facing today:

Lack of high-quality medical data as a result of:

- *Lack of phenotypic understanding.* For many diseases, the symptoms are non-specific and often do not fit the typical picture of the disease. Due to their phenotypic heterogeneity, rare diseases have highly diverse clinical manifestations and unpredictable progression rates. These factors make it difficult for physicians to make an accurate diagnosis and determine an optimal treatment strategy.
- *Lack of patient sample availability.* Patient samples to study the disease are in short supply, making development of drugs difficult. Even more, dedicated pharmacological models are more commonly developed for common diseases. The generation and storage of rare disease samples is therefore a crucial prerequisite for drug development for rare diseases.
- *Lack of comprehensive and curated information.* A full understanding of the causes of a rare disease requires multiomic information, as well as detailed clinical information. Moreover, thorough medical validation processes must be conducted to ensure the quality of this information. While there are a few, limited rare disease databases available to the market, such as parts of ClinVar and HGMD, they are not specifically set up to service the rare disease industry and, due to their nature, lack medical curation. Consequently, this limits the accuracy and utility of that data for clinical diagnoses and decision-making.

- *Lack of ethnically diverse datasets.* The majority of existing rare disease datasets only capture individuals in developed regions of the world, where healthcare expenditure is disproportionately higher. This disparity yields population datasets that are specific to such regions and does not capture the full ethnic and hereditary nature that may be present in various rare diseases. For example, as published in *Nature*, even though unique genetic mutations are present across many different ethnicities, 87% of all genetic datasets are of European descent.

Difficulties in the early identification of patients. Identifying rare disease patients is difficult given the small patient population for each rare disease. In addition, the population for each of the rare diseases is typically also scattered and diverse, which makes it more difficult to gain access to patients and collect sufficient real-world data to perform meaningful analyses to obtain a better understanding of the rare diseases. The lack of sufficient understanding of the clinical manifestations of rare disease makes it even more challenging to derive accurate diagnoses. The ability to access relevant patients with a particular rare disease and to access appropriate expertise, a physician network, and datasets via a repository, improves the accuracy of disease identification and facilitates the development of new treatments and diagnostic procedures.

Lack of biomarkers. The small patient populations, phenotypic heterogeneity, homogenous datasets and lack of curated information for rare diseases all impede biomarker discovery. Without an identified biomarker, the ability to diagnose and ultimately treat a patient in a timely manner is diminished. Delayed diagnoses and limited knowledge of available treatments can lead to incorrect patient management, further disease progression and/or invasive or detrimental treatments. For example, patients suffering from Gaucher disease and cystic fibrosis can have average life expectancies of only eleven years and one year, respectively, if no treatments are available, leaving limited time for effective treatment if not diagnosed early. In addition, the lack of an identified biomarker can create hurdles in obtaining drug approval as biomarkers can be beneficial in clinical development, specifically in monitoring how effectively a patient is treated by a drug. Biomarkers are also used to correlate with genetic changes, in particular if mutations affect the activity of the protein encoded to a different degree.

Difficulties in orphan drug development and commercialization as a result of:

- *Clinical Trial Recruitment.* Relevant patient populations are rare and typically spread across large geographical regions, making adequate patient recruitment for clinical trials particularly difficult, which can delay development.
- *Trial Design and Dose Selection.* Small patient populations do not allow for multiple parallel studies in the same indication. This also applies to dosages, where the number of dose levels studied may be limited by the practical considerations of running a trial. As a result of these limitations, careful thought must be given to study design in order to optimize clinical trial success.
- *Patient Management.* In an orphan drug trial, clinical management of individual patients can be difficult. Understanding the burden of disease and managing the patient and family experience within a study is key. Because of the progressive nature of many rare diseases, it is crucial to enroll patients at a time where treatment has the highest potential to be effective. Furthermore, the nature of diseases can be very severe, as highlighted by the significant number of pediatric rare disease patients – making it an additional challenge to run a clinical trial.
- *Eligibility Criteria.* Eligibility criteria influences the type of patient eligible to participate in a clinical study. Consequently, this dynamic interferes with the establishment of a database that captures clinical efficacy and safety data which can be extrapolated to a larger network of patients with the same disorder.
- *Understanding the End Market.* Obtaining accurate epidemiological data is crucial for pharmaceutical companies to appropriately size the ultimate end market for a given drug in development. Given the small patient populations, it can be a challenge for pharmaceutical companies to recover the costs of rare disease drug development. As a result, this may impede initial investment in rare disease therapies.
- *Sponsored testing for patient finding.* Once a rare disease drug is commercialized, the limited number of identified patients and challenges associated with diagnosis make it difficult for physicians and pharmaceutical companies to find individuals who would benefit from an approved therapy. In order to market a commercial drug more successfully, improved datasets are needed to aid in patient identification.

Our Vision

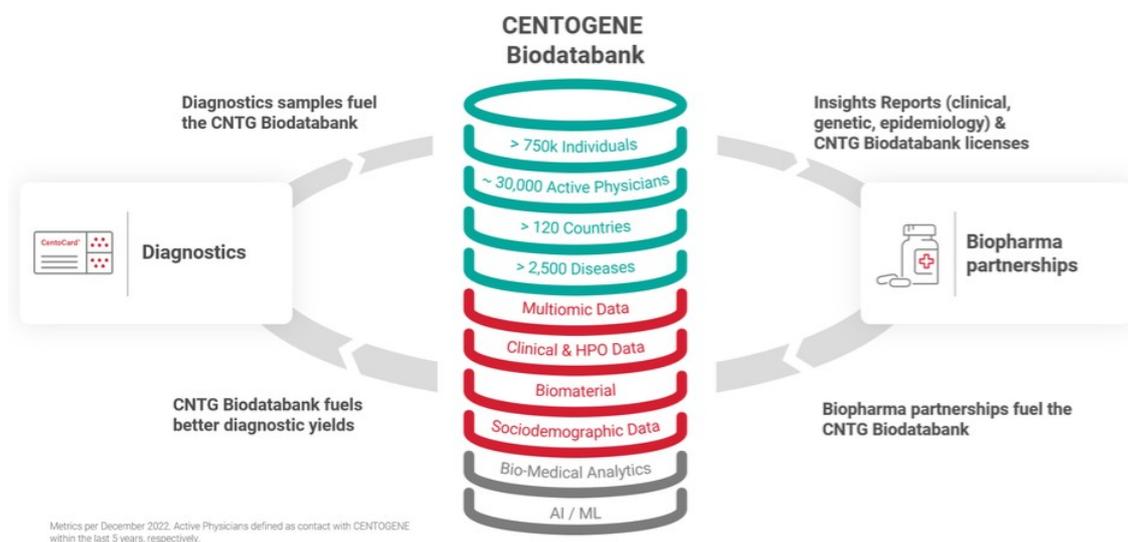
We have an integrated approach with a detailed, global understanding of the genetic basis and the clinical phenotype of rare hereditary diseases, which we believe will unlock the ability to target rare and neurodegenerative diseases and provide critical knowledge that will guide drug development and monitoring, and ultimately improve health outcomes for patients. We perform analysis on the patients' data that we receive from our Pharmaceutical and Diagnostic segments as well as from our research projects using a multiomic approach, which utilizes phenomic, genomic, transcriptomic, epigenomic, proteomic, and metabolomic data sets. The combination of the varying "omics" provides deep insights in the pathogenesis of rare and neurodegenerative diseases. The value in such a holistic diagnostic process has resulted in a shift from data generation to interpretation-based diagnostics, whereby the development and use of biomarkers and tests is the central element in bringing rationality to treatment decisions for patients. High-quality, standardized clinical information supporting medical interpretation is a crucial element of the diagnostic process and leads to greater knowledge of the causes and symptoms of rare and neurodegenerative diseases. We believe a combination of worldwide data and detailed access to multiomic data will aid in the development of new treatments and reduce the costs associated with drug discovery, development, and commercialization.

The CENTOGENE Biodatabank

Centogene's integrated multiomic data repository provides unique real-world data in rare and neurodegenerative diseases.

The CENTOGENE Biodatabank sits in the middle of all of Centogene's activities. It drives both our diagnostic business as well as our pharmaceutical partnerships. We have captured data from more than 750,000 individuals from all over the world with a huge variety of clinical phenotypes and genetic information and the number of unique variants in the CENTOGENE Biodatabank is over 70 million. This unique data asset, together with its multiomic lab capabilities, helps Centogene to diagnose rare disease patients with a high diagnostic yield. It also supports our pharmaceutical activities ranging from drug and target discovery to clinical development to market access and expansion. All of these activities further fuel the CENTOGENE Biodatabank with multi modal data including multiomic data, clinical information, sociodemographic data and the patient biomaterial. With this, we believe Centogene created a positive feedback loop where diagnostic excellence and pharmaceutical partnerships create additional data which in turn helps patients via improved diagnostics and accelerated discovery, development, and commercialization of treatments in cooperation with our pharmaceutical partners.

A graphical description of our platform is shown below:



The Strengths of the CENTOGENE Biodatabank

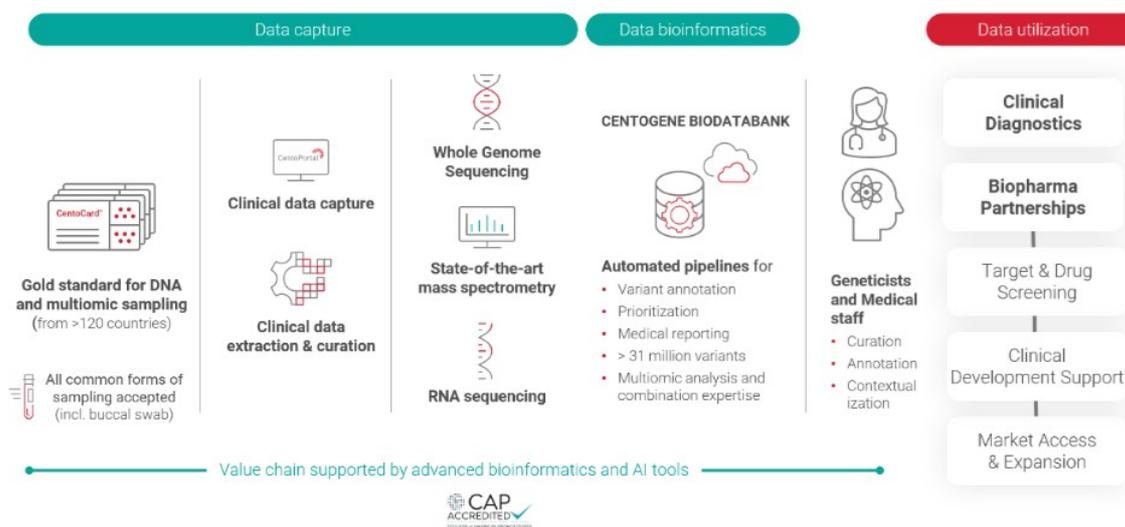
Our platform is intended to streamline and accelerate the development of treatments for rare and neurodegenerative diseases, and aids in the understanding of how to identify new rare disease patients and how to recognize and quantify market opportunities in patient populations. We believe we offer the following solutions for the industry:

- **Extensive repository to identify rare and neurodegenerative disease patients:** The CENTOGENE Biodatabank includes multiomic data that reflects a global population, as well as a biobank of these patients' blood samples. This capability has been facilitated by our development of the CentoCard, a convenient logistical solution. CentoCard is CE-Marked and easily stored, allowing for massive amounts of data aggregation from around the world. Additionally, where we have optional research consent from the patients in the CENTOGENE Biodatabank, we have the ability to retest their biomaterials in our biobank. We are able to provide information about available treatment options to the physicians in our medical reports, therefore adding to the physician's decision-making tools in determining treatment for their patients. We believe this solution reflects the world's largest real-world integrated multiomic data repository in rare and neurodegenerative diseases, thereby allowing us to assemble a knowledge base from which to derive accurate diagnoses and epidemiological information. We have relationships with a global network of specialists at rare disease "centers of excellence." With these relationships and the logistical advantages of CentoCard, we are able to continuously grow our repository from the collection of new patient samples and related patient data.
- **Ethnically diverse datasets:** The CENTOGENE Biodatabank has the advantage of holding samples from a broad range of ethnicities, with more than 70% being of samples of non-European descent. Our repository covers a substantial majority of ethnicities, as we have performed diagnostic tests for patients in over 120 highly diverse countries. Without the ability to recognize ethnicity-specific patterns, the interpretation of genetic variants in patients is difficult and a patient's physician may fail to find an accurate diagnosis. The mutation frequency distribution within one ethnicity can vary significantly from that of other ethnic groups within the same rare disease population. For example, a mutation in the Caucasian population might have a significant functional impact and cause a disease, but the exact same mutation in the Mongolian population might be without any functional consequence. With access to data from a more diverse patient population, we are able to improve the interpretation of genetic variants, whether benign or causative.
- **Curated information in the CENTOGENE Biodatabank:** We have built a truly differentiated repository of multimodal data, including sociodemographic, clinical and multiomics data as well as biomaterial, covering over 2,500 rare diseases. As of December 31, 2022, the CENTOGENE Biodatabank included more than 750,000 individuals and approximately 500,000 dried blood spots cards stored in our own physical biobank which enables retrospective analysis for research consented samples. Whole Exome Sequencing ("WES") data and Whole Genome Sequencing ("WGS") data is available for approximately 110,000 and 17,000 individuals, respectively. Equally notable is our network of approximately 30,000 active physicians with whom we have been in contact in the last five years.
- **Geographic diversity:** The CENTOGENE Biodatabank includes individuals representing over 120 highly diverse countries. It is observed that the largest share of data within our repository relates to Europe followed by the Middle East. In Europe, Germany and Italy are the top contributors. In the Middle East, Saudi Arabia and Iran contribute a large inflow of patients. Many cases of genetic rare diseases are observed in these regions and we have established a strong network of physicians.



- Data creation:** At the core of our business is the CENTOGENE Biodatabank – allowing us to assemble an extensive knowledge base in rare and neurodegenerative diseases. We collect this detailed level of data in our repository through our easy-to-use CentoCard, which allows us to capture blood samples of potential patients with a low cost of distribution, accompanied by the patients’ medical histories and completed consent forms from the physicians. The data is then validated by professionals using a systematic and scientific approach.

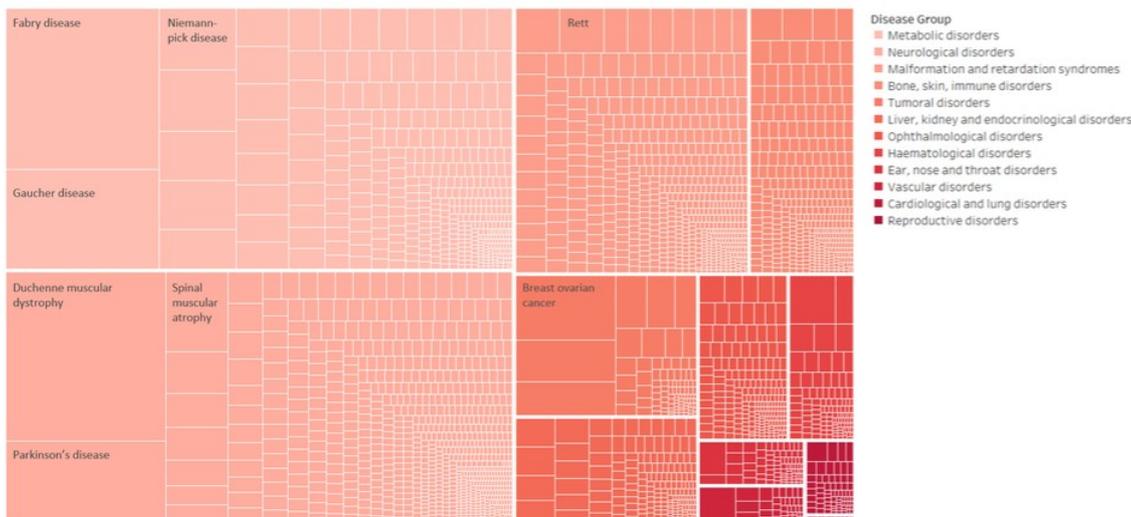
Our team of scientists collects, annotates and reviews the phenotypic, genetic and other clinically relevant data of patient samples to ensure the highest medical validity of each sample. We also employ Human Phenotype Ontology (“HPO”) coding to accurately track and standardize sample phenotype and genotype data. The data curation is performed by our professional scientists with strong backgrounds in human genetics. Our methodological approach to information curation ensures we provide accurate data relevant to clinical diagnoses and decision-making. In this way, we believe that the CENTOGENE Biodatabank brings rationality to the interpretation of global multiomic data.



Therapeutic Areas and Disease Focus

We believe that our broad expertise in rare diseases is reflected in the CENTOGENE Biodatabank, with approximately 750,000 patients and over 2,500 rare diseases represented. The CENTOGENE Biodatabank contains comprehensive clinical, multiomic, and sociodemographic data for these cohorts. We have seen in multiple cases that these cohorts are the most comprehensive cohorts accessible.

Our data from genetically diagnosed patients encompasses the whole spectrum of diseases, with a focus on metabolic and neurological disorders. In total, more than 12 therapeutic indications are covered, including dysmorphology, bone, skin, immunological, tumoral, gastrointestinal, hematological, and cardiovascular disorders, among others.



In addition to powering our diagnostic capabilities, the CENTOGENE Biodatabank’s depth and richness of information has allowed us to uncover and describe new gene-disease associations. This repository also powers our R&D efforts to explore and validate candidate biomarkers and potential new therapies for some of the diseases on which we are experts.

Generally, multimodal data sets of cohorts of rare disease patients enable a rapid R&D cycle by generating data-driven insights and developing a better understanding of disease biology. They aid in solving unmet medical needs for the patients and their families, allowing better diagnostics, uncovering the biological factors that determine diverse disease outcomes (disease modifiers), discovering/validating useful disease biomarkers, and mining candidate drug targets.

Data Partnerships

Based on conversations with academic and commercial partners, we believe that the multimodal data in the CENTOGENE Biodatabank is very valuable. We have different data partnership models in place under the umbrella term “the CENTOGENE Biodata Network”.

Both with *Insight Reports* as well as with *Biodata Licenses*, we enable knowledge partners to tap into the richness of the CENTOGENE Biodatabank to improve diagnostics, accelerate target discovery and validation, and find and validate new biomarkers and novel gene-disease relationships. Further, the data helps to accelerate and de-risk clinical and observational studies and supports the commercialization with information for market access and expansion. The Biodata Network allows us to offer the right partnership model depending on our partners’ needs so that the data of research consented patients can be used to advance discovery and support patients and their families all over the world.

Our Core Business Commercialization Strategy

We are committed to improving health outcomes by accelerating the diagnosis and access to available treatment options for rare and neurodegenerative patients.

Our solutions from our core businesses are offered to our clients via two channels:

- **Pharmaceutical:** Solutions from the core businesses are primarily acquired by pharmaceutical partners, whereas interest from other types of strategic partners, such as CROs, is increasing.
 - **Target and Drug Screening:** The heart of this product offering is the development of patient-derived cell-models and multiomics as well as biomarker/assay identification and validation;
 - **Clinical Development:** This product offering includes epidemiology and patient finding as well as genetic biomarker profiling for observational studies, patient multiomic profiling, stratification, modelling, and efficacy markers for POC/PhII/III as well as patient identification and diagnostics for POC/PhII/III;
 - **Market Access and Expansion:** The core of this offering is three-fold:
 - Real-world registry and early access programs
 - Patient stratification, genetic and biomarker profiling, and modelling; and
 - Patient identification and diagnostics.
 - **The CENTOGENE Biodata Network:** In addition to the above-mentioned offerings, Centogene differentiates itself from the market through the CENTOGENE Biodatabank and the capabilities to deliver tailored *Insight reports* and *Biodata Licenses*.

Revenues from our Pharmaceutical segment are generated primarily from partnership agreements with our pharmaceutical partners, which can be structured on a fee per analysis basis, milestone basis, fixed fee basis, royalty basis or a combination of these. For the year ending December 31, 2022, €16.1 million, or 33.9%, of our total revenues were derived from our pharmaceutical segment. For the year ended December 31, 2021, €17.015.6 million, or 44.1%, of our total revenues were derived from our Pharmaceutical segment.

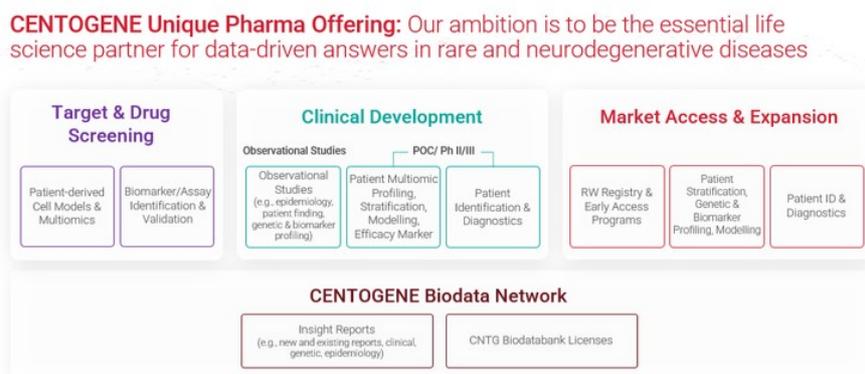
- **Diagnostics:** Our Diagnostics segment provides genetic sequencing and diagnostics interpretation and medical reporting services to patients through our distribution partners or prescribers, in laboratories and institutions, who are typically physicians and geneticist. We offer a broad diagnostic testing portfolio for rare and neurodegenerative diseases, covering over 19,000 genes. Our key products are our WGS and WES, as well as our multiomic testing solution. Together, these products represent the most comprehensive approach to identifying disease-causing variants. Revenues from our Diagnostics segment are typically generated by set fees per diagnostic test or per bundle of diagnostic tests, under contracts or per price/discount agreements with our clients. In turn, the biomaterial, clinical information and data collected from our diagnostics services allow us to continue to grow the CENTOGENE Biodatabank. For the year ended December 31, 2022, €31.4 million, or 66.1%, of our total revenues were derived from our Diagnostics segment. For the year ended December 31, 2021, €26.6 million, or 63.0%, of our total revenues were derived from our Diagnostics segment.

Pharmaceutical Partnerships

Comprehensive partnerships with biopharmaceutical/pharmaceutical companies support de-risked processes and improved outcome from early drug discovery through clinical development to commercialization.

The offerings to pharmaceutical companies consist of the following key categories: (i) Target and Drug Screening; (ii) Clinical Development; (iii) Market Access and Expansion; and (iv) the CENTOGENE Biodata Network. We currently have partners in each of these categories. While Target and Drug Screening as well as the CENTOGENE Biodata Network are still in the early stages, we expect that Clinical Development as well as Market Access and Expansion will be the key growth drivers for 2023.

The below chart demonstrates the unique pharmaceutical product offering per category.



Strategic Partnerships: Large CROs manage a volume of well over 100 proposals for clinical trials in rare diseases per year. Each individual offer involves a large amount of work because it also involves extensive research into the potential distribution of study sites. We believe that with Centogene, selected CROs can now not only shorten this process, but also substantially improve the quality. The robustness of the CENTOGENE Biodatabank enables us to offer a unique competitive advantage, which makes us an ideal partner for CROs. Not only can the ramp up of the study be faster due to the potential use of patients already known to Centogene; it is also supported with prospective patient identification by Centogene, which can be initiated immediately after the project has been awarded. Strategic partners such as CROs see the advantage of working with Centogene to implement more efficient and faster study projects.

Centogene had 41 ongoing collaborations with 28 different pharmaceutical partners during 2022, and the projects covered all phases of from target and drug screening through clinical development to market access and expansion.

In Vitro Molecular Screening

A full understanding of a given rare and neurodegenerative disease and the ability to identify and target the right molecules is essential for drug development. With access to Centogene’s biological samples, *in vitro* molecular screening efforts can aid to accelerate drug discovery efforts. Combined with access to our biobank and data repository, the pharmaceutical partners are able to gain novel insights into the natural history of diseases, the broad spectrum of the different clinical symptoms as well as the genotype-phenotype correlation. Moreover, in situations where several genes can cause the same clinical symptoms, and therefore potentially cloud an accurate diagnosis, Centogene is able to identify additional genes that aid in the accurate diagnosis with the knowledge gathered in in the CENTOGENE Biodatabank.

Epidemiological Studies

The ability of pharmaceutical companies to identify patients early and to optimize their clinical trials is key to the development of treatments for rare and neurodegenerative diseases. Centogene offers epidemiological studies that will provide partners with important input on design and site feasibility data as well as identify the right patients for future clinical studies. Epidemiological studies can target a specific country or region of interest, and thereby enable a better understanding of market potential.

By collaborating with Centogene, pharmaceutical partners are able to specify the rare or neurodegenerative disease of interest as focus for an interventional clinical trial. Available epidemiological data is identified and enhanced with genetic and phenotypic information from the CENTOGENE Biodatabank. From there, the pharmaceutical partners are able to better understand and define specific conditions or eligibility criteria that patients must meet for a clinical study.

Hereafter, a patient selection and identification program is defined. We start by identifying existing patients in the CENTOGENE Biodatabank who fit the defined criteria. If the needed cohort of patients exceeds the number of patients available in our data repository, Centogene’s global network of key opinion leaders, clinical labs and specialist physicians can be leveraged. As a result, we are able to help our pharmaceutical partners optimize their clinical trials by more effectively selecting relevant patient groups and by leveraging our detailed understanding of the epidemiological data of the specific disease.

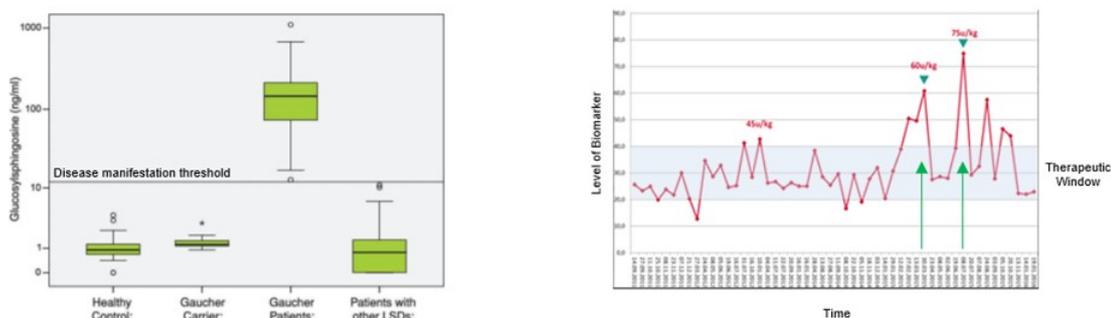
Biomarker Development

Biomarkers are key tools employed across the continuum of rare disease drug development. Namely, they are utilized to support diagnosis, classify genetic variants of uncertain significance, serve as a companion diagnostic, demonstrate treatment efficacy, as well as monitor disease progression. Furthermore, biomarkers enable more efficient and economical patient diagnosis than genetic testing and allow mass screening programs for large patient cohorts. Biomarkers can also be relevant for precision medicine.

In the development of a high-quality biomarker for a given rare disease, both heterogenous and homogeneous cohorts of patients with known phenotypic and genotypic aspects are needed to identify/validate the sensitivity and specificity of a biomarker for a given disease. We believe the CENTOGENE Biodatabank is the world’s largest real-world integrated multiomic data repository in rare and neurodegenerative diseases, and additionally contains a vast source of healthy control individuals against whom we are able to identify the characteristics of unique biomarkers. Therefore, Centogene is ideally positioned to lead the market in rare disease biomarker development.

As of December 31, 2022, Centogene has developed and capitalized eight biomarkers covering five diseases, including aromatic L-amino acid decarboxylase (AADC) deficiency, Gaucher disease, transthyretin amyloidosis, Farber disease and Hereditary angioedema. Of these eight biomarkers, only four have a carrying value as of December 31, 2022 (Gaucher disease, AADC and transthyretin amyloidosis). In addition, Centogene has commercialized and used additional biomarkers as laboratory developed tests.

With proprietary biomarkers, Centogene can also qualitatively measure a patient’s response to approved drugs and to drugs in clinical trials, and using this data helps to determine the optimum treatment dosage for each patient. This not only helps to accelerate the development of drugs by demonstrating the efficacy of the drugs in clinical trials, but also allows patients, physicians and reimbursement agencies to better understand the impact of the drugs. The below graphs demonstrate how Lyso-Gb1, Centogene’s first commercialized biomarker, can be used for patient screening and monitoring in the context of Gaucher disease:



* Based on a combination of our biomarker and a genetic confirmatory test (Rolfs et. al., 2013.)

The left graph demonstrates the sensitivity and specificity of the Lyso-Gb1 (Glucosylsphingosine) biomarker for Gaucher disease. According to a 2017 study, patients who are not suffering from Gaucher disease show a Lyso-Gb1 level of less than 12 nanograms per mL blood, whereas patients with Gaucher disease display elevated levels of Lyso-Gb1. Based on the definition of the cut-off of 12ng/ml Lyso-Gb1, we can demonstrate a 100% sensitivity and close to 100% specificity, which means the Lyso-Gb1 biomarker, when combined with a confirmatory genetic test, can provide 100% accuracy in identifying patients suffering from Gaucher disease, and also those who are not suffering from the disease.

The right graph demonstrates how Lyso-Gb1 biomarker can also be used to titrate the proper enzyme replacement therapy dosage in each individual patient. An increase of the Lyso-Gb1 level indicates that the dosage of the enzyme replacement therapy needs to be adjusted. After adjustment, Lyso-Gb1 levels decreased to an almost normal level. This is valuable for demonstrating drug efficacy to relevant authorities for approval, and also for demonstrating to reimbursement agencies that individualized treatment and dosage may be required for the patient.

Genetic Screening of High-Risk Populations

Once a treatment is available for a rare or neurodegenerative disease, early identification of patients is critical so that patients can be treated before they have reached the stage of irreversible progression. Centogene is able to support pharmaceutical partners in market access and label expansion through patient identification efforts by leveraging our knowledge and performing genetic and biochemical screening on large groups of patients with the risk profile of a given disease. This can be done by using our biomarkers or a tailored genetic test. If a positive diagnosis is concluded, we provide physicians with a medical report, which helps physicians make clinically relevant decisions for the treatment of their patients. For negative diagnoses, further testing options may be available.

Research and Development Validation

Based on our extensive expertise in rare diseases and our access to detailed genetic data, our pharmaceutical partners can approach us for guidance during their drug development endeavors. More specifically, pharmaceutical partners can ask Centogene to engage in their clinical trial design and potentially complement it with multiomics capabilities. All of these services are aimed at optimizing clinical development efforts.

Key Partnerships

Shire/Takeda

In January 2015, we entered into an agreement with Shire, now a subsidiary of Takeda Pharmaceutical Company Limited, to provide certain diagnostic testing capabilities to Shire and its affiliates in order to enhance early diagnosis of patients suffering from lysosomal storage and other rare diseases, including Fabry disease, Gaucher disease and Hunter syndrome. Our unique expertise and repository of data contributes to Takeda's mission to shorten the time it takes for rare disease patients to get diagnosed. In connection with this agreement, we receive a fixed annual fee plus additional service-based payments related to regulatory and diagnostic sequencing activities.

In addition, in 2018, we entered into a new research agreement with Shire relating to their ongoing drug development efforts in HAE. As part of this agreement, we are conducting an extensive epidemiological study leveraging our data repository and network of physicians at centers of excellence to gain unique insights into HAE and to support Takeda's ongoing clinical development efforts. This study was finalized in April 2022.

In December 2021, we extended our Global Master Service Agreement with Takeda to March 2023. This continuous partnership allows us to continue diagnosing and connecting rare disease patients globally.

Evotec International GmbH ("Evotec")

In July 2018, we entered into an agreement with Evotec to support and jointly expedite their identification of new small molecule treatments in the field of glucocerebrosidase deficiency ("Gaucher disease"). Evotec identifies active pharmaceutical ingredients based on the induced pluripotent stem cells ("iPSC") that are generated from fibroblasts we obtain from skin biopsies of patients. We believe our collaboration will aid in the acceleration of drug development through the adoption and application of more accurate cellular models of the target disease and specific biomarkers to monitor such diseases. Our collaboration combines Evotec's cellular compound screening platform and drug discovery capabilities with our medical and genetic insights to develop a high throughput platform to test innovative small molecules in Gaucher disease. In connection with this agreement, we received an initial payment in 2018 and milestone payments as well as further royalty fees on net sales of products developed from this collaboration in 2018 and 2019. In July 2020, we expanded our agreement with Evotec into an extensive collaboration for the discovery of both targets and therapies for Gaucher Disease ("GD"). The use of patient-derived, tissue-specific disease models, which have been created using our iPSC platform, allows for proof-of-concept evaluations in GD. The collaboration combines Evotec's expertise in high throughput screening and compound generation along with our genomic and metabolomic platforms to discover novel therapies for the treatment of GD patients. This collaboration has been extended in December 2022 until March 2023.

Denali Therapeutics (“Denali”)

In September 2018, we entered into a strategic collaboration with Denali for the global identification and recruitment of LRRK2 positive Parkinson’s disease patients. We will utilize our CentoCard and extensive network with centers of excellence to conduct a targeted global recruitment campaign focused on the early identification and characterization of LRRK2 positive Parkinson’s patients for the recruitment into Denali’s clinical trials. Given that we believe Denali’s study is the leading clinical investigation of LRRK2 inhibitors for the treatment of Parkinson’s disease, there is no large global existing cohort of identified patients with the LRRK2 mutation in the early phase of the disease. We aim to overcome those challenges and accelerate the enrollment of further patients into this clinical study and consequently facilitate Denali’s drug development process. In connection with this collaboration, we receive ongoing payments for patient enrollments and are eligible for success-based and commercial milestones and reimbursement of selected costs. The study has reached a significant milestone of testing over 12,500 participants by end of 2022 and was further extended in December 2022 to recruit and genetically test additional patients over the next few years. The study will focus its efforts on 48 sites across 10 countries, consisting of Argentina, Belgium, Brazil, Germany, Israel, Italy, Portugal, Spain, the U.K., and the U.S.

Pfizer Inc. (“Pfizer”)

In July 2019, we entered into a strategic collaboration with Pfizer, pursuant to a global master scientific services agreement (“MSSA”). In addition to the MSSA, we entered into a statement of work (“SOW”) in November 2019 to provide testing and analysis services to Pfizer for patients in the United States or Puerto Rico with transthyretin amyloid cardiomyopathy (“ATTR-CM”), patients suspected of having ATTR-CM, or individuals with a confirmed family history of hereditary ATTR-CM. This collaboration ended in September 2022.

In October 2019, we entered into a data access and collaboration agreement (“DACA”) with Pfizer, pursuant to which we granted Pfizer access to our data repository, which may be used in the discovery and validation of novel genetic and biochemical targets for the potential development of new therapies for rare diseases. This agreement ended in October 2022.

Our Diagnostic Solutions

Overview and Product Offering

Our diagnostic solutions segment provides diagnostic testing services to patients exclusively through our network of distribution partners and our diagnostics clients, who are typically physicians, laboratories, universities, or hospital facilities. Our Diagnostic segment serves over 100 countries due in part to our CentoCard solution enabling an efficient and simple transfer of the sample from the point of care to the lab. Additionally, our online platform, CentoPortal, allows our clients to quickly and easily place orders and obtain information related to their patients’ test results, as well as benefit from advancements in rare and neurodegenerative disease research, which we update on a regular basis. We provide a high-quality, end-to-end clinical diagnostics solution, which includes pretest clinical counseling performed by our medical experts whenever necessary, sample preparation, sequencing using NGS and other technology, clinical interpretation using our manual and automated bioinformatics pipelines, and medical reporting by our specialists.

Of the more than 5,600 identified rare hereditary diseases, in many cases not only is there no treatment available, but even the natural course of the disease and the relevant tests to diagnose the disease are unknown or underdeveloped. In order to further improve the understanding of rare hereditary diseases and to provide a better and earlier diagnosis for rare disease patients, we continuously develop new testing products to provide the most effective diagnosis products to our physician clients, leveraging insights from the CENTOGENE Biodatabank and our deep medical expertise.

In 2022, we launched MOx (multiomics solutions) as an add-on to our standard Exome and Genome single omic testing. Up until 2021, Centogene was mainly perceived as a genetics company but realized it has strong skills in multiple technologies which could be, to be leveraged for multimodal testing to generate superior disease insights. Multimodal testing is gaining more attention as research shows favorable clinical utility or potential in:

- Increasing diagnostic yield in unresolved patients with challenging phenotypes;
- Stratification of VUS after WES/WGS; and

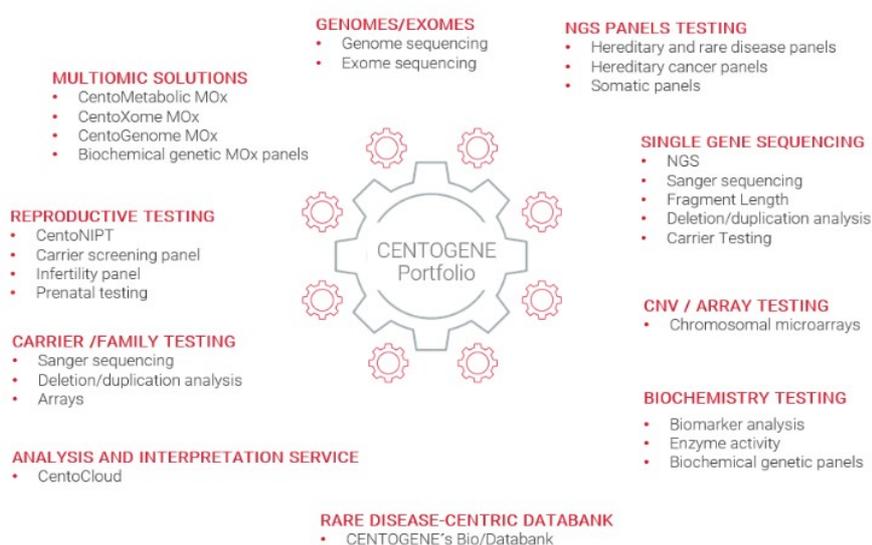
- Prognostic and predictive testing, monitoring, or subscription sales opportunity.

We believe that only a few competitors have begun to establish multiomics testing (e.g., Transcriptomics/RNA after WES/WGS). During 2022, we successfully launched CentoXome® and CentoGenome® MOx and managed to upsell 25% of standard WES/WGS orders to a MOx-solution. By looking at each patient from different angles, we are able to combine deep knowledge and multiomic insights for a holistic view – enabling early diagnosis, improved prognosis, and precision medicine.

As of December 31, 2021, we offered a comprehensive testing portfolio of over 5,000 different tests covering over 19,000 genes, from single gene to WGS-based products. We also offered differentiated comprehensive testing solutions including multiomic solutions, CNV analysis, biochemical testing, reproductive health and prenatal testing, among others.

In 2022, we announced the global release of CentoCloud®, a SaaS platform enabling decentralized analysis, interpretation, and reporting of genomic variants linked to rare diseases. The CentoCloud SaaS platform provides rapid and reliable medical reports, which can be challenging for sequencing laboratories due to bioinformatics resource as well as medical expertise limitations. Based on the decentralization of genetic testing and the CENTOGENE Biodatabank, as well as AI-based clinical interpretation, CentoCloud also enables access to high quality medical reporting.

Additionally, labs and research institutions can purchase NGS target enrichment panels in collaboration with Twist Bioscience (“Twist”) to help accelerate their research, and also have the option of using CentoCloud for the identification, prioritization, and classification of human genetic variants to expedite diagnostic analysis.

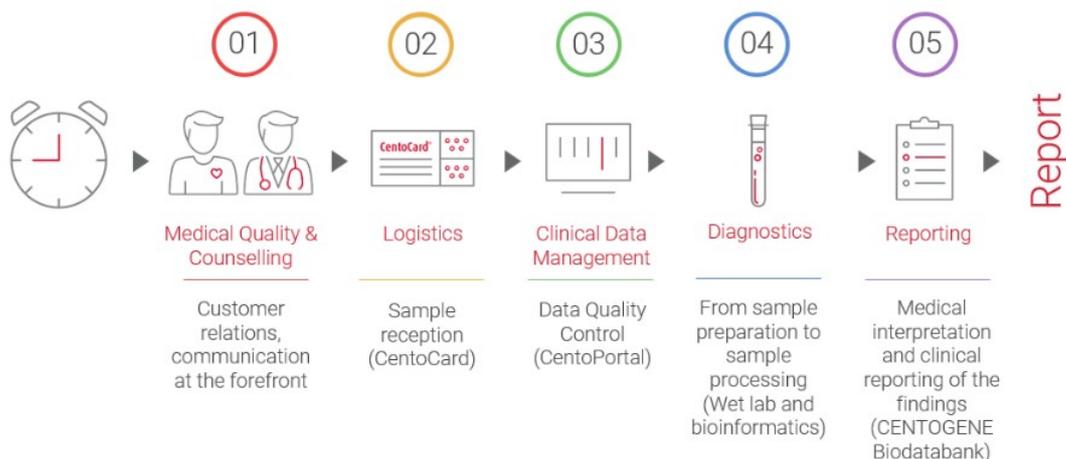


Overview of the Diagnostic Process

Our diagnostics processes are designed with the aim of providing the highest quality diagnosis within the shortest turnaround time. We currently perform the majority of our diagnostic services for our diagnostics and pharmaceutical businesses in our clinical laboratory located in Rostock, Germany, which is certified under CLIA and accredited by the CAP. Additionally, we perform certain of these services in our Cambridge, Massachusetts, United States facility, which is also certified under CLIA, accredited by the CAP and permitted by the Massachusetts State Clinical Laboratory Program.

We strive to provide the best quality of diagnostics testing, not only by following the strictest quality criteria complying with CAP, and CLIA certifications and adhering to ISO 15189 standards supported by our multidiscipline quality management system (“QMS”), but also by following applicable and market standard Good Laboratory Practice (“GLP”) and Good Manufacturing Practice Regulations (“GMP”) guidelines. Our processes are highly efficient and have been designed to deliver our medical report back to the physician within 30 days from receipt of the sample, even for our most complex tests.

Our diagnostics process is defined by our five-step process:



- Medical Quality and Counseling:** Rare disease specialists review the patient’s clinical records and confirm that the physician has requested the appropriate genetic test with regard to the patient’s individual circumstances and medical history. In all cases, the physician is required to provide us with a completed patient consent form, which our staff review for adequacy prior to the performance of any diagnostic services.
- Logistics:** We use the CentoCard collection method for obtaining the majority of our samples. This standardized procedure allows us to extract high-quality biological material from DBS on CentoCard, including DNA (for molecular diagnostics), protein (for enzymatic and biomarker assays) and metabolites (for biomarker assays).
- Clinical Data Management:** Physicians are able to order our diagnostic tests for a particular patient either online through our CentoPortal platform or by email or mail.
- Diagnostics:** Once a patient sample is received, we prepare the biological material for testing by taking an extract of the DNA from the relevant sample. Depending on the test requested by the physician, we would then proceed to run any number of our diagnostic services listed above.

 - Once produced, the data is entered into a sophisticated series of our proprietary computational algorithms designed to detect and identify known pathogenic variants. The sequenced data is analyzed using our fully validated and automated bioinformatics pipeline and annotated with information from the CENTOGENE Biodatabank. The CENTOGENE Biodatabank is key to the diagnostics process as it is used as the basis of comparison with the patient’s sequenced data. This analyzed genetic information, together with the patient’s medical history and clinical data, is then interpreted by our medical experts, a team of trained human geneticists and doctors. All identified mutations along with their annotations will undergo a manual validation against the medical history of the patient in order to ensure accuracy.

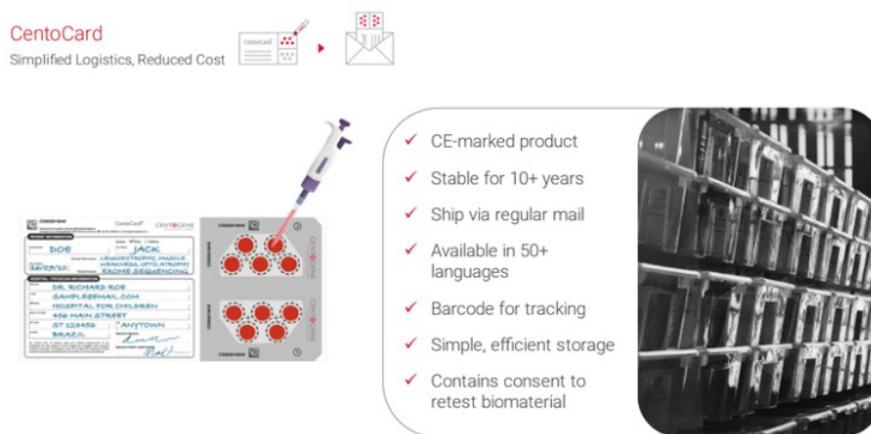
- Additionally, our bioinformatics pipelines provide a highly automated approach to analysis of variant classification, CNV identification and other genetic data. To augment our bioinformatics pipelines, we have developed a database to store all variant information, which is part of the CENTOGENE Biodatabank, and is the basis for our evaluation and interpretation of genetic data. We have developed an in-house variant prioritization and classification system, named CentoPrio, to enhance our interpretation capabilities. CentoPrio takes advantage of the vast amount of genotypic and phenotypic data stored in our databases. Through the use of proprietary algorithms and machine learning algorithms (AI), we combine this data with current medical knowledge to prioritize particular variants that have been identified in previously closed patient cases.
- **Reporting:** Our test reports deliver clinically relevant information in a manner that seamlessly integrates into physician practices. A standard report contains a summary of the test result and provides our analysis, recommendations and detailed description of the patient's relevant genomic alterations and a full data record for consolidation with the patient's medical records. The report also identifies noteworthy absences of genomic alterations and summaries of, and references to, supporting data from peer-reviewed publications. If requested by the physician, we also provide information on variants in genes not associated with the patient's disease or symptoms but that nonetheless contain medically actionable information (such as incidental or secondary findings).
- All of our medical reports are written by professional medical experts facilitated by our automated report writing technology and are reviewed and approved by our Chief Medical and Genomic Officer before distribution. Physicians obtain one report per patient diagnosis while our pharmaceutical partners obtain genomic information that has been provided with express patient consent and de-identified in accordance with HIPAA and other relevant health information privacy procedures. All reports are easily accessible through our online platform, CentoPortal.

Our Solutions for Providing High-Quality Data

Centocard

Our sample collection method is a CE-Marked DBS collection kit, CentoCard (as shown below), which is translated into more than 30 languages and has market authorization in more than 30 countries. CentoCard is sent to physicians as part of a five-component kit: (1) the CentoCard, (2) a genetic or other testing informed consent form, (3) an instruction leaflet, (4) a self-addressed return envelope and (5) a plastic sleeve for the used CentoCard to be sealed in once the sample is obtained. In order to obtain the sample, a small amount of blood is drawn from a patient by his or her physician and placed on designated spots on the CentoCard. This sample is then left to dry for approximately two hours, during which time the sample stabilizes. Each CentoCard produced has a unique barcode that allows for the card to be traced at all times. It is delivered to our laboratory in Rostock, Germany, along with a signed consent form, from anywhere in the world via regular post. Samples collected on CentoCard are considered non-biohazardous materials, which allows them to be mailed across many borders without the need for certain customs declarations.

We use the CentoCard collection method to obtain the majority of our samples. This standardized procedure allows us to extract high-quality biological material and perform most of our diagnostic tests from a portion of a single DBS on the CentoCard. Using CentoCard, we are able to provide a solution where necessary molecular and biochemical tests can be run simultaneously using the same patient sample. Given that the biomaterial stabilizes on CentoCard, we are able to retest the existing patient samples multiple times for more than 10 years from initial sample collection.



CentoPortal

After a physician creates an online account on CentoPortal by following a few easy steps, the physician can order a test product of his or her choosing, provide and sign a patient consent online, provide an overview of the patient's medical history, track the samples and progress of the diagnostic test and download the final medical report once the process is complete. Access to the CentoPortal requires secured authentication. This helps prevent unauthorized access, unauthorized use or loss of patient data.

Biobank

We have established a high-quality biorepository for use in our research and development collaborations with our pharmaceutical partners. Our biobank provides a large diversity of positive test cases in the field of inherited rare diseases and comprises original patient materials characterized through our genetic and/or biochemical diagnostics and with associated clinical information. The biobank operates under robust quality standards and is the first CAP accredited repository outside the United States. It is also compliant with the new ISO20387 standard and comprises materials from patients who have consented to the use of such materials in research. All of our samples have gone through our rigorous process of documentation, analysis and data evaluation by our in-house experts.

Metabolic Biomarker Development Process

So long as an adequate patient cohort exists for any of the 7,000 identified rare diseases, of which approximately 80% have a genetic origin, we believe unique biomarkers can be established. However, the prerequisite is for up- or down-regulated metabolites to be present in the sample medium (e.g. blood) of pathologic or control cases. We may either develop a biomarker on our own, in which case we choose the rare disease to be analyzed using a biomarker, or we may develop a biomarker at the request of a pharmaceutical company, in which case we typically adapt a biomarker for a specific rare disease identified by the pharmaceutical company. In both cases, we own the rights to the biomarker or biomarker test, but in circumstances where a pharmaceutical company is funding the biomarker development process, we may agree to parameters for use of the biomarker going forward.

The first step to the biomarker development process is the identification of patients suffering from a particular disease compared to a respective control group of healthy individuals. To perform this, our repository, which we refer to as the data lake, is browsed for samples to perform patient stratification. Patients with a phenotype and/or genotype known to be an indicator of the particular disease for which we plan to develop the biomarker are compared with a large cohort of healthy control individuals. We can conduct this process with a disease cohort of as few as ten patients in the case of metabolic diseases, although it is our experience that a higher number of patients (i.e., approximately 40) could result in a more specific biomarker target validation. The samples included in the analysis (patients and controls) must be of the same type (e.g., DBS, plasma, tissue) and contain the same anticoagulant. The control samples must be matched to the pathological samples by sample age, patient age, gender, origin, and storage condition. Information on ongoing treatments is important since it has an effect on the patient's metabolic profile. In addition, our clinical study department is involved with the identification and recruitment of patients when there is a lack of patients identified in our repository.

The extraction of metabolites from a sample is performed in a highly standardized manner as the results of the biomarker discovery depend on the stability of the samples and the uniformity of the extraction process. We then analyze the samples using an untargeted high resolution hybrid mass spectrometer to obtain a full metabolic profile. The resulting differences found between the patient cohort profiles and the control cohort profiles are identified using statistical and mathematical algorithms as well as methods based on AI.

Machine learning (“ML”) algorithms and statistical methods help us to identify correlations between different data in an efficient and more accurate manner, and to discover patterns that would not be discovered manually. ML also allows us to perform fully automated pattern recognition on multidimensional data (e.g., retention time, collision cross section, monoisotopic ion mass, fragmentation pattern) obtained from mass spectrometry.

In 2020, we built an integrated biomarker development platform that substantially simplifies and accelerates the search and confirmation of metabolomic biomarkers. The platform allows us to align arbitrary numbers of mass spectrometry measurements. As of December 31, 2022, the metabolic profiles of more than 12,000 individuals are available in one aligned dataset within our CentoMetabolome data base. On this dataset, we can perform virtual experiments qualitatively for biomarker development. Since no further biomaterial is consumed after the one-time initial measurement, an unlimited number of experiments can be performed. The functionality is integrated in a user-friendly platform and therefore accessible to biological experts without knowledge about machine learning. The platform supports the search for biomarker candidates as well as screening of patients.

The mass spectrometry peaks (signals) identified by the platform are then investigated with other mass spectrometric techniques (fragmentation and targeted mass spectrometry) to identify the metabolites underlying the signal (so-called structural elucidation). Subsequently, using estimate on the structural identity of the biomarker candidate, a pure synthesized standard is measured to confirm the structural assignment and inspected to determine if the biomarker candidate is present in the metabolic pathway that is affected by the disease (biological interpretation).

Validation Tests

As more patients are enrolled to the clinical trials, we are also able to perform further validation tests for biomarkers so that it could be used for longitudinal monitoring. Validation is a three-to-six-month process during which the biomarker and its characteristics are assessed, which helps to determine the range of conditions under which the biomarker will give reproducible and accurate data. Approximately 50 to 100 patients in a disease cohort are needed to complete the validation process and approximately 8,000 to 10,000 different measurements are needed to comply with all CAP/CLIA/ISO requirements.

Research and Development

We are dedicated to scientific research and development in order to continuously improve the industry’s understanding of epidemiology and its analysis of clinical heterogeneity as an aid to the diagnosis of rare and neurodegenerative diseases and facilitate the discovery and development of new drugs.

We undertake scientific research and clinical studies, both independently and together with our pharmaceutical partners, with the aim of positively contributing to the global understanding of rare and neurodegenerative diseases, as well as to improve the accuracy of diagnosis and to support the development of effective treatments for rare diseases. The CENTOGENE Biodatabank, which represents over 750,000 individuals from over 120 highly diverse countries and contains over 400,000 biosamples, is key to our research and development. Clinical data captured combined with WGS, transcriptomics and metabolomics allows unique insights into disease pathologies. It enables our research in rare disease genomics and biomarker development and serves as a starting point for drug discovery. Cellular disease models serve as a starting point for testing hypotheses of pathological mechanisms. For this, patient derived IPS cells are differentiated towards mature cellular phenotypes. Disease causing mutations in those cells enable the establishment of cellular disease models and when comparing to healthy cells allows target and drug discovery with the aim of reverting a pathological phenotype towards a healthy phenotype.

We published over 60 scientific papers in 2022 (+20% more than in 2021). The highlights from our publications include: Centogene led work to describe multiomic diagnostics in metabolic disorders in the *European Journal of Human Genetics* (Almeida et al., 2022; PMID: 35614200), co-authorship in the discovery of a novel gene for immune dysregulation in the *Journal of Clinical Investigation* (PMID: 36006710), and work characterizing a novel disease gene leading to a liver disease published in *Nature Genetics* (PMID: 35864190).

In terms of technical innovation, we have worked on the evaluation and development of filtercard-based transcriptomic analysis, since the addition of transcriptomic data in our multiomic product offering ultimately defines a key differentiator in Centogene-unique capabilities. By August 2022, we could conclude on a successful proof-of-concept that clinical-quality RNA-analysis is possible in DBS filtercard samples from routine diagnostics opening up a variety of future products in diagnostics and pharmaceutical research. By the end of 2022, the protocols had been refined and handed over into production for CAP/CLIA validation and product launch is anticipated for 2023.

Our major on-going clinical studies, other than those related to biomarker development, are as follows as of December 31, 2022.

Peptide-Based Immunization for Colon- and Pancreas-Carcinoma (PICOP-Global)

In June 2019, we announced the initiation of a 24-month global proof of concept study focusing on the identification of tumor specific neoantigens, which we anticipate will be used by our partners as the basis for developing a personalized, immune-based therapy to trigger patients' own immune responses against tumors.

In 2022, we successfully concluded on the PICOP-study protocol with more than 200 cancer patients recruited in Germany and Pakistan. Furthermore, the somatic variant analysis for neopeptide prediction was established and validated within the program and high-quality neopeptides for anti-tumor vaccination have been defined in the samples. The financial support through the ministry of economics in Mecklenburg-Western Pomerania, Germany was fully claimed and realized.

Induced pluripotent stem cells (iPSC) program

Since early 2019, we have independently conducted an iPSC program (the "iPSC Program") with the aim of supporting orphan drug development in a more cost effective and efficient manner, in particular for the development of orphan drugs related to rare neurodegenerative, metabolic, and cardiovascular diseases. Human iPSCs, first reported in 2007, are reprogrammed from somatic cells and are self-renewal cells that can produce different types of cells. In the drug discovery process for rare diseases, iPSC technology is particularly important in providing information on the clinical spectrum of such diseases by generating disease specific cells which can be used to evaluate novel therapeutics.

As of December 31, 2022, 1,250 individuals from around the world donated skin biopsies. As part of our iPSC Program, we are currently in the process of reprogramming these biopsies into iPSC for a number of metabolic rare diseases and differentiating the cells into a number of disease-relevant cell types (macrophages, microglia and neurons). We currently establish patient-derived macrophage disease models in Gaucher disease and Niemann-Pick disease type C. Once completed, the iPSC Program will further support orthogonal target validation as well as further biomarker discovery that we undertake.

Hereditary Transthyretin-Related Amyloidosis Study (TRAMoniTTR)

Following the success of the TRAM2 study, where approximately 5,000 individuals were screened for TTR mutations resulting in the identification of almost 60 individuals with this rare neurodegenerative disease, a longitudinal study focusing on TTR-positive individuals was designed and initiated with the support of our pharmaceutical partner Alnylam. As of the end of 2022, 2,393 subjects have been screened in 50 German centers. To date, 63 individuals with TTR mutations have been recruited for follow-up visits and the samples are used for comprehensive multiomic characterization to define and validate TTR-specific biomarkers using transcriptomics and metabolomics.

Our major ongoing collaborative drug discovery efforts making use of our unique insight into disease mechanisms are as follows as of December 31, 2022.

Rostock International Parkinson's Disease Study (ROPAD)

By the end of 2020, the ROPAD Study, which was initiated in May 2019 to investigate the genetic factors in Parkinson's disease, achieved its goal of recruiting and genetically characterizing more than 10,000 subjects with Parkinson's Disease (PD). In total, more than 300 LRRK2-PARK patients and almost 1,200 GBA-PARK were genetically identified among other rarer forms of genetic PD, such as PRKN, SNCA, PINK1, and others. In March 2021, we started to prepare an extension of the concept ("ROPAD2"), where, more than 2,500 PD patients were to be enrolled until March 2022 according to a partnership contract with Denali Therapeutics. By the end of 2021, the recruitment exceeded 400 subjects per month and more than 1,200 participants were analyzed. In parallel, we prepared for extension of the protocol beyond 2,500 PD patients throughout 2022 and 2023. This next phase of the ROPAD Study will focus on 48 targeted sites across 10 countries – maximizing regional efforts to generate insights into the genetic factors of PD, such as LRRK2 genetic variation. The extension was signed by the end of 2022.

Epidemiological Study in Frontotemporal Dementia (EFRONT)

We have been conducting a large observational study to advance the genetic understanding of frontotemporal dementia (FTD) since May 2021. The EFRONT study aims to enroll and complete data-rich genetic testing for over 2,500 FTD diagnosed or suspected patients to learn more about the genetic makeup of the disease. The EFRONT study is being conducted with support from Alector, Inc., a clinical-stage biotechnology company pioneering immuno-neurology.

EFRONT study participants with genetic mutations in the progranulin (GRN) gene will have the option to enroll in Alector's Phase 3 INFRONT-3 clinical trial of tozozinemab, an investigational therapeutic candidate designed to increase progranulin levels for the treatment of FTD.

Epidemiological Analysis for Hereditary Angioedema Disease (EHA)

In 2022, the EHA study has successfully recruited the extension phase with additional 1,200 individuals. A final report was shared with Takeda in 2022, marking the final milestone and study completion.

European Alpha-Mannosidosis Patient Epidemiological Program (EUMAP)

EUMAP is an international, multicenter, observational, longitudinal monitoring study to investigate the prevalence of Alpha-Mannosidosis in participants at risk for Alpha-Mannosidosis. Recruitment for EUMAP was sponsored by Chiesi. Although the initial target to recruit 1,000 patients by September 2020 was not met due to the delays caused by the COVID-19 pandemic, we added nearly 250 patients in 2021. The total number of recruited patients at the end of 2021 was 677. The EUMAP study was mutually terminated after 767 patients were recruited. A final report was shared with Chiesi in September 2022 as final milestone marking project completion.

Drug discovery in Gaucher Disease

In January 2022, we entered the third year of a collaborative effort with Evotec to discover novel small molecule drug candidates to target the unmet medical needs in Gaucher disease. The combination of our unique understanding of genetics, transcriptomics, metabolomics and IPS derived cellular disease models in Gaucher disease, and Evotec's outstanding drug discovery capabilities make uniquely position this collaboration to advance the discovery of drug candidates to glucocerebrosidase (GBA-1), a gene described as causative in Gaucher disease. After finishing high throughput screening, the next phase of drug discovery (a hit to lead chemistry program) was initiated, which resulted in progress towards proof of concept in an animal model of Gaucher disease. IPSc derived disease macrophages were used to show the efficacy of drug candidates using a Centogene proprietary biomarker.

Our Operations

Sales and Marketing

As of December 31, 2022, we had a sales force of approximately 65 employees and consultants in our Diagnostics segment. Our sales team members are all trained in key account management and/or genetic diagnostics and are able to discuss the different diagnostic and workflow needs of doctors, physicians, and genetic counselors. With our global footprint, we support rare and neurodegenerative disease patients around the world. We have a 5-region structure (North America (NAMER), Latin America (LATAM), Europe, the Middle East & Africa (EMEA), and Asia Pacific (APAC)), and each of the geographical regions is led by a Regional General Manager supervising a team of sales and clinical liaisons.

In 2022, we continued to expand our direct footprint and our distribution network in our Diagnostics Segment to further increase the sample volumes in targeted geographic areas. We strengthened our Southern European market presence in Italy, Spain, and Portugal, as well as in Israel by expansion of sales resources. As part of our North America strategy, we also decided to invest in establishing a local presence in Canada with dedicated sales resources in East and West Canada. In Latin America, we decided to change our go-to-market strategy by establishing a local sales team in Colombia, taking over from distribution partners.

In 2022, we also significantly built up the team within our Pharmaceutical segment – underlining our strategic focus to better serve our existing partners, to increase collaborations with new partners, and to expand our collaboration model. As of December 31, 2022, we had a team of approximately 17 employees and consultants in our Pharmaceutical segment. Our Pharma team brings a significant amount of experience within the life science industry, which we expect to transfer to increased activities within this segment.

Information Technology Platforms

Our IT infrastructure platform is based on state-of-the-art standardized components. We run our systems according to the following hybrid production model in an effort to optimize cost and service levels:

- Systems that require a short distance-to-lab infrastructure are run in-house in separate, protected server rooms;
- Tailored systems with special requirements and heightened security use outsourced infrastructure as a service provided by Datagroup AG, which is GDPR-compliant. These services are provided by two datacenters in Frankfurt and our lab in Rostock, which are connected by two independent and encrypted 10GB landlines; and
- Highly standardized, high-volume requirements use cloud services provided by Amazon Web Services (“AWS”) and Microsoft.

All services are based on virtualized server systems with central storage components accompanied by backup and restore services, centrally managed network services, firewall systems, internet, databases and workplace services. System monitoring and events are implemented for all relevant systems with a central monitoring solution and central network scanner controls. Centrally managed user accounts are handled in the directory system.

Information security is highly valued and the principles of confidentiality, integrity and availability of information are a part of our core values. Information is protected by a variety of controls and procedures, including firewalls, password protections, data encryption (in storage and in transit) and malware protection tools. All internet-facing applications are regularly security tested. All personal data processing services are evaluated by our data protection officer and information security officer and documented in accordance with GDPR. Additionally, our data services are certified across a variety of industry security standards, including ISO 9001 (which aims to ensure we consistently provide services and products that meet customer and regulatory security expectations) and ISO 27001 (which standards ensure the data in our database are secured).

Our workflows and processes are supported by various specialized applications. For example, via our user-friendly online portal “CentoPortal,” analyses ranging from individual diagnostic requests to requests for pharmaceutical projects with high throughput testing can be ordered. Physicians can view the status of the samples they submitted and download a complete medical report. Upon receiving samples, we digitize all information to support a fully digital internal workflow. This starts with a web application for sample entries, where information is transferred automatically by interfaces to our laboratory information system. This information forms the basis of our medical reports, which are made available to doctors for download. Data is shared between CentoPortal and our laboratory information systems through a fully automated interface.

Artificial Intelligence

Since 2018, we have been using AI to further automate our processes, obtain new insights about rare diseases from mass data sets and generate new knowledge-driven business models. For example, we use AI to enhance our biomarker discovery process. This allows us to shorten data analysis time from weeks to minutes and to identify multiple biomarkers or additional biomarker patterns in our multiomic datasets. We also use AI to automate our curation process and the identification of genetic and/or metabolic modifiers.

We believe that the CENTOGENE Biodatabank provides us with a competitive advantage for driving the development of new and effective AI tools, as the foundation of any successful AI program is high-quality data in a volume that can effectively generate results. The higher quality the data and the more data that are available, the better chance we have of building machine learning models with high predictive power and accuracy.

We employ AI methods in the following domains:

Intelligent Character Recognition

Intelligent character recognition (“ICR”) at the sample entry stage enables us to fully digitize all information contained in sample order paperwork. Even on handwritten texts, our ICR technology achieves significant performance. This allows us to obtain accurate patient information at the initial stage of the diagnostics process and reduces the likelihood of human error.

Clinical Information Extraction

We extract clinical information from diagnostic reports, using natural language processing methods. Text recognition analyses PDF medical reports and detects clinical status, family history, HPO terms, age, and other data. The data is subsequently applied to enrich cases in our CENTOGENE Biodatabank.

Anomaly Detection in NGS data

We implemented an AI function that identifies lab contaminations at the sample or library preparation stages. This provides corrective measures and counter measures for future applications. The algorithm is programmed to recognize “normal” data and alerts its users when an anomaly is detected. Information regarding the anomaly is provided by the algorithm detailing its top-k indicators and comparisons are made to similar anomalies detected in the past along with the respective reported results and subsequent actions taken. This solution is fully developed but not yet deployed.

Variant Prioritization

We have deployed a new variant prioritization tool based on our in-house AI capability. This tool identifies the most likely disease-causing genes based on the CENTOGENE Biodatabank, in order to further accelerate our and our partners’ diagnostics processes and is in particular aimed to enhance the diagnostics process for WES and Clinical Exome Sequencings (“CES”).

With our clinical exome panel, which covers over 19,000 genes with known associated clinical phenotypes and covers over 3,700 diseases, the result of the sequencing process usually discovers between 70,000 and 150,000 variants per individual. However, the majority of these variants are benign or unrelated to the observed disease phenotype of the patient. With our huge data repository built up from the last 15+ years, and a curated database with standardized HPO terms, our tool is able to rank the variants from most to least relevant. Based on such “ranked” variants, we can then compare the HPO terms of a new patient with the results of prior, anonymized patients included in our repository with variants in the same gene. This allows us to provide a diagnosis in a more rapid, comprehensive and accurate manner, especially for patients with very rare or as yet undescribed diseases.

Variant Classification

In 2015, the American College of Medical Genetics and Genomics (ACMG) and the Association for Molecular Pathology (AMP) published a joint consensus recommendation for interpretation of genetic variants. ACMG's recommended standards classify genetic variants, based on 28 criteria, into five categories: pathogenic, likely pathogenic, variant of uncertain significance (VUS), likely benign and benign. We have implemented a semi-automated variant classification tool that classifies variants detected in a sample based on ACMG's recommended standards. Our tool will significantly reduce the time taken to interpret the clinical significance of genetic variants and increase the quality such interpretation.

AI-Based Artifact Detection Tool

Artifact discovery via current diagnostic workflows such as visual inspection and sanger sequencing for WGS cases requires a lot of manual work. This method of discovery is inefficient, error prone and risks important variants being missed in the discovery process. By applying our artifact prediction model, we can improve the reliability of the data by distinguishing true variant calls from sequencing errors in WGS samples, and prioritize true variants in the evaluation processes which results in a reduction of analysis effort and increases the diagnostic efficiency. Subsequently, a report is provided to our medical experts for the interpretation of variant sequencing quality which categorizes the results into one of three classes: "likely artifact", "likely true", and "unknown".

Artifact detection is a tool used for the classification of small sequence variants (SNPs, InDels) into likely artifacts, unknown, or likely variant. It enables the automated detection of artifacts in VCF-files using machine learning algorithms. The model is based on gradient boosting classification, which uses an ensemble of so-called weak learners to create a strong learner, yielding reliable classification results.

Automated Curation Report

Our curators are responsible for the collection, association, update and review of genetic and phenotypic data of cases analyzed at Centogene to assure the highest level of data quality. The automated curation process supports our curation process with a set of rules encoding the expert knowledge and classifying newly incoming cases as well as reclassifying the old ones if new genomic insights result from research.

Biomarker Discovery & Support of Metabolomic Processes

We built a proprietary, AI-powered biomarker platform called CentoMetabolome. This internally developed platform has the potential to revolutionize the detection of new biomarkers by accelerating components of biomarker development that previously required months to complete to a few weeks. This includes supporting metabolome screening and identifying biomarker candidates. The integration of AI-based methods into a user-friendly platform enables the medical experts to perform high-quality and high-performance biomarker experiments, with integrated quality control checks. In addition, we have been awarded the Health-i Award for the development of this platform, which recognizes companies that are transforming healthcare domestically and internationally. The Health-i Award winners were selected by industry and research experts for initiatives that are aimed at transforming the next era of healthcare through innovation.

Multiomic Analysis

We extended a multiomic platform for genomics and metabolomics integration and visualization, from the focus on Gaucher disease to also include Parkinson's disease. The platform consists of a comprehensive multiomic map of genes, mutations, metabolic reactions, enzymes, and regulatory elements of the focus diseases. The map allows for the overlay of our genomic, metabolomics and phenomic data, the performance of perturbation experiments of expression parameters for phenotype prediction and the analysis of fold change data. This platform is capable of being extended to transcriptomics and proteomics. It provides a unique, innovative model for understanding system biology and allows for the selection of targets for drug discovery. The extension allows for the investigation of the interplay between Gaucher disease and Parkinson's disease, with associated pathways. Inbuilt applications within the platform also allow correlations between genomic and metabolomic data, and extraction of pathways and differential metabolites to further enable biological understanding of diseases.

Genome-wide association studies (GWAS) pipeline

We have developed a genome-wide association studies (GWAS) pipeline to identify genetic modifiers. This pipeline includes different statistical tests, both at the variant and at the gene level. The implementation allows for variant filtering based on different quality criteria, as well as specific genetic principles. In addition, different gene collapsing models are defined based on variant properties such as minor allele frequency (MAF) and the predicted variant effect.

Big Data (Data Lake)

Many rare diseases share phenotypic and genetic traits which interests biopharma companies involved in drug development and commercialization. Patient, diagnostic, genetic, transcriptomic, proteomic, metabolic and phenotypic information extractable from patient samples are stored in different data formats with different applications and workflows. To optimize the infrastructure for cross-departmental data evaluation, we developed the BigData platform as a way forward to provide a low-cost scale solution for data storage and processing. It enables users to perform analytics and data science through a flexible, scalable and cloud-based platform across patient biomarker and bioinformatics data.

The Big Data solution is an analytical and reporting platform which changes traditional cross-departmental (silos) into a highly scalable, available system for data storage and analytics.

Healthcare Reimbursement

Reimbursement of genetic or other testing differs markedly among countries and evolves rapidly based on advancements in technologies and cost. It is a challenge for insurers or public payers to decide when to reimburse for genetic or other tests that are offered by healthcare providers. One of the reasons this is difficult is that often there are alternative treatments with differing results, which insurers may not be able to easily evaluate

Depending on the billing arrangement and applicable law, we may be reimbursed for genetic or other testing services by third-party payors that provide coverage to the patient, such as an insurance company or managed care organization, or by physicians or other authorized parties (such as hospitals or independent laboratories) that order our tests or refer tests to us. In the years ended December 31, 2022, and 2021, we derived between 1% and 2% of our total revenue from United States third-party payers that includes managed care organizations and other healthcare providers. In the years ended December 31, 2022, and 2021, we derived less than 1% of our total revenue from EU insurance companies and managed care organizations based in the European Union.

We have strategically determined to focus on countries around the globe where the prevalence of rare hereditary diseases is high or the availability of national genetic or other testing and interpretation is to some extent limited and therefore the complete reimbursement or partial payment by the government for our services is more likely. Therefore, the major markets for our diagnostics business currently include the Middle East, Western Europe, parts of Eastern Europe, Latin America, North America, South Asia and parts of South-East Asia. In most of our markets, our diagnostics tests are billable directly to the party submitting the request for a test to us.

Data Management

Data is the basis for all of our diagnostic and research processes. We are generating approximately up to 25TB of new data in the lab every month. The data is stored in our own infrastructure as well as in a certified third-party data center and with AWS. The software solutions supporting these processes are based on modern database architecture, and all of our critical systems are fully redundant and backed up in real-time to these facilities.

Further, we implement our big data concept based on architecture. Because we store a vast amount of raw data in our repository, we are able to aggregate data to gain new insights. Data gathering and variant curation are procedures developed and implemented in a web-based software (developed and maintained by Centogene N.V.) that is compliant with the HUGO Gene Nomenclature Committee (the "HGNC"), the Human Genome Variant Society (the "HGVS") and HPO nomenclatures. The software integrates in-house sample management systems and analysis platforms with external databases and utilizes a combination of computer-based tools and manual review in order to assure the accuracy, efficiency and quality of curation process.

Quality Management System (QMS)

We document and maintain a QMS that integrates the compliance of our processes with various *in vitro* diagnostic medical device legislations, and laboratory requirements. Our QMS is supported by standard operating procedures, educational and staff training plans, internal and external proficiency and competency programs, internal and external auditing, quality improvement indicators and pre-post analytical quality controls, including equipment maintenance, negative and positive controls, change management, post-market surveillance, employees and customer health and safety, and document control programs. Our QMS processes comply with various regulatory requirements, including:

- **42 CFR §493** *Laboratory Requirements*
- **21 CFR §820** *Quality System Regulation*
- **ISO 15189** *Medical laboratories –Requirements for Quality and Competence*
- **ISO 13485** *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*
- **Regulation (EU) 2017/746 (IVDR)** *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices*
- **Directive 98/79/EC (IVDD)** *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices*

We believe our QMS is built to withstand the rigorous review and auditing requirements of global medical device regulations, clinical trial requirements and good clinical laboratory practice requirements to ensure our patients and clients receive the highest quality level of care and service.

Client data protection is of high importance to us, as we provide solutions to our clients in more than 120 different countries with varying requirements. We protect our clients and employees through an informed consent process, which goes through a rigorous legal review with in-country specialists and our internal HIPAA and GDPR compliance policies. We continuously monitor all electronically archived and incoming data through these channels.

Data Acquisition and Curation

Curation is the process of collection, association, updating and reviewing epidemiologic, phenotypic and genetic data of patients analyzed by us into a structured and standardized format. It uses a combination of computer-based tools and manual review in order to assure the accuracy, efficiency and quality of the curation process.

Data acquisition. Data gathering and variant curation procedures are developed and implemented in a web-based software which is compliant with the HGNC, HGVS and HPO nomenclatures allowing collection of variants detected in nuclear coding, nuclear non-coding and mitochondrial genes. The software integrates in-house sample management systems and analysis platforms with external databases providing the curator with a comprehensive and straightforward overview of the evidence regarding genotype-phenotype correlation available both in-house and external.

The data is gathered by a combination of manual submission and data importation following an individual-oriented model where characteristics belonging to a particular individual (including patient information, clinical data, methodology and detected genetic variants) are stored and associated together.

Our uniform classification of variants is an important step in improving our understanding of disease pathogenicity. There are approximately 3 billion base pairs in an individual genome, which translates to approximately 200 gigabytes of data that can be obtained from a single sequencing process. The classification of variants which we record in the CENTOGENE Biodatabank follows the American College of Medical Genetics and Genomics and Clingen guidelines for variant classification, differentiated into five categories: pathogenic, likely pathogenic, variant of uncertain clinical significance, likely benign or benign. If a diagnostic test is finalized without assigned clinical significance we still include the data under an “unclassified” quality status. This information can then be used as comparative data for future diagnostic tests. This systematic classification of variants is based on a highly qualified and standardized curation process, which allows us to provide our clients with high-quality clinical interpretations of newly identified variants, and also ensures that changes in variant classification will be communicated and reflected in our clinical interpretations in a timely manner.

As industry knowledge on variant frequencies increases, we reevaluate the variant classifications contained in our database on a regular basis to ensure our system incorporates the most up-to-date information. Additionally, given the number of rare diseases that have yet to be fully diagnosed and the speed of advancements in the rare disease industry, we regularly revisit “uncertain” patient data to reassess prior clinical interpretations against this new industry knowledge.

Database curators. Our curators are scientists with strong backgrounds in human genetics. They continuously undergo extensive training to ensure curation consistency and standardization. They assure that data is properly associated and interpreted and that there are no inconsistencies or discrepancies against detected in-house observations and from external sources. They close the curation process by manual approval that reviewed and curated data comply with standard in-house procedures.

Curation workflow. To provide high-quality data, our curation process is divided in three phases: variant-wise, individual-wise and error-wise procedures.

- *Curation by variant.* To begin the curation process, the variant-linked information is reviewed. This includes approval of variant nomenclature, terminology, accuracy, consistency, and record completeness.
- *Curation by individual.* To start curation on a patient-by-patient basis, all variants detected in an individual must be approved. This process aims to assure that the data belonging to an individual follows the guidelines for clinical reporting closely and that all associated data agrees with our established guidelines and applicable industry standards. The following factors are considered critical for the clinical statement: variant clinical significance, patient genotype, inheritance pattern of the disorder, the sex of the patient and the phenotypic description, when available.
- *Curation by warning.* To maintain data quality and consistency, regular quality control (QC) checks are performed in curated data. The QC check process consists of checking and correcting variant, individual and other curated data related warnings detected using pre-established scripts.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection of the CENTOGENE Biodatabank, proprietary biomarkers, products, solutions and other know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing valid and enforceable intellectual property rights of others. We seek to protect our proprietary position by, among other things, filing EU, U.S. and certain foreign patent applications related to our biomarkers, where patent protection is available. Our policy is to seek patent protection and trademark registration for commercially valuable assets we develop, as appropriate, and maintain as trade secrets other aspects of our genetic rare disease information platform, processes and know-how. We also rely on proprietary technologies, methods and processes, product designs and branding that we have developed.

Notwithstanding these efforts, we cannot be sure that patents will be granted with respect to any patent applications we have filed or may file in the future, and we cannot be sure that any issued patents will not be challenged, invalidated, or circumvented or that such patents will be commercially useful in protecting our technology. Moreover, trade secrets can be difficult to protect. While we have confidence in the measures we take to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. For more information regarding the risks related to our intellectual property, please see “Item 3. Key Information—D. Risk Factors—Intellectual Property Risks Related to Our Business.”

Patents

Each patent family in our patent portfolio typically includes one or more priority-forming patent applications on the basis of which an international patent application (an application filed under the Patent Cooperation Treaty (“PCT”)) is filed, after which national and regional patent applications are prosecuted in various jurisdictions. As of December 31, 2022, our patent portfolio was as follows:

- With regard to our biomarker for Gaucher disease, we own two issued U.S. patents, one pending U.S. non-provisional patent application, issued patents in Australia, China, Europe, Israel, Japan and Russia, and pending patent applications in the following foreign jurisdictions: Brazil, Canada, Europe, and Hong Kong. The two issued European patents have been validated in one or more contracting states of the European Patent Convention. These issued patents, and any patents granted from such applications, are expected to expire in 2032, without taking potential patent term extensions or adjustments into account.
- With regard to our biomarker for Niemann-Pick disease, we own three issued U.S. patents, one pending U.S. non-provisional patent application, issued patents in Australia, Brazil, Europe, Israel, Japan and Mexico, and pending patent applications in the following foreign jurisdictions: Australia and Canada. The one issued European patent has been validated in one or more contracting states of the European Patent Convention. These issued patents, and any patents granted from such applications, are expected to expire between 2032 and 2034, without taking potential patent term extensions or adjustments into account.
- With regard to our biomarker for cystic fibrosis, we own one pending U.S. non-provisional patent application, one issued patent in Israel, and pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada, Europe, Israel, and Hong Kong. Any patents granted from such applications are expected to expire in 2037, without taking potential patent term extensions or adjustments into account.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent’s term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

We have entered into agreements with the University of Rostock and a related scientific institute pursuant to which such parties have fully transferred to us interests that they had co-owned with us with respect to patents and patent applications relating to our biomarkers for Gaucher disease, and Niemann-Pick disease. Pursuant to the terms of these agreements, we were required to pay a total of €150,000 in upfront transfer fees and are obligated to pay royalties below 1% on net sales generated by the applicable patents in the future.

Trade Secrets and Trademarks

In addition to patent protection, we also rely on trade secrets, know-how, continuing technological innovation, and confidential information to develop and maintain our proprietary position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including, the CENTOGENE Biodatabank. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties.

Our brand is very important to us, as it is a symbol of our reputation and representative of the goodwill we seek to generate with our customers. Consequently, we have invested significant resources in the protection of our trademarks. We seek trademark protection in the United States and in foreign jurisdictions where available and when appropriate. We own registered trademarks for “Centogene” in Europe, the United States and other jurisdictions, including Canada and Japan.

Regulation

Our diagnostics and pharmaceutical businesses are highly regulated due to our operation of clinical laboratories in Rostock, Germany and Cambridge, Massachusetts, United States and because of our provision of diagnostic services and our development of proprietary biomarkers. In addition, we are subject to a variety of regulations and industry standards worldwide governing, among other things, data privacy, distribution of our products and patents and trademark licensing.

The key U.S. and European regulations that are applicable to our business are discussed in more detail below. Whether or not we obtain FDA clearance or approval or a CE Mark for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the use of a diagnostic or other product in those countries. The requirements and processes governing patient consents, product registration and pricing vary from country to country.

United States Regulation

Our business is subject to and impacted by extensive and frequently changing laws and regulations in the United States at both the federal and state levels. These laws and regulations include regulations particular to our business and laws and regulations relating to conducting business generally. We also are subject to inspections and audits by governmental agencies. Set forth below are highlights of the key United States regulatory schemes applicable to our business.

CLIA and State Regulation

Because we operate clinical laboratories, we are required to hold certain United States federal and state licenses and certifications to conduct our business. We are subject to CLIA regulations in the United States, which establish quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed. Our laboratories in Rostock, Germany and Cambridge, Massachusetts, United States are CLIA-certified and accredited by CAP, as well as CAP ISO 15189 accredited. In addition, we are required to meet certain laboratory licensing requirements for states with regulations beyond CLIA. For more information on state licensing requirements, see “—Regulation—United States Regulation—State Laboratory Testing.”

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. CLIA also requires that we hold a certificate applicable to the type of work we perform and comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring that they be certified by the federal government and comply with various operational, personnel, facilities administration quality and proficiency requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. Laboratories must register and list their tests with the Centers for Medicare & Medicaid Services, or CMS, the agency that oversees CLIA. CLIA compliance and certification is also a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries and for many private payors. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

We are subject to a survey and inspection every two years to assess compliance with program standards and may be subject to additional unannounced inspections. Laboratories performing high-complexity testing are required to meet more stringent requirements than laboratories performing fewer complex tests. In addition, a laboratory like ours that is certified as “high-complexity” under CLIA may develop, manufacture, validate and use proprietary tests referred to as LDTs. While laboratories that offer LDTs are subject to the FDC Act, in addition to CLIA, the FDA has generally exercised enforcement discretion towards these tests. In compliance with CLIA requirements to establish performance specifications, including accuracy, precision, specificity, sensitivity and a reference range for any LDT used in clinical testing, our LDTs have undergone full analytical validation.

In addition to CLIA requirements, we elect to participate in the accreditation program of CAP. CMS has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. Inspection by CAP is performed in lieu of CMS for accredited laboratories. Because we are accredited by the CAP Laboratory Accreditation Program, we are deemed to also comply with CLIA.

State Laboratory Testing

CLIA also provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and several states have implemented their own more stringent laboratory regulatory schemes. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or prescribe record maintenance requirements. Our clinical operations at our Cambridge, Massachusetts, United States, laboratory are required to meet certain state laboratory licensing and other requirements, which in some areas are more stringent than CLIA requirements. This lab is also subject to Massachusetts Department of Public Health clinical laboratory permitting requirements. In October 2018, we received our CLIA permit to perform high complexity genetic testing in our Cambridge, Massachusetts, United States, lab. Our Massachusetts Department of Public Health clinical laboratory permit application was reviewed, and the lab was inspected. It passed accreditation with no deficiencies and was issued a Massachusetts license for high complexity testing in November 2018. We have been permitted to begin testing in November 2018.

During the COVID-19 pandemic in 2021, we put our lab operations on hold in accordance with CAP regulations and sent US samples out to the central lab in Rostock, Germany; the latter also being CAP accredited. In August 2022, we restarted our lab operations in Cambridge, Massachusetts under a new CAP/CLIA accreditation and applied for renewal of our Massachusetts state license. The state of Massachusetts approved our application and allowed us to operate in the state of Massachusetts in September 2022.

Two states, New York, and Washington are CLIA-exempt, however, and as such have their own regulatory requirements to which we may be subject. CMS deemed both New York and Washington as CLIA-exempt because their licensing and supervisory programs are more stringent than that run by CMS and the CDC. New York requires clinical laboratories that accept specimens from New York residents to have both a CLIA and New York Clinical Laboratory Evaluation Program (“CLEP”) permit. CLEP approval can take up to a year and can be costly and time-consuming. Washington State does not require clinical laboratories to have a CLIA permit but does require the clinical laboratory to apply for a Washington State lab permit.

Several states in the United States require the licensure of out-of-state laboratories that accept specimens from those states. For example, New York requires a laboratory to hold a permit which is issued after an on-site inspection and approval of testing methodology and has various requirements over and above CLIA and CAP, including those for personnel qualifications, proficiency testing and physical facility, equipment, and quality control standards. Each of our CLIA laboratory locations, including our site in Massachusetts, holds the appropriate licensure for the activities performed at that location. CLEP permit requires LDTs that are offered to New York State patients must be submitted for approval before they can be marketed or offered in New York. The Company is in the process of obtaining the requisite approvals for its LDTs.

From time to time, other states, such as California, Rhode Island, Maryland, New York, and Pennsylvania, may require out-of-state laboratories to obtain licensure to accept specimens from the state, even though the laboratory is not located in such state. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements. We are currently licensed in Florida, Pennsylvania, Maryland, Rhode Island, and California and are in the process of obtaining a New York State license.

Many states have also implemented genetic or other testing and privacy laws imposing specific patient consent requirements and protecting test results. In some cases, we are prohibited from conducting certain tests without a certification of patient consent by the physician ordering the test. Requirements of these laws and penalties for violations vary widely. We review our obligations regarding genetic or other testing and consent periodically. If we identify states with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

FDA

In the United States, medical devices are subject to extensive regulation by the FDA, under the FDC Act, and its implementing regulations, and other federal and state statutes and regulations. The laws and regulations govern, among other things, medical device development, testing, labeling, storage, premarket clearance or approval, advertising and promotion and product sales and distribution. To be commercially distributed in the United States, medical devices must receive from the FDA prior to marketing, unless subject to an exemption, either approval of a PMA (for most Class III devices), clearance of a 510(k) premarket notification or classification pursuant to a de novo submission. Typically, exemptions are granted for Class I devices.

IVDs are types of medical devices that can be used in the diagnosis or detection of diseases, conditions or infections, including, without limitation, the presence of certain chemicals, genetic information or other biomarkers. Predictive, prognostic and screening tests, such as carrier screening tests, can also be IVDs. A subset of IVDs is known as analyte-specific reagents (“ASRs”). ASRs consist of single reagents and are intended for use in a diagnostic application for the identification and quantification of an individual chemical substance in biological specimens. ASRs are medical devices, but most are exempt from 510(k) review. As medical devices, ASRs have to comply with some QSR provisions and other device requirements, such as establishment registration, device listing and medical device reporting.

The Federal Food, Drug and Cosmetic Act (FDCA) classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk devices. Many Class I devices are exempt from FDA premarket review requirements. Class II devices, including some software products to the extent that they qualify as a device, are deemed to be moderate risk, and generally require clearance through the premarket notification(510(k)) clearance, process in order to be commercially distributed. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device’s safety and effectiveness. Class III devices typically require Premarket Approval (PMA) within the FDA’s Divisions before they are marketed. A clinical study is almost always required to support a PMA application and is sometimes required for 510(k) clearance. All clinical studies of investigational devices must be conducted in compliance with any applicable FDA and Institutional Review Board requirements. Devices that are exempt from FDA premarket review requirements must nonetheless comply with general post-market controls as described below, unless the FDA has chosen to exercise enforcement discretion and not regulate them.

510(k) clearance pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA’s satisfaction that the proposed device is substantially equivalent to a previously 510(k)-cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of PMA applications. The previously cleared device is known as a predicate. The FDA’s 510(k) clearance pathway usually takes from three to 12 months, but it can take longer, particularly for a novel type of product.

PMA pathway. The PMA pathway requires proof of the safety and effectiveness of the device to the FDA’s satisfaction. The PMA pathway is costly, lengthy and uncertain. A PMA application must provide extensive preclinical and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. As part of its PMA review process, the FDA will typically inspect the manufacturer’s facilities for compliance with QSR requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The PMA review process typically takes one to three years but can take longer.

De novo pathway. If no predicate device can be identified, the product is automatically classified as Class III, requiring a PMA application. However, the FDA can reclassify, or use “de novo classification,” for a device for which there was no predicate device if the device is low or moderate risk. The FDA will identify “special controls” that the manufacturer must implement, which often include labeling and other restrictions. Subsequent applicants can rely on the de novo product as a predicate for a 510(k) clearance. The de novo route is less burdensome than the PMA process. A device company can ask the FDA at the outset if the de novo route is available and submit the application as one requesting de novo classification. The de novo route has been used for many IVD products.

Post-market general controls. After a device, including a device exempt from FDA premarket review, is placed on the market, numerous regulatory requirements apply. These include the QSR, labeling regulations, registration and listing, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur) and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA).

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an untitled or public warning letter to more severe sanctions such as fines, injunctions and civil penalties; recall or seizure of products; operating restrictions and partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMAs already granted; and criminal prosecution.

Research use only. Research use only (“RUO”) products belong to a separate regulatory classification under a long-standing FDA regulation. RUO products are not regulated as medical devices and are therefore not subject to the regulatory requirements discussed above. The products must bear the statement: “For Research Use Only. Not for Use in Diagnostic Procedures.” RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and they cannot be intended for human clinical diagnostic use. A product labeled RUO but intended to be used diagnostically may be viewed by the FDA as adulterated and misbranded under the FDC Act and is subject to FDA enforcement activities, including requiring the supplier to seek clearance or approval for the products. Our LDT uses instruments and reagents labeled as RUO in our laboratories.

Laboratory-developed tests. LDTs have generally been considered to be tests that are designed, developed, validated and used within a single laboratory. The FDA takes the position that it has the authority to regulate such tests as medical devices under the FDC Act. The FDA has historically exercised enforcement discretion and has not required clearance or approval of LDTs prior to marketing. In addition, New York CLEP separately approves certain LDTs offered to New York State patients. The Company is in the process of obtaining the requisite approvals for its LDTs in New York.

On October 3, 2014, the FDA issued two draft guidance documents regarding oversight of LDTs. These draft guidance documents proposed more active review of LDTs. The draft guidance has been the subject of considerable controversy, and in November 2016, the FDA announced that it would not be finalizing the 2014 draft guidance documents. On January 13, 2017, the FDA issued a discussion paper which laid out elements of a possible revised future LDT regulatory framework, but did not establish any regulatory requirements.

The FDA’s efforts to regulate LDTs have prompted the drafting of legislation governing diagnostic products and services that sought to substantially revamp the regulation of both LDTs and IVDs. Congress may still act to provide further direction to the FDA on the regulation of LDTs.

We believe that the majority of the tests we currently offer meet the definition of LDTs, as they have been designed, developed and validated for use in a single CLIA-certified laboratory. If our tests are LDTs, they are currently not subject to FDA regulation as IVDs.

HIPAA and HITECH

Under the administrative simplification provisions of HIPAA, as amended by the HITECH Act, the United States Department of Health and Human Services issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and protecting the privacy and security of protected health information used or disclosed by healthcare providers and other covered entities. Three principal regulations with which we are required to comply have been issued in final form under HIPAA: privacy regulations, security regulations and standards for electronic transactions, which establish standards for common healthcare transactions. The privacy and security regulations were extensively amended in 2013 to incorporate requirements from the HITECH Act.

The privacy regulations cover the use and disclosure of protected health information by healthcare providers and other covered entities. They also set forth certain rights that an individual has with respect to their protected health information maintained by a healthcare provider, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity and availability of protected health information that is electronically transmitted or electronically stored. The HITECH Act, among other things, established certain protected health information security breach notification requirements. A covered entity must notify affected individual(s) and the United States Department of Health and Human Services when there is a breach of unsecured protected health information. The HITECH Act also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts. The HIPAA privacy and security regulations establish a uniform federal “floor” that healthcare providers must meet and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents that is more prescriptive than HIPAA.

These laws contain significant fines and other penalties for wrongful use or disclosure of protected health information. Additionally, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and the HITECH Act, payments to us may be delayed or denied.

United States Federal and State Fraud and Abuse Laws

In the United States, there are various fraud and abuse laws with which we must comply, and we are potentially subject to regulation by various federal, state and local authorities, including CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the DOJ and individual U.S. Attorney offices within the DOJ, and state and local governments. We also may be subject to foreign fraud and abuse laws.

In the United States, the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for patient referrals for, or purchasing, leasing, ordering or arranging for the purchase, lease or order of, any healthcare item or service reimbursable under a governmental payor program. Courts have stated that a financial arrangement may violate the Anti-Kickback Statute if any one purpose of the arrangement is to encourage patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. Violations may result in imprisonment, criminal fines, civil money penalties and exclusion from participation in federal healthcare programs. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition to the administrative simplification regulations discussed above, HIPAA also created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs.

Finally, another development affecting the healthcare industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or *qui tam* provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The *qui tam* provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by submitting a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from \$11,181 to \$22,363 for each false claim. These civil penalties are also adjusted for inflation periodically.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program.

Physician Referral Prohibitions

Under a United States federal law directed at "self-referral," commonly known as the "Stark Law," there are prohibitions, with certain exceptions, on referrals for certain designated health services, including laboratory services, that are covered by the Medicare and Medicaid programs by physicians who personally, or through a family member, have an investment or ownership interest in, or a compensation arrangement with, an entity performing the tests. The prohibition also extends to payment for any testing referred in violation of the Stark Law. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

Corporate Practice of Medicine

Approximately 30 states in the United States have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California's Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings.

Other United States Regulatory Requirements

Our laboratories are subject to United States federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

The U.S. Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for healthcare employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

European Regulation

European sales of medical and diagnostic devices are subject to European regulations. The time required to obtain clearance or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different. Set forth below are highlights of the key European regulatory schemes applicable to our business.

European Conformity Marking ("CE Mark") and Certifications

The primary regulatory bodies in Europe are the European Parliament and the Council, which have adopted three directives (Directive 90/385/EEC relating to active implantable medical devices, Directive 92/43/EEC on medical devices and Directive 98/79/EG relating to IVD) regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical and diagnostic devices. Devices that comply with the requirements of the relevant regulation will be entitled to bear the CE Mark indicating that the device conforms to the essential safety and performance requirements of the applicable regulation and, accordingly, can be commercially distributed throughout the member states of the European Union and the contracting states of the European Economic Area. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system, review of technical documentation and specific testing of the manufacturer's device. Such an assessment may be required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 13485 certification is a voluntary standard. Quality systems that implement relevant harmonized standards establish the presumption of conformity with the essential requirements for a CE Mark.

We currently have 3 In-vitro Diagnostic Medical Devices, CentoCard, and CentoNIPT, which must be in compliance with Directive 98/79/EG and Regulation (EU) 2017/746 (which became fully applicable as of May 26, 2022), to affix the CE Mark. Regulation 2017/745 (which became fully applicable as of May 26, 2021) is applicable for all our Medical Devices to affix the CE Mark. We use EN ISO 13485:2016 as the Quality Management Standard for Medical Devices and In vitro Diagnostic Medical Devices.

Currently, there is an ongoing legislative procedure proposing a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain European Union legislative acts, which would also apply to medical devices. It is currently unclear whether and to what extent the proposal will be enacted.

Laboratory-Developed Tests

As currently a majority of our diagnostic testing is run at our laboratory in Rostock, Germany, the European Union and German legislation on *in vitro* diagnostic medical devices applies. As of May 26, 2022, when the new IVDR became applicable, the general safety and performance requirements set out in Annex I IVDR are applicable also to IVD manufactured and used only within health institutions. Overall, the exemptions for LDTs are now narrowed, as even health institutions that use LDTs, among other institutions, will have to provide information upon request on the use of such devices to their relevant authorities and the particular health institution will have to draw up a declaration which it is required to make publicly available. If those conditions are not met and/or diagnostic tests are manufactured and used only within health institutions but not “on an industrial scale”, or – effective from May 26, 2028 – if the health institution cannot justify in its documentation that the target patient group’s specific needs cannot be met (or cannot be met at the appropriate level of performance) by an equivalent IVD already available on the EU market, such tests will qualify as IVDs with the IVDR, generally applying with full applicability. Additionally, U.S. regulation applies to our laboratory-developed tests (see “Regulation—Regulation States Regulation—Laboratory-developed tests” for more information).

General Data Protection Regulation

In May 2016, the European Union formally adopted the GDPR, which applied to all EU member states as of May 25, 2018 and replaced the EU Data Protection Directive. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for “sensitive information,” which includes health and genetic information of data subjects residing in the European Union. The GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides an individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer “adequate” privacy protections. It has increased our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of transactions from which we may gain access to personal data. Furthermore, many of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. There is still significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR in the medical and research fields. For example, it is not yet clear if such authorities will conduct random audits of companies subject to the GDPR or will only respond to complaints filed by individuals who claim their rights have been violated. Enforcement actions to date in other industries has resulted in significant fines and other penalties. Failure to comply with the requirements of the GDPR and the related national data protection laws of EU member states, which may deviate slightly from the GDPR, may result in material fines.

European Fraud and Abuse Laws

In Europe, various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives, or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010 faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

In Germany, interactions between pharmaceutical and medical device companies and physicians, other healthcare professionals and healthcare organizations are subject to the general criminal law regime covering anti-bribery in the public and private sectors, respectively, as well as to more recently enacted specific provisions in the German Criminal Code (Strafgesetzbuch – StGB) covering anti-bribery in the healthcare sector in connection with the prescription and procurement of medicinal products and medical devices and the allocation of patients or material for diagnostic purposes. Obligations to report payments to healthcare professionals or healthcare organizations are currently limited to members of certain industry associations. Marketplace activities and medical claims are regulated by the Healthcare Advertising Act (Heilmittelwerbeengesetz – HWG) and the Act against Unfair Competition (Gesetz gegen unlauteren Wettbewerb – UWG) allowing competitors, among others, to seek interim injunctions in ex-parte proceedings, and by consumer protection laws.

Violations of these laws may subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, injunctions, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal, and state and foreign laws and regulations, proposed and implemented, that could impact our future operations and business.

Competition

We believe, for our core business, that we are the company offering the most comprehensive services to both diagnostics and pharmaceutical partners in the rare and neurodegenerative disease field, with highly curated data combining multiomic datasets and proprietary biomarkers. Our principal competitors are existing mainstream diagnostic companies or companies specializing in certain rare diseases, as well as cloud-based bioinformatic companies and entities that offer open-source, uncurated genetic databases. However, these companies do not offer curated information or as broad of a testing portfolio for rare diseases in as many geographical regions as we do. For example, we have found that the genetic mutation causing the same rare diseases and the phenotypical patterns may vary depending on the ethnicity of the patients, which we have identified based on our global data sets. Such unique insights may not be available to other companies that do not have the same global and diversified scope of patient data.

Our principal competitors in our Diagnostics segment include mainstream diagnostic testing companies as well as labs or hospital conglomerates which offer similar services. In our Pharmaceutical segment, our competitors include companies offering services to pharmaceutical companies.

With the continuous development of NGS technology, the cost of genetic sequencing is anticipated to decrease, and there may be companies intending to compete with us by performing sequencing at lower prices in order to obtain the relevant data to construct a similar database and repository. However, given the current limitations in the rare disease field, as well as the required quantity and quality of the data in order to make any relevant analysis, we believe the CENTOGENE Biodatabank is the leading real-world integrated multiomic data repository in rare and neurodegenerative diseases, due to its focus, data quantity, and data diversity (ethnic, geographic, etc.).

Legal Proceedings

For more information, see “Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Legal Proceedings.”

C. Organizational Structure

Our parent company is Centogene N.V. (the “Company”). Centogene B.V. was incorporated on October 11, 2018. In connection with our initial public offering which closed on November 12, 2019, we executed a corporate reorganization whereby Centogene B.V. was converted into Centogene N.V., and Centogene N.V. became the holding company for Centogene AG (now Centogene GmbH).

Our major subsidiaries are listed below.

Name	Country in which primary activities are pursued	Equity interest (%)	
		Dec 31, 2022	Dec 31, 2021
Centogene GmbH ⁽¹⁾	Germany	100	100
Centogene FZ-LLC	United Arab Emirates	100	100
Centogene US, LLC	USA	100	100
Centogene GmbH ⁽²⁾	Austria	100	90
Centogene India Pvt. Ltd.	India	100	100
Centogene Switzerland AG	Switzerland	100	100
CentoSaf e B.V.	Netherlands	100	100
Centogene d.o.o. Belgrade	Serbia	100	100
Dr. Bauer Laboratoriums GmbH ⁽³⁾	Germany	—	—

(1) Centogene IP GmbH and Centogene Shared Service GmbH were merged with Centogene GmbH on January 1, 2021.

(2) The Group acquired the remaining 10% of Centogene GmbH, Austria that it did not already own in 2022.

(3) See note 4 – Basis of consolidation.

D. Property, Plants and Equipment

Our headquarters are located in Rostock, Germany, where we occupy approximately 8,500 square meters of office and laboratory space that was originally constructed by us. In July 2019, Centogene AG (now Centogene GmbH) entered into a sale and leaseback transaction, pursuant to which we sold our Rostock headquarters building to a third party for €24,000 thousand. We then leased the building from the third party for a period of 12 years at a fixed rate per month with the option to extend twice. In addition, a bank guarantee of €3,000 thousand (which we have secured by cash deposit of €1,500 thousand) is required to be maintained during the lease period. In February 2020, we entered into another lease contract for the further expansion of our Rostock headquarters. The additional lease contract covers a total area of approximately 2,850 square meters of offices, staff facilities and storage spaces. In July 2022, we replaced this contract with a new lease contract for the further expansion of our Rostock headquarters. The additional lease contract covers a total area of approximately 1,474 square meters of offices, staff facilities and storage spaces, and will commence in 2025, when the building is expected to be completed by the lessor. The lease is charged at a fixed rate and covers a fixed period of five years, with the option to extend once for another five years. The lease cannot be terminated during the fixed five-year period, but we are permitted to sub-lease to a third party.

In September 2018, we also opened an office and laboratory facility in Cambridge, Massachusetts. We rented the premises with a two-year lease covering approximately 168 square meters. In June 2019, we rented additional premises of approximately 194 square meters. In July 2021, we reduced the premises to approximately 51 square meters. The lease will end June 30, 2023.

Both laboratories in Rostock, Germany and in Cambridge, Massachusetts, are equipped with the most advanced technologies for clinical diagnostics, clinical studies and research and development. We strive to follow the strictest quality criteria at all times and both laboratories are certified by the Centers for Medicare and Medicaid Services and accredited by the College of American Pathologists. To further enhance flexibility in capital management, we may purchase some of the leased laboratory equipment. These leases usually cover a period of two to four years, and our obligations under these leases are secured by the lessor’s title to the leased assets.

In addition to our laboratories, we have sales and administrative offices located in Berlin (Germany), Cambridge (Massachusetts, United States), Belgrade (Serbia), Vienna (Austria), Dubai (United Arab Emirates), Delhi (India) and Zug (Switzerland), allowing us to further expand our international footprint. The office located in Vienna (Austria) is expected to be closed in 2023. Considering the continuous expansion of our business, we relocated our office to Berlin, Germany in October 2019. The new office covers an area of approximately 1,770 square meters and was leased for a period of 12 years without an extension option. Until the end of the lease period for our Berlin, Germany office, we must provide a bank guarantee of €257 thousand (which we collateralized with a cash deposit of €128 thousand).

We are not aware of any environmental issues or other constraints that would materially impact the intended use of our facilities.

As of December 31, 2022, we employed approximately 517 highly qualified personnel (including consultants) from 59 nationalities.

Item 4A. Unresolved Staff Comments

None

Item 5. Operating and Financial Review and Prospects

A. Operating Results

The following discussion of our financial condition and results of operations should be read in conjunction with Centogene's audited consolidated financial statements as of December 31, 2022 and 2021 and for the years ended December 31, 2022, 2021 and 2020 and the notes thereto, included elsewhere in this Annual Report. The following discussion is based on our financial information prepared in accordance with IFRS as issued by the IASB, which may differ in material respects from generally accepted accounting principles in the United States and other jurisdictions. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "Item 3—D. Risk Factors" and elsewhere in this Annual Report.

Overview

We are a commercial-stage company with our core businesses focused on rare and neurodegenerative diseases that transforms real-world clinical and genetic or other data into actionable information for patients, physicians and pharmaceutical companies. Our goal is to bring rationality to treatment decisions and to accelerate the development of new orphan drugs by using our knowledge of the global rare disease market, including epidemiological and clinical data and innovative biomarkers. We have developed the CENTOGENE Biodatabank of multimodal data: Sociodemographic, clinical, multiomic data as well as biomaterial included from over 750,000 individuals. As of December 31, 2022, more than 500,000 DBS cards are stored in our own physical biobank which enables retrospective analysis for research consented samples. For approximately 110,000 individuals WES data and for 17,000 individuals WGS data is available. Equally notable is our network of approximately 30,000 active physicians we have been in contact with in the last five years. We believe this represents the only platform that comprehensively analyzes multi-level data to improve the understanding of rare hereditary diseases, which can aid in the identification of patients and improve our pharmaceutical partners' ability to bring orphan drugs to the market.

We also leveraged our diagnostics expertise and entrepreneurial capabilities, to rapidly contribute to the worldwide COVID-19 response. We developed and commenced testing for COVID-19 in mid-2020, offering comprehensive and high quality COVID-19 testing solutions, mostly in Germany, our home country. This includes our COVID-19 tests, which received Emergency Use Authorizations ("EUA") from the FDA in July 2020; our CentoKit-19, a fully validated sample collection kit which can either be used by healthcare professionals or self-administered by individuals; and our Corona Test Portal, a secure digital platform allowing seamless registration and result notification.

We have identified two reportable segments:

- **Pharmaceutical.** Our Pharmaceutical segment provides a variety of products and services to our pharmaceutical partners, including target and drug screening, clinical development, market access and expansion, as well as CENTOGENE Biodatabank Licenses and Insight Reports. Our information platforms, access to rare and neurodegenerative disease patients and their biomaterials, and our ability to develop proprietary technologies, such as biomarkers, enable us to provide services to our pharmaceutical partners in all phases of the drug development process as well as post commercialization. Revenues from our Pharmaceutical segment are generated primarily from collaboration agreements with our pharmaceutical partners. As of December 31, 2022, we collaborated with 28 pharmaceutical partners. In addition, we have developed six biomarkers covering diseases. Since early 2020, we started to pursue a metabolomics approach for establishing a biomarker discovery pipeline for rare hereditary diseases. Our new approach will include a tandem mass spectrometry methodology and AI and, combined with the large volume of datasets in the CENTOGENE Biodatabank, has proven successful in the identification of new biomarkers. The new biomarker candidates are identified and then further validated and optimized in epidemiological clinical trials.

- **Diagnostics.** Our Diagnostics segment provides targeted genetic sequencing and diagnostics services to our clients worldwide, who are typically physicians, laboratories or hospitals, either directly or through distributors. As of December 31, 2021, we believe we offer the broadest diagnostic testing portfolio for rare diseases, covering over 19,000 genes using over 5,000 different tests. Our key products are our WGS and WES, as well as our multiomic testing solution. In turn, the data collected from our diagnostics services and biomaterials allow us to continue to grow the CENTOGENE Biodatabank.

We discontinued our COVID-19 business in the three months ended March 31, 2022:

- **COVID-19 testing.** While not a core business, due to its growth and financial significance in relation to our total activities, our COVID-19 testing business has been managed and reported as a separate segment since the third quarter of 2020. We started offering COVID-19 testing in March 2020. Our initial COVID-19 test was a molecular diagnostic test performed for the in vitro qualitative detection of RNA from the SARS-CoV-2 in oropharyngeal samples from presymptomatic probands according to the recommended testing by public health authority guidelines. It was also validated in our CAP/CLIA/ISO certified analytical laboratory and received EUA from the FDA for use by authorized laboratories. The majority of these tests were performed in airport locations at the Frankfurt, Hamburg, Dusseldorf, and Berlin airports. Furthermore, tests were offered through collaborations with the state government and other companies. This segment was fully phased out in the first quarter of 2022 and is therefore presented as discontinued operations.

Our revenue for the year ended December 31, 2022, was €47,473 thousand, an increase of €5,239 thousand, or 12%, from €42,234 thousand for the year ended December 31, 2021. Our revenue for the year ended December 31, 2021, was €42,234 thousand, an increase of €3,781 thousand, or 9.0%, from €38,461 thousand for the year ended December 31, 2020. Our Pharmaceutical and Diagnostics segments contributed 33.9% and 66.1%, respectively, of our total revenues for the year ended December 31, 2022, as compared to 37.0%, and 63.0% respectively, of our total revenues for the year ended December 31, 2021, and 44.1%, and 55.9% respectively, of our total revenues for the year ended December 31, 2020. Test requests received by our Pharmaceutical and Diagnostics segments for the year ended December 31, 2022, were approximately 36.6 thousand and 69.2 thousand, respectively, representing a decrease of approximately 34% and an increase of 21%, respectively as compared to approximately 55.4 thousand and 57.1 thousand test requests, respectively, received for the year ended December 31, 2021.

Test requests received by our Pharmaceutical and Diagnostic segments for the year ended December 31, 2021, were approximately 55.4 thousand and 57.1 thousand, respectively, representing a decrease of approximately 18.3% and 36.3%, respectively, as compared to approximately 67.8 thousand and 41.9 thousand test requests, respectively, received for the year ended December 31, 2020.

Since the inception of our business, our research and development has been substantially devoted to our biomarkers and interpretation solutions. For the year ended December 31, 2022, we incurred research and development expenses of €17,488 thousand, a decrease of €1,809 thousand, or 9.4%, from €19,297 thousand for the year ended December 31, 2021. For the year ended December 31, 2021, we incurred research and development expenses of €19,297 thousand, an increase of €4,362 thousand, or 29.2% from €14,935 thousand for the year ended December 31, 2020. During the years ended December 31, 2022, 2021 and 2020, we received test requests of approximately 3,415, 8,300 and 5,400, respectively, for our internal research and development projects.

Our loss before taxes from continuing operations for the year ended December 31, 2022, was €38,596 thousand, a decrease of €18,824 thousand, or 33%, from €57,422 thousand for the year ended December 31, 2021. Our loss before taxes from continuing operations for the year ended December 31, 2021, increased by €2,392 thousand, or 4%, from €59,814 thousand for the year ended December 31, 2020. Our loss before taxes from continuing operations for the year ended December 31, 2022, included a gain on reversal of financial asset impairment of €432 thousand due to improved collection of aged accounts receivable resulting in a positive re-assessment of receivables and contract assets arising from contracts with customers. Our loss before taxes from continuing operations for the year ended December 31, 2021, included an impairment of €827 thousand related to certain identified biomarkers as part of the Company's restructuring initiative which began in Q4 2021. Our loss before taxes for the year ended December 31, 2020, included an impairment of €3,636 thousand related to certain identified biomarkers as part of the Company's strategy reassessment which began in Q4 2020. Our loss before taxes for the year ended December 31, 2022, also included share-based compensation expenses of (€169) thousand, as compared to €8,035 thousand for the year ended December 31, 2021, and €5,648 thousand for the year ended December 31, 2020.

Important Developments

Going Concern

As an early commercial-stage company, we are still in progress towards reaching break-even on our Diagnostic and Pharmaceutical segments. We are subject to a number of risks similar to those of other development and early commercial stage companies. These risks include, among other things, the failure to enter into and successfully execute further collaborations with pharmaceutical partners, the failure to generate revenue from our development portfolio and risks associated with research, development, testing and obtaining related regulatory approvals in relation to our product candidates. Our ongoing success and ultimately the attainment of profitable operations depends on future uncertain events which include, among other things, obtaining adequate financing to promote our commercial and development activities until we can generate sufficient revenues to support our operating cash requirements.

We have incurred operating losses since inception. For the year ended December 31, 2022, we incurred a net loss of €31.9 million (of which €38.6 million are related to loss from operations, resulting in an operating cash outflow of €26.5 million). As of December 31, 2022, we had generated an accumulated deficit of €141.3 million, and had an equity position of €7.4 million.

Our management has prepared cash flow forecasts and considered our cash flow requirement for the next three years, principally focused on the twelve-month period from the date of the approval of the consolidated financial statements. These forecasts show that further financings will be required during the course of the next 12 months assuming, among others, that development programs and other operating activities continue as currently planned. As of December 31, 2022, we had cash and cash equivalents of €36.0 million with relatively low short term debt obligations of €3.4 million. In addition, we entered into the Loan and Security Agreement on January 31, 2022. Under the terms of the Loan and Security Agreement, we drew down USD 25.0 million on January 31, 2022, and received a second tranche of USD 20.0 million the secured loan on December 22, 2022. The Loan and Security Agreement also includes covenants such that the Group is required to maintain product revenue of at least €30.0 million as of the last day of each fiscal quarter and on a trailing twelve-month basis prior to obtaining the second tranche €40.0 million on or after obtaining the second tranche. Both tranches mature on January 29, 2027, with amortized repayments commencing March 1, 2025. The loans extended under the Loan and Security Agreement bear monthly interest payments at an interest rate of 7.93% per annum plus the 1-month CME Term SOFR reference rate as published by the CME Group Benchmark Administration Limited (subject to a floor of 0.07%). In addition, pursuant to a securities purchase agreement and a warrant agreement, each signed with certain investors and dated January 31, 2022, we also received €15.0 million in exchange for the issuance of an aggregate of 4,479,088 common shares at a price per share of USD 3.73 and warrants initially exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares at an initial exercise price per common share of USD 7.72. The warrants are exercisable immediately as of the date of issuance and will expire on December 31, 2026.

Effect of COVID-19 Pandemic

The COVID-19 pandemic has had a global impact and continues to cause many governments to maintain measures, such as quarantines, travel restrictions, closures of borders, and mandatory maintenance of physical distance between individuals to slow the spread of the outbreak. Since the second quarter of 2020, the COVID-19 pandemic resulted in a slowdown in our diagnostics and pharmaceutical segments. As part of our initiative to assist local, national and international authorities, as well as other partners in their efforts to facilitate the earliest possible diagnosis of COVID-19 and thereby contribute to allowing society to return to a “new” normal, we commenced testing for COVID-19 in March 2020.

During the year ended December 31, 2021, we continued the COVID-19 testing activities that started in 2020 with a leading role in providing testing services at airports in Germany. Furthermore, new variants of the virus have emerged since mid-December 2020 which prompted large-scale vaccination campaigns across many countries in Europe. As a result, the vaccinated number of individuals increased across many countries in Europe which led to relaxed testing regulations in many countries during the year.

During the three months ended March 31, 2022, we continued the COVID-19 testing activities that started in 2020. There were no investments made in the COVID-19 business in the three months ended March 31, 2022. Total investments in COVID-19 testing as at December 31, 2021, amounted to €2,834 thousand, of which €2,480 thousand related to property, plant and equipment and €354 thousand to intangible assets. These investments have been fully depreciated and amortized as of March 31, 2022.

Total gross profit for our COVID-19 business for the three months ended March 31, 2022, was €4,263 thousand representing a decrease of €6,169 thousand or of 59.1% as compared to €10,432 thousand in the prior year period. The decrease in gross profit within the COVID-19 business (which we report as a discontinued operation) is primarily due to the significant decline in COVID-19 testing orders.

During 2021 management updated its long-term outlook for the COVID-19 testing business, which led to management's decision to initiate a wind down process in which lease contracts at unprofitable COVID-19 testing sites would not be renewed and a laboratory in Hamburg would be closed. Similarly, we significantly ramped down COVID-19 related inventory levels to align with the needs of the remaining test sites and laboratories. As at March 31, 2022, all COVID-19 operations at testing sites had ceased as all COVID-19 testing site contracts expired in the first quarter of 2022.

For further information, see "Note 9 – Discontinued operations" to our consolidated financial statements as of December 31, 2022 and December 31, 2021.

Research and Development

We continued to expand our medical and genetic knowledge of rare genetic diseases, with the vision of shortening the diagnostics odyssey of rare disease patients and accelerating the development of new orphan drugs. In particular, we focused on the following collaborations during the year:

- Collaboration with Evotec SE ("Evotec") in the research, discovery and development of medical solutions for rare diseases related to the protein target glucocerebrosidase ("GBA"), a well-known enzyme deficiency linked to Gaucher disease. This collaboration combines our global proprietary rare disease platform and biomarker expertise, with a jointly developed induced pluripotent stem cell ("iPSC") platform, drug discovery and development capabilities of Evotec.
- Collaboration with PTC Therapeutic, Inc ("PTC") to expand our existing partnership to several new regions including many countries in Europe, the Middle East, and Latin America to provide genetic testing and 3-O-Methyldopa (3-OMD) biomarker analytics to help identify patients with Aromatic L-amino Acid Decarboxylase (AADC) deficiency.
- Collaboration with Alnylam Pharmaceuticals ("Alnylam") to expand its existing epidemiology and biomarker work through the initiation of a new clinical program (TRAMoniTTR) focused on Hereditary Transthyretin Amyloidosis (hATTR). Through the newly executed agreement, the Company will provide specific analyses regarding anonymized TTR patient populations with a focus on long-term longitudinal data.

Follow-on Equity Offering

In July 2020, we completed a follow-on public offering of 3,500,000 common shares of the Company (the "Follow-on Equity Offering"), consisting of 2,000,000 common shares offered by the Company and 1,500,000 common shares offered by selling shareholders at a price to the public of \$14.00 per common share (i.e., €12.71 per share). Aggregate offering proceeds, net of underwriting discounts, commissions and transaction costs, to the Company were €22 million.

Financial Operations Overview

Revenue

Our revenue is principally derived from the provision of pharmaceutical solutions and diagnostic tests enabled by our knowledge and interpretation-based platform.

We expect our revenue to increase over time as we continue to expand our commercial efforts internationally with a focus on further growth in our Pharmaceutical segment. We expect revenue from our Diagnostics segment to grow in absolute terms but decrease as a proportion of total revenue if there is growth in our Pharmaceutical segment.

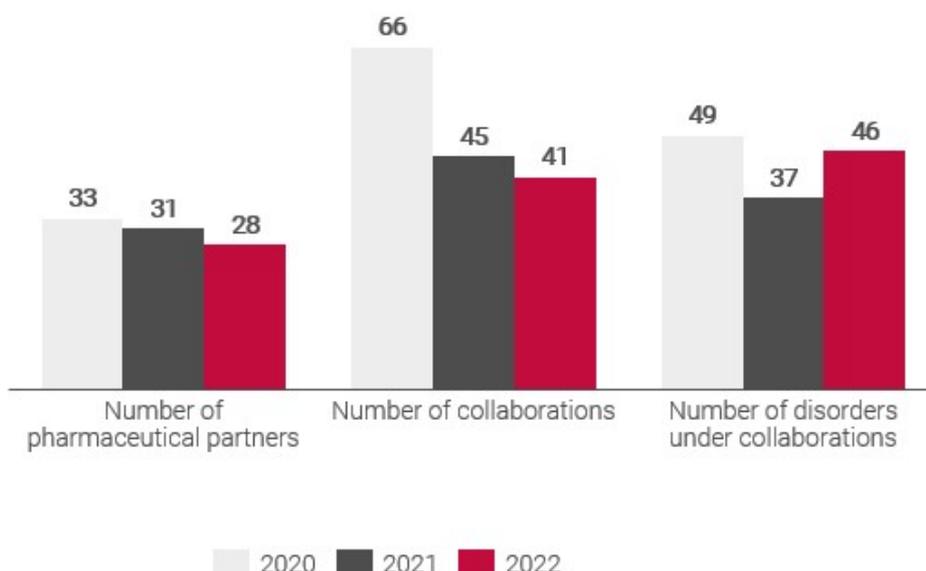
Changes in revenue mix between our Pharmaceutical and Diagnostic segments can impact our results period over period. We typically incur lower costs for the provision of solutions in our Pharmaceutical segment and therefore generate higher returns from our Pharmaceutical segment contracts than from our Diagnostics segment contracts.

Pharmaceutical segment

We generate revenue in our Pharmaceutical segment from the solutions we provide to our pharmaceutical partners to accelerate their development of treatments for rare hereditary diseases. Our data-driven studies are not only able to provide valuable information for drug target discovery, but also allow a better and more targeted design of clinical trials afterwards. Our biomarkers can be used not only in effective identification of rare disease patients, but also used to demonstrate the efficacy of the drugs, perform longitudinal monitoring and titrate the dosage needed of individual rare disease patients. Our partnership agreements are structured on a fee per analysis basis, milestone basis, fixed fee basis, royalty basis or a combination of these. We recognize our revenue from the rendering of solutions to our pharmaceutical partners as such service is performed, or upon the achievement of certain milestones if applicable to the partnership agreement.

During the year ended December 31, 2022, we entered into 13 new collaborations and successfully completed 17 collaborations resulting in a total of 41 ongoing collaborations. Over 46 disorders are covered by our current and historic collaborations. During the year ended December 31, 2021, we entered into 18 new collaborations and successfully completed 39 collaborations resulting in a total of 45 ongoing collaborations, covering 37 disorders. During the year ended December 31, 2020, we entered into 16 new collaborations, and successfully completed 26 collaborations resulting in a total of 66 ongoing collaborations, covering 49 disorders.

Number of pharmaceutical partners, collaborations and disorders: 2020 - 2022



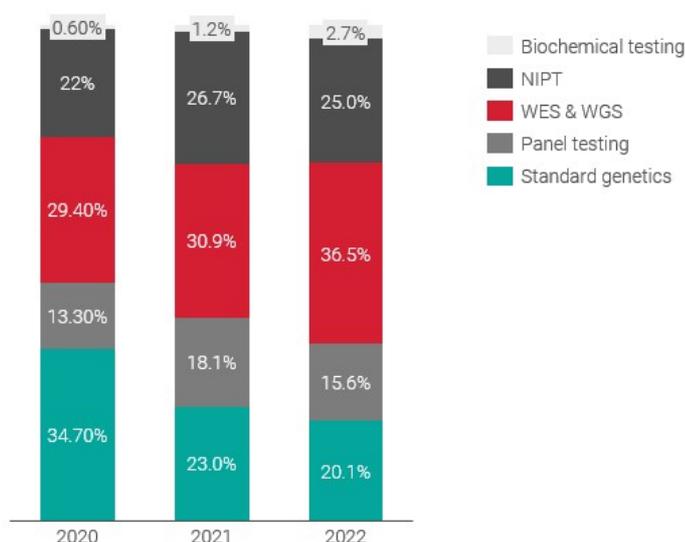
The timing of entry into new contracts with our pharmaceutical partners can be difficult to predict. Accordingly, we can experience different revenue patterns quarter-to-quarter and year-over-year due to the satisfaction of performance obligations involving significant upfront and milestone fees due from our pharmaceutical partners. We recognize revenue for upfront fees at a point in time when the right to use the intellectual property is transferred to the customer, while revenue for milestone payments is recognized over time using an input method based on the work rendered by us, or at a point in time when the applicable provisions for over-time recognition are not present (e.g., the sale of CentoCard filter cards).

During the year ended December 31, 2022, we entered into collaboration agreements with certain pharmaceutical partners, which resulted in upfront fees payable to us of over € 566 thousand, which will be recognized over time and during the partnership period. During the year ended December 31, 2021, we entered into collaboration agreements with certain pharmaceutical partners, which resulted in upfront fees payable to us of over €455 thousand for set up fees, will be recognized over time and during the partnership period. During the year ended December 31, 2020, we did not enter into collaboration agreements with pharmaceutical partners that included upfront fees.

Diagnostics segment

We generate revenue in our Diagnostics segment primarily from genetic sequencing and diagnostics services, such as WES and WGS. The test requests received by our Diagnostics segment for the years ended December 31, 2022, 2021 and 2020 were split amongst our primary testing products as follows:

Order requests by Diagnostic segment



We provide these services in over 120 countries either through third-party distributors or directly to our diagnostics clients, who are typically physicians, labs or hospital facilities. Revenues are based on a negotiated price per test or on the basis of agreements to provide certain testing volumes over defined periods. Revenue from the rendering of clinical diagnostic services (sequencing, interpretation and reporting) is recognized over time by reference to the percentage of completion of the service on the reporting date, assessed on the basis of the work rendered. We strategically focus on countries around the globe where the prevalence of rare hereditary diseases is high or the availability of national genetic testing and interpretation is to some extent limited and therefore the complete reimbursement or partial payment by the government for our services is more likely. The major markets for our diagnostics business currently include the Middle East and North Africa region, Scandinavia, parts of Central and Eastern Europe, Latin America, North America and parts of Asia. In most of our markets, our diagnostics tests are billable directly to the party submitting the request for a test to us.

Cost of Sales and Operating Expenses

Our cost of sales and our operating expenses support all of the products and services that we provide to our customers and, as a result, are presented in an aggregate total for the business segments. We allocate certain overhead expenses, such as maintenance and depreciation to cost of sales and operating expense categories based on headcount and facility usage. As a result, overhead expense allocation is reflected in cost of sales and each operating expense category.

Cost of Sales

Cost of sales consists of cost of consumables, supplies and other direct costs such as personnel expenses, depreciation of laboratory equipment, amortization of biomarkers, repair and maintenance costs, shipping costs, as well as certain allocated overhead expenses.

We expect these costs in absolute terms will increase as we grow our revenue but to decrease as a percentage of revenue over time as our Pharmaceutical segment revenue increases and as we continue to implement operational efficiencies. During the year ended December 31, 2022, our cost of sales represented 58.4% of our total revenue, as compared to 68.0% for the year ended December 31, 2021, and 91.8% for the year ended December 31, 2020. The decreased share in 2022 was mainly due to operational efficiencies implemented and reduced fixed overhead costs.

Research and Development Expenses

Our research and development (“R&D”) expenses consist primarily of costs incurred for the research and development of new products and solutions, in particular our biomarkers, and the development of our IT driven and interpretation-based solutions. In the three fiscal years ended December 31, 2022, 2021 and 2020 we spent €60,415 thousand on research and development, of which €8,695 thousand was capitalized as intangible assets.

Expenses for research activities are recognized through profit or loss in the period in which they are incurred, unless they reach the development stage and prove to be technically and commercially feasible, upon which the expenses are capitalized. With respect to biomarkers, expenses are capitalized when the target validation process is completed and commercialization is probable. With respect to IT driven solutions, expenses are capitalized upon the completion of our internal validation test. Before such dates, any development costs are recognized in profit or loss.

Research and development which we conduct pursuant to our pharmaceutical partnership agreements is typically limited to a specific rare disease. As a result, our research and development expenses may vary substantially from period to period based on the timing of our research and development activities or our pharmaceutical partners, including due to the entry into, renegotiation of or termination of our partnership agreements. Our research and development expenses may also be impacted by changes in regulatory requirements and healthcare policies globally, particularly in respect of the validation and patent application processes that we conduct for our biomarkers.

During the year ended December 31, 2022, our research and development expenses represented 36.8% of our total revenue, as compared to 45.7% for the year ended December 31, 2021, and 38.8% for the year ended December 31, 2020. The decrease is partly due to reduced amortization in the current year as a result of impairment of biomarkers that took place in 2021. In addition, the decrease is attributable to reduced research and development-based personnel expenses arising as a result of organizational synergies achieved in 2021. We continue to innovate our information platform, develop additional products and solutions and expand our data management resources.

General Administrative Expenses

Our general administrative expenses include costs for our personnel, premises, IT operations, accounting and finance, legal and human resources functions. These expenses consist principally of salaries, bonuses, employee benefits, travel, and share-based compensation, as well as professional services fees such as consulting, audit, tax and legal fees and general corporate costs, insurance costs and allocated overhead expenses. We account for all general administrative expenses as incurred.

During the year ended December 31, 2022, our general administrative expenses represented 68.6% of our total revenue, as compared to 103.0% for the year ended December 31, 2021, and 98.0% for the year ended December 31, 2020. The decrease was mainly related to a decrease in general administrative related personnel expenses of which the primary contributor was a reversal in share-based payments expenses. Additionally, the reversal is attributable to reductions in senior management headcount as well as synergies achieved from the restructuring implemented in 2021. The share-based compensation expenses included in general administrative expenses for the years ended December 31, 2022, 2021 and 2020 amounted to (€169) thousand, €8,035 thousand and €5,658 thousand, respectively. See also Note 21.

Selling Expenses

Our selling expenses consist of costs from our sales organization, which includes our direct sales force and sales management, client services, distributor relations, marketing and business development personnel. These expenses primarily include salaries, commissions, bonuses, employee benefits and travel, as well as marketing and educational activities and allocated overhead expenses. We expense all selling expenses as incurred.

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During the year ended December 31, 2022, selling expenses accounted for 20.9% of our total revenue, as compared to 22.1% for the year ended December 31, 2021, and 19.7% for the year ended December 31, 2020. The increase was mainly due to the strategic buildup of the Pharmaceutical team as well as increased sales commissions paid in the Diagnostics segment. We expect that our selling expenses will continue to grow as we continue to increase our business footprint and expand our business development efforts in our Pharmaceutical segment.

Other Operating Income / (Expenses)

Other operating income and expenses primarily includes government grants, gain on disposal of property, plant and equipment and exchange rate gains or losses.

Government grants contain performance-based grants to subsidize research, development and innovation in the state of Mecklenburg-Western Pomerania from funds granted by the European Regional Development Fund (“R&D Grants”). Furthermore, government grants contain investment grants related to the construction of our headquarters in Rostock, Germany in prior years and purchase of equipment for laboratory atomization (“Investment Grants”). R&D Grants that compensate our research and development expenses are recognized directly in profit or loss, while R&D Investment Grants are initially recognized as deferred income and subsequently released to profit or loss on a systematic basis over the useful life of the related asset. We received different government grants in the state of Mecklenburg-Western Pomerania from funds granted by the European Regional Development Fund to subsidize our research, development and innovation.

During the year ended December 31, 2022, we received R&D Grants of €506 thousand, as compared to €168 thousand and €763 thousand for the year ended December 31, 2021 and December 31, 2020, respectively. The government grant that we receive, can fluctuate from period to period.

Results of Operations

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

	For the Years Ended December 31,	
	2022	2021
	(€ in thousands)	
Consolidated statements of comprehensive loss:		
Revenue	47,473	42,234
Cost of sales	27,712	28,735
Gross profit	19,761	13,499
Research and development expenses	17,488	19,297
General administrative expenses	32,587	43,480
Selling expenses	9,924	9,326
Impairment of financial assets	—	827
Gain on reversal of financial asset impairment	432	—
Other operating income	3,773	2,894
Other operating expenses	741	86
Operating loss	(36,773)	(56,623)
Changes in fair value of warrants	2,574	—
Interest and similar income	512	3
Interest and similar expenses	4,909	802
Finance costs, net	(1,823)	(799)
Loss before taxes from continuing operations	(38,596)	(57,422)
Income tax expenses	107	(70)
Loss for the year from continuing operations	(38,703)	(57,352)
Net income from discontinued operations, net of tax	6,862	11,106
Loss for the period	(31,841)	(46,246)
Other comprehensive income/(loss)	(76)	543
Total comprehensive loss for the year	(31,917)	(45,703)

Revenue

Revenue increased by €5,239 thousand, or 12%, to €47,473 thousand for the year ended December 31, 2022 from €42,234 thousand for the year ended December 31, 2021, mainly driven by revenue from our Diagnostic segment.

The breakdown of our revenue by segment was as follows:

	For the Years Ended	
	December 31,	
	2022	2021
Revenue by segment:		
Pharmaceutical	16,115	15,641
Diagnostics	31,358	26,593
Total Revenue	47,473	42,234

Pharmaceutical segment

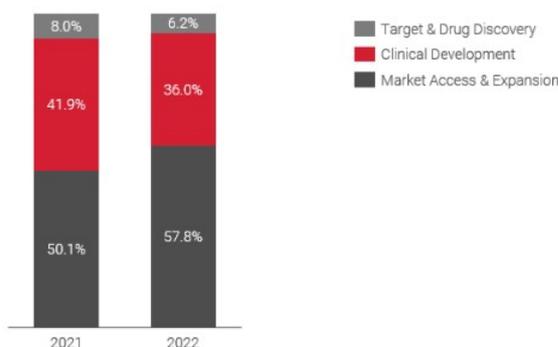
Revenues from our Pharmaceutical segment were €16,115 thousand for the year ended December 31, 2022, an increase of €474 thousand, or 3%, from €15,641 thousand for the year ended December 31, 2021. This increase was primarily driven by development progress in clinical studies (namely the ROPAD-Denali study and EFRONT-Alector study). We collaborated with 28 pharmaceutical partners, as of December 31, 2022, compared to 33 active partners as of December 31, 2021.

During the year ended December 31, 2022, we entered into 13 new collaborations and successfully completed 17 collaborations resulting in a total of 41 active collaborations on December 31, 2022, compared to 45 active collaborations as of December 31, 2021. Revenues from our new collaborations totaled €1,108 thousand for the year ended December 31, 2022, with upfront payments of €566 thousand related to setup fees.

During the year ended December 31, 2021, we entered into 18 new collaborations and successfully completed 39 collaborations resulting in a total of 415 active collaborations as of December 31, 2021, compared to 66 active collaborations as of December 31, 2020. Revenues from our new collaborations totaled €2,323 thousand for the year ended December 31, 2021, with upfront payments of €455 thousand related to setup fees. During the year ended December 31, 2020, we entered into 16 new collaborations and completed 26 collaborations, decreasing the total number of active/completed collaborations to 66, from 76 active collaborations as of December 31, 2019. Revenues from our new collaborations totaled €968 thousand for the year ended December 31, 2020, which amount did not include any upfront fees.

We have been successful in entering into collaborations with pharmaceutical partners in the early stages of drug development, which puts us in a position to provide more support to the development process and increases our potential to secure further collaborations for the same drugs, such as biomarker developments. The graphic below shows our revenues for the year ended December 31, 2022 and 2021 resulting from our collaborations with our pharmaceutical partners split between the drug development stages. For further details on each of our drug development stages, please see “Item 4. Information on the Company—B. Business Overview—Pharmaceutical Solutions.”

Pharmaceutical drug development stages: 2021 - 2022

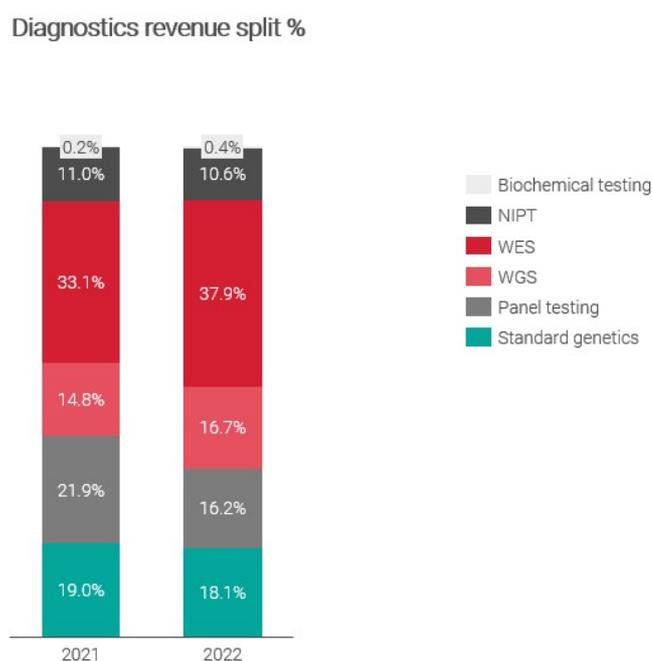


During the year ended December 31, 2022, revenues from one pharmaceutical partner represented 15.5% of our total revenues, as compared to 24.8% for the year ended December 31, 2021.

Diagnostics segment

Revenues from our Diagnostics segment were €31,358 thousand for the year ended December 31, 2022, an increase of €4,765 thousand, or 18%, from €26,593 thousand for the year ended December 31, 2021. We received approximately 69,243 test requests in our Diagnostics segment during the year ended December 31, 2022, representing an increase of approximately 21% as compared to approximately 57,100 test requests received for the year ended December 31, 2021.

For the years ended December 31, 2022 and 2021, our total Diagnostic segment revenues were split amongst our primary testing products as follows:



The increase in revenues was primarily related to an increase in order intakes for panel testing, WES and WGS during the year ended December 31, 2022. Total revenues from panel testing, WES and WGS for the year ended December 31, 2022, amounted to € 22,706 thousand, representing an increase of 13.98% as compared to €19,921 thousand for the year ended December 31, 2021. The total number of panel testing, WES and WGS order intakes received in the Diagnostics segment for the year ended December 31, 2022, was approximately 36,057, representing an increase of 28.95% as compared to approximately 27,962 test requests received for the year ended December 31, 2021.

Revenue by geographical region

The breakdown of our revenue from all our segments, in the aggregate, by geographical region was as follows:

	For the Years Ended	
	December 31,	
	2022	2021
	(€ in thousands)	
Revenue by geographical region:		
Europe	6,288	5,915
<i>of which: Germany</i>	307	211
<i>of which: Netherlands</i>	7	6
Middle East	19,922	16,432
<i>of which: Saudi Arabia</i>	12,433	9,865
North America	16,570	16,583
<i>of which: United States</i>	16,505	16,396
Latin America	3,907	2,593
Asia Pacific	786	711
Total Revenue	47,473	42,234

In cases where our pharmaceutical partners are developing a new rare disease treatment, we generally anticipate that the final approved treatment will be made available globally. As a result, we allocate the revenues of our Pharmaceutical segment by geographical region by reference to the location where each pharmaceutical partner mainly operates, which is based on the region from which most of their revenues are generated. The allocation of revenues in our Diagnostics segment is based on the location of each customer.

Our North America region contributed €16,570 thousand to revenue for the year ended December 31, 2022, a decrease of (€13) thousand, or 21%, from €16,583 thousand for the year ended December 31, 2021. Revenues from the North America region represented 34.9% of our total revenues for the year ended December 31, 2022, as compared to 39.3% for the year ended December 31, 2021.

Our Middle East region contributed €19,922 thousand to revenue for the year ended December 31, 2022, an increase of €3,490 thousand, or 21%, from €16,432 thousand for the year ended December 31, 2021. This revenue increase was primarily attributable to the increase in sales of panel testing, WES and WGS tests.

Our Europe region contributed €6,288 thousand to revenue for the year ended December 31, 2022, an increase of €373 thousand, or 6% from €5,915 thousand for the year ended December 31, 2021. This increase was mainly driven by increased revenues from the Diagnostics segment. Revenues from the Europe region represented 13.2% of our total revenues for the year ended December 31, 2022, as compared to 14.0% for the year ended December 31, 2021.

Cost of Sales

Cost of sales increased by €1,023 thousand, or 4%, to €27,712 thousand for the year ended December 31, 2022, from €28,735 thousand for the year ended December 31, 2021. Cost of sales for the year ended December 31, 2022, represented 58.4% total revenue, a decrease of 9.6 percentage points as compared to 68.0% for the year ended December 31, 2021.

Cost of sales incurred by our Pharmaceutical and Diagnostic segments for the year ended December 31, 2022, represented 45.3% and 65.1% of revenues from the respective segments, a decrease of 28.7 percentage points and 0.1 percentage points, respectively, as compared to 74.0% and 65.2%, respectively, for the year ended December 31, 2021. The 28.7 percentage point decrease for our Pharmaceutical segment was mainly due to reduced depreciation of €2,100 thousand to €800 thousand for the year ended December 31, 2022, from €2,900 thousand for the year ended December 31, 2021, as well as changes in the product mix.

Gross Profit

The recovery of our core business segments (Diagnostics and Pharmaceutical segments combined) generated total gross margin of €19,761 thousand or 42% of revenues which represents an increase of €6,443 thousand or 10.1 percentage points in the year ended December 31, 2022, as compared to €13,318 thousand or 32% of revenues in the previous year ended December 31, 2021.

Research and Development Expenses

The table below gives a breakdown of our research and development expenses for the years ended December 31, 2022 and 2021.

	For the Years Ended December 31,	
	2022	2021
	(€ in thousands)	
Wages and salaries and social security expenses	7,074	8,021
Laboratory supplies and consumable costs	—	301
IT development costs	5,654	4,422
Depreciation and amortization expenses	2,927	3,900
Development and patent costs	747	1,564
Others	1,086	1,089
Total research and development expenses	17,488	19,297

Research and development expenses decreased by €1,809 thousand, or 9.4%, to €17,488 thousand for the year ended December 31, 2022, from €19,297 thousand for the year ended December 31, 2021. This mainly represents personnel costs, IT-related expenses incurred in our research that do not qualify for capitalization, increased depreciation and amortization and other costs such as consumables, patent applications, legal costs and external consultant costs.

General Administrative Expenses

The table below gives a breakdown of our general administrative expenses for the years ended December 31, 2022 and 2021.

	For the Years Ended December 31,	
	2022	2021
	(€ in thousands)	
Wages and salaries, social security and termination expenses	11,155	13,664
Share-based payment expenses	(169)	8,035
Legal, audit and consulting expenses	7,742	5,048
Travelling, corporate communication and event expenses	1,055	1,386
IT operational costs	2,815	3,513
Insurance premiums	2,956	4,432
Recruitment expenses	265	1,062
Depreciation and amortization expenses	3,381	1,949
Others	3,387	4,391
Total general administrative expenses	32,587	43,480

General administrative expenses decreased by €10,893 thousand, or 25.1%, to €32,587 thousand for the year ended December 31, 2022, from €43,480 thousand for the year ended December 31, 2021, principally due to a decrease in personnel costs (largely consisting of a reversal in share-based payments expense), as well as reductions in senior manager headcount, the corresponding decrease in directors' and officers' insurance premiums and other synergies obtained from the restructuring implemented in 2021. The general administrative expenses included share-based compensation expenses of (€169) thousand for the year ended December 31, 2022, a decrease of €8,204 thousand as compared to €8,035 thousand for the year ended December 31, 2021. See also Note 21.

Selling Expenses

Selling expenses increased by €598 thousand, or 6.4%, to €9,924 thousand for the year ended December 31, 2022, from €9,326 thousand for the year ended December 31, 2021, principally due to an increase in personnel expenses.

Impairment of financial assets

There were no impairment expenses for financial assets incurred for the year ended December 31, 2022, representing a decrease of €827 thousand from €827 thousand for the year ended December 31, 2021.

Gain on reversal of financial asset impairment

A gain on reversal of financial asset impairment was recorded for the year ended December 31, 2022 due to improved collection of aged accounts receivable resulting in a positive re-assessment of receivables and contract assets arising from contracts with customers. The gain on reversal of financial asset impairment for the year ended December 31, 2022 was €432 (December 31, 2021: EUR nil).

Other Operating Income / (Expenses)

Other operating income increased by €879 thousand, or 30.4%, to €3,773 thousand for the year ended December 31, 2022, from €2,894 thousand for the year ended December 31, 2021, principally due to VAT refunds received based on a change made to the VAT tax declarations of Centogene GmbH in agreement with the tax administration in Germany for 2020, 2021 and 2022 financial years.

Other operating expenses increased by €655 thousand, or 761.6%, to €741 thousand for the year ended December 31, 2022, from €86 thousand for the year ended December 31, 2021, principally due to foreign exchange differences.

Interest and Similar Income / (Expenses)

Interest and similar income increased by €509 thousand to €512 thousand for the year ended December 31, 2022, from €3 thousand for the year ended December 31, 2021.

Interest and similar expenses increased by €4,107 thousand, or 512.2%, to €4,909 thousand for the year ended December 31, 2022, from €802 thousand for the year ended December 31, 2021, principally due to interest paid on the Oxford loan as well as foreign currency losses.

Loss Before Taxes for the Year from Continuing Operations

As a result of the factors described above, our loss before taxes for the year ended December 31, 2022 was €38,596 thousand, a decrease of €18,826 thousand, or 32.8%, from €57,422 thousand for the year ended December 31, 2021.

Segment Adjusted EBITDA

Our Segment Adjusted EBITDA was as follows:

	For the Years Ended December 31,	
	2022	2021
	(€ in thousands)	
Segment Adjusted EBITDA:		
Pharmaceutical	6,802	4,915
Diagnostics	6,497	3,208
	13,299	8,123

Adjusted EBITDA from our Pharmaceutical segment was €6,802 thousand for the year ended December 31, 2022, an increase of €1,887 thousand, or 38%, from €4,915 thousand for the year ended December 31, 2021. This increase was attributable to the increase in revenues from the Pharmaceutical segment, as well as the decrease in cost of sales.

Adjusted EBITDA from our Diagnostic segment was €6,497 thousand for the year ended December 31, 2022, an increase of €3,289 thousand, or 103%, from €3,208 thousand for the year ended December 31, 2021. This increase was primarily attributable to an increase in revenues during the year and improved collection of aged accounts receivable resulting in a positive re-assessment of receivables and contract assets arising from contracts with customers.

For further information about how we calculate Adjusted EBITDA, how it is used and our reconciliation of segment Adjusted EBITDA to the most comparable IFRS measure of the Group, see “Note 7 — Segment information and revenue from contracts with customers” of our consolidated financial statements as of and for the year ended December 31, 2022.

For the discussion of our results of operations for the year ended December 31, 2020 compared to year ended December 31, 2021, see “Financial Operations Overview — Year Ended December 31, 2020, compared to Year Ended December 31, 2021” included in our annual report for the year ended December 31, 2021, on Form 20-F (File No. 001-39124) filed with the SEC on March 31, 2022.

Quarterly Data

	2022				2021			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(unaudited, In EUR thousands)							
Revenue	10,191	11,198	12,403	13,682	9,793	9,209	9,661	13,571
Cost of sales	6,450	6,586	6,568	8,108	6,208	6,617	6,828	9,082
Gross profit	3,741	4,612	5,835	5,574	3,585	2,592	2,833	4,489
Research and development expenses	4,614	4,457	4,412	4,005	4,335	4,053	3,821	7,088
General administrative expenses	7,906	9,378	9,818	5,485	11,596	10,494	10,406	10,984
Selling expenses	2,394	2,798	2,959	1,773	1,949	1,942	2,206	3,229
Impairment of financial assets	116		87	(203)	71	544	471	(259)
Gain on reversal of financial asset impairment		1,035		(603)				
Other operating income	733	657	1,194	1,189	366	1,276	1,011	241
Other operating expenses	1	506	633	(399)	34	2	-	50
Operating loss	(10,557)	(10,835)	(10,926)	(4,455)	(14,034)	(13,167)	(13,060)	(16,363)
Loss for the period from continuing operations	(11,180)	(11,887)	(12,701)	(2,935)	(14,293)	(13,466)	(13,358)	(16,235)
Net income from discontinued operations, net of tax	4,601	1,539	58	664	9,227	5,110	(8,587)	5,356
Loss for the period	(6,579)	(10,348)	(12,643)	(2,271)	(5,066)	(8,356)	(21,945)	(10,879)
Total comprehensive loss for the period	(6,485)	(10,419)	(12,643)	(2,370)	(4,945)	(8,547)	(21,859)	(10,352)
Loss per share- Basic and diluted (in EUR)	(0.28)	(0.38)	(0.47)	(0.09)	(0.23)	(0.38)	(0.97)	(0.46)

Restatement of previously issued financial statements

During the preparation of the unaudited financial results for the second quarter ended June 30, 2022, the Group identified unadjusted differences related to revenue recognized and impairment losses for the years ended December 31, 2021, December 31, 2020 and December 31, 2019 and trade receivables outstanding as of December 31, 2021, 2020 and 2019 for the Diagnostics segment.

The Group restated the relevant amounts for the previously issued financial statements. Refer to “Note 2.4 - Restatement of previously issued financial statements” to our consolidated financial statements for the year ended December 31, 2022, 2021 and 2020 for further details.

The impact of the restatements on the consolidated statements of comprehensive income for the years ended December 31, 2021, 2020 and 2019 are as follows:

in EUR k	For the year ended Dec 31,			For the year ended Dec 31,		
	2021 (as previously reported)	Adjustments	2021 (as restated)*	2020 (as previously reported)	Adjustments	2020 (as restated)*
Revenue	189,923	(1,355)	188,568	128,381	(710)	127,671
Cost of sales	161,765	(1,317)	160,448	83,437	-	83,437
Gross profit	28,158	(38)	28,120	44,944	(710)	44,234
Research and development expenses	19,297	-	19,297	14,935	-	14,935
General administrative expenses	46,739	-	46,739	40,160	-	40,160
Selling expenses	9,860	-	9,860	8,026	-	8,026
Impairment of financial assets	1,140	(313)	827	3,738	(102)	3,636
Other operating income	2,936	331	3,267	2,394	-	2,394
Other operating expenses	86	-	86	182	-	182
Real estate transfer tax expenses	-	-	-	-	-	-
Operating loss	(46,028)	606	(45,422)	(19,703)	(608)	(20,311)
Loss for the period	(46,852)	606	(46,246)	(21,378)	(608)	(21,986)
Total comprehensive loss	(46,309)	606	(45,703)	(21,426)	(608)	(22,034)
Loss per share- Basic and diluted (in EUR)	(2.06)	0.03	(2.04)	(1.02)	(0.03)	(1.05)

(*) For further information, please refer to Note 2.4 to our consolidated financial statements as of December 31, 2022 and 2021 and for the three years ended December 31, 2022, 2021 and 2020 included elsewhere in this Annual Report).

B. Liquidity and Capital Resources

Overview

Our cash requirements are principally for working capital and capital expenditures of all our businesses, including expansions and improvements to our laboratory facilities, technology infrastructure and research and development activities. In fiscal year 2022 and beyond, we anticipate that our capital expenditures in our rare disease business will increase from prior periods as we continue to increase our research and development efforts. Historically, our main source of liquidity has been our secured loans, municipal loans and government funding of research programs, and proceeds from our initial public offering. In July 2020, we completed the Follow-on Equity Offering and received net offering proceeds, after deducting underwriting discounts and commissions, of €22 million. In January 2022, we entered into the Loan and Security Agreement in the total amount of USD 45.0 million (€40.2 million) and secured an additional €15 million through issuance of common shares and warrants.

Our financial condition and liquidity are and will continue to be influenced by a variety of factors, including our ability to continue to generate cash flows from our operations, our capital expenditure requirements, and the impact of geopolitical conditions on financial markets and the global economy.

Considering cash and cash equivalents as of December 31, 2022, of € 36.0 million with relatively low short term debt obligations of € 3.4 million, the Group has prepared cash flow forecasts and considered the cash flow requirement for the Company, principally focused on the twelve-month period from the date of the approval of these consolidated financial statements. Management updated their cash flow forecasts based on an amendment signed for the Group’s Loan Facility as of April 30, 2023. Accordingly, in addition to the short-term portion of the loan, the Group is also required to prepay USD 5.0 million of the loan upon the first new business development or financing transaction the Group will enter and to maintain at least EUR 9.1 million in unrestricted cash on deposit in collateral accounts. These forecasts show that we do not currently have sufficient funds to continue maintaining our operating activities for the next 12 months. Consequently, our current circumstances indicate the existence of a material uncertainty that may cast significant doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that investors will lose all or a part of their investment. As we seek additional financing to fund our business activities in the future and while there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

We are pursuing a number of additional restructuring initiatives that could extend our cash runway until our operating cash flows reach break-even. In addition to measures intended to reduce our operating expenditure, we are in active discussions with various counterparties regarding new private equity financing and/or additional debt (which may be convertible debt) financing. We are also pursuing additional potential financing initiatives such as strategic collaborations and marketing, distribution or licensing arrangements, business and asset divestitures and / or grant funding, among other things. If we are unable to obtain funding in an amount, on terms and at the time that we desire, we could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our preclinical, clinical and regulatory efforts, which could adversely affect our business prospects.

The consolidated financial statements for the year ended December 31, 2022, do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that would be necessary, should we be unable to continue as a going concern.

Our known material liquidity needs for periods beyond the next twelve months are described below in “—F. Tabular Disclosure of Contractual Obligations.”

Contractual Obligations

The table below presents the residual contractual terms of the financial liabilities as of December 31, 2022, including estimated interest payments. The figures are undiscounted gross amounts, including estimated interest payments and interest on undrawn loan funds, but without showing the impact of offsetting.

	Total contractual cash flows	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	More than 5 years
Bank overdrafts	3,374	3,374	—	—	—
Secured bank loans	59,473	4,194	33,167	22,112	—
Lease liabilities	17,713	2,817	4,780	3,187	6,929
Short term and low value leases	83	59	24	1	—
Trade payables and purchase obligations	6,317	6,317	—	—	—
Total	86,960	16,761	37,971	25,299	6,929

Lease liabilities include leases related to lease contracts for land and buildings, offices as well as various items such as motor vehicles and other equipment which are accounted for according to IFRS 16, and measured at the present value of lease payments over the lease term at the commencement date of the leases.

Lease liabilities also include contractual cash flows in relation to the expansion of the Rostock headquarters that are not accounted for yet. The future lease payments for this non-cancellable lease contract are Euro nil within one year, €1,272 thousand within five years and €318 thousand thereafter (December 31, 2021: €107 thousand within one year, €2,370 thousand within five years and €4,219 thousand thereafter).

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Material Transactions

Private Placement of Common Shares and Warrants

On January 31, 2022, we entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) with the purchasers named therein (the “Investors”) and a Warrant Agreement (the “Warrant Agreement”) with the Investors. Pursuant to the Securities Purchase Agreement and the Warrant Agreement, we agreed to sell to the Investors (i) an aggregate of 4,479,088 common shares at a price per share of USD 3.73, and (ii) warrants initially exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares at an initial exercise price per common share of USD 7.72 (the “Warrants”), for aggregate gross proceeds of €15.0 million. The Warrants are exercisable immediately as of the date of issuance and will expire on December 31, 2026 and it is accounted for as liability.

The Securities Purchase Agreement and the Warrant Agreement contain customary representations and warranties from the Company and the Investors and customary closing conditions. The closing of the Private Placement occurred on January 31, 2022 (the “Closing Date”).

The Company also agreed pursuant to the Securities Purchase Agreement and the Warrant Agreement, among other things, to indemnify the Investors from certain liabilities arising out of or based in whole or in part on the inaccuracy of the representations and warranties of the Company contained in those respective agreements or the failure of the Company to perform its obligations thereunder.

Each of the Investors is a party to the Company’s existing Registration Rights Agreement, dated November 12, 2019 (as amended, the “Registration Rights Agreement”) (one Investor having executed a joinder thereto prior to the Closing Date). Pursuant to the Registration Rights Agreement, we have agreed under certain circumstances to file a registration statement to register the resale of the securities held by such Investors, subject to certain exceptions, as well as to cooperate in certain public offerings of such securities.

Loan and Security Agreement

On January 31, 2022 (the “Closing Date”), the Company, Centogene GmbH, CentoSafe B.V. and Centogene US, LLC (together, the “Borrowers”), entered into the Loan and Security Agreement with Oxford Finance LLC and the other financial institutions or entities from time to time parties to the Loan and Security Agreement (collectively, referred to as “Lenders”) and Oxford, in its capacity as collateral agent for itself and the Lenders (in such capacity, “Agent”). Under the Loan and Security Agreement, the Lenders agreed to make available to the Borrowers certain term loans in an aggregate principal amount of up to \$45.0 million, subject to funding in two tranches as follows: (a) on the Closing Date, a loan in the aggregate principal amount of \$25.0 million (the “Term A Loan”) and (b) on and after the Term B Milestone (as defined below) until the earlier of 60 days thereafter and July 31, 2023, a loan in the aggregate principal amount of USD 20.0 million (the “Term B Loan” and collectively with the Term A Loan, the “Term Loans”). The obligations of the Lenders to fund the Term B Loan are subject to our achievement of product revenues from our diagnostics and pharmaceutical services segments of at least USD 50.0 million calculated on a trailing twelve month basis as of the last day of any fiscal month (such achievement, the “Term B Milestone”). As security for the Borrowers’ obligations under the Loan and Security Agreement, the Borrowers granted the Lenders a first priority security interest on the Borrowers’ assets.

The maturity date of the Term Loans is January 29, 2027, with amortized payments commencing March 1, 2025 in 24 equal monthly payments. The Term Loans bear an interest rate of 7.93% per annum plus the 1-month CME Term SOFR reference rate as published by the CME Group Benchmark Administration Limited (subject to a floor of 0.07% and 4.13% for Term A Loan and Term B Loan, respectively), based on a year consisting of 360 days.

At any time following the Closing Date, the Borrowers may prepay an amount of not less than all of the then outstanding principal balance and all accrued and unpaid interest on the Term Loans, subject to at least fifteen days’ prior written notice to the Agent and the payment of a prepayment fee equal to (x) if made on or prior to the first anniversary of the Closing Date, 3.0% of the principal amount being prepaid, (y) if made after the first anniversary of the Closing Date but on or prior to the second anniversary of the Closing Date, 2.0% of the principal amount being prepaid and (z) otherwise, 1.0%.

The Loan and Security Agreement contains customary affirmative covenants, negative covenants and events of default, including covenants and restrictions that, among other things, require the Borrowers to satisfy a financial covenant, restrict Borrowers' ability to transfer cash to their subsidiaries, and in certain circumstances restrict the ability of the Borrowers to incur liens, incur additional indebtedness, engage in mergers and acquisitions, make distributions or make asset sales without the prior written consent of Lenders. A failure to comply with these covenants could permit the Lenders to declare the Borrowers' obligations under the Loan and Security Agreement, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination, as described above.

On July 28, 2022, we amended the Loan and Security Agreement to expand the scope of Permitted Indebtedness and Permitted Liens thereunder and each as defined therein. Later that year, we achieved the Term B Milestone and became eligible to draw down the outstanding \$20.0 million of commitments under the Term B Loan. On December 22, 2022, we borrowed the Term B Loan and received a net disbursement under the Oxford Facility of \$19,697,253.22 after accounting for fees, expenses and accrued interest.

We amended the Loan and Security Agreement for a second time on April 30, 2023 to permit (i) the delivery of our audited consolidated financial statements for the fiscal year ended December 31, 2022 thirty days later than is otherwise required and (ii) the listing of our common shares on NASDAQ Capital Market. The Second Amendment introduced new requirements that (i) we prepay any outstanding loans under the Loan and Security Agreement in an amount of \$5.0 million (plus fees, interest and expenses, in each case, pursuant to the terms of the Loan and Security Agreement) upon the first new business development or financing transaction we enter and (ii) we maintain at least €9.1 million in unrestricted cash on deposit in collateral accounts subject to Oxford's perfected security interest granted under the Loan and Security Agreement.

Comparative Cash Flows

Comparison of the Years Ended December 31, 2022 and 2021

The following table sets forth our cash flows for the periods indicated:

	For the Years Ended December 31,	
	2022	2021
	(€ in thousands)	
Consolidated statements of cash flows from continuing operations		
Cash flow (used in) continuing operating activities	(35,496)	(42,635)
Cash flow (used in) continuing investing activities	(1,553)	(2,494)
Cash flow (used in)/ from continuing financing activities	46,798	(2,403)
Net (decrease)/ increase in cash and cash equivalents	9,750	(47,532)
Cash and cash equivalents at the beginning of the period	17,818	48,156
Effect of movements in exchange rates on cash held	(961)	(36)
Cash flow from discontinued activities	9,348	17,231
Cash and cash equivalents at the end of the period	35,955	17,818

Operating Activities

Our cash flow used in, or from, continuing operating activities primarily relates to changes in the components of our working capital, including cash received from pharmaceutical partners and diagnostics clients, as well payments made to our suppliers.

For the year ended December 31, 2022, cash flow used in continuing operating activities was €35,496 thousand, a decrease of €7,139 thousand as compared to cash flow used in continuing operating activities of €42,635 thousand for the year ended December 31, 2021. The difference was mainly attributable to cost saving measures implemented during the year resulting in improved results from operating activities.

Investing Activities

Our cash flow used in, or from, investing activities consists of investments in intangible assets, plant, property and equipment, grants received for investments in property, plant and equipment and cash received from disposals of property, plant and equipment. More specifically, cash used in investment activities in our rare and neurodegenerative disease business included mainly costs incurred in the development of new products and solutions, and the development of our IT driven and interpretation-based solutions. It also includes investment in property, plant and equipment used in the laboratories and other business operations.

For the year ended December 31, 2022, cash flow used in continuing investing activities was €1,553 thousand, as compared to cash flow used of €2,494 thousand in continuing investing activities for the year ended December 31, 2021. The decrease was mainly due to the reduction in investments made in intangible assets.

Financing Activities

Our cash flow generated from and used in continuing financing activities primarily relates to the Oxford Loan and Security Agreement and financial lease liabilities for the year ended December 31, 2022.

For the year ended December 31, 2022, cash flow from continuing financing activities was €46,798 thousand, an increase of €44,395 thousand as compared to cash flow used in continuing financing activities of €2,403 thousand for the year ended December 31, 2021.

Our cash flow provided by continuing financing activities for the year ended December 31, 2022, was primarily driven by additional shares issued to certain investors and the drawdown of the Oxford Loan and Security Agreement (incorporating Tranche A and Tranche B) which contributed €40,568 thousand in aggregate.

Cash used in financing activities includes repayment of lease liabilities of €4,314 thousand as of December 31, 2022, a decrease of €70 thousand as compared to repayment of €4,244 thousand for the year ended December 31, 2021.

For the discussion of our cash flows for the year ended December 31, 2020, compared to year ended December 31, 2021, see “Comparative Cash Flows —Year Ended December 31, 2020, compared to Year Ended December 31, 2021” included in our annual report for the year ended December 31, 2021 on Form 20-F (File No. 001-39124) filed with the SEC on March 31, 2022.

Indebtedness

Syndicated Loan Facility

On August 4, 2015, we entered into a loan agreement (as amended or supplemented to date, the “Syndicated Loan Facility”) with certain German commercial banks. The Syndicated Loan Facility consists of four tranches. As of December 31, 2022, there were no balances outstanding under Tranches A, B, C and D. As of December 31, 2021, we had €2,834 thousand outstanding under the Syndicated Loan Facility, of which €505 thousand was outstanding under Tranche B and €2,329 thousand was outstanding under the Tranche D. As of December 31, 2020, we had €1,596 thousand outstanding under the Syndicated Loan Facility, of which €968 thousand was outstanding under Tranche B and €628 thousand was outstanding under the Tranche D Loan.

The Tranche B Loan has been used to purchase laboratory equipment on a pro rata basis. In addition, it served to refinance rental purchases for short-term investments in laboratory equipment and IT equipment. The Tranche D Loan serves us as a working capital line in an aggregate amount of €2,500 thousand.

Revolving Credit Agreements

We have entered into two further secured bank overdraft agreements totaling €1,000 thousand which we use to finance our day-to-day business operations. €998 thousand was utilized as of December 31, 2022, €981 thousand was utilized as of December 31, 2021. Our first €500 thousand bank overdraft agreement had an initial floating interest rate of 4.23% per annum (adjusted on EURIBOR) when utilized as an overdraft facility. This is secured by a term deposit of €500 thousand. Our second €500 thousand bank overdraft agreement had an initial floating interest rate of 4.5% per annum when utilized as an overdraft facility and is secured by a term deposit of €500 thousand.

C. Research and Development, Patents and Licenses, etc.

For a description of our research and development policies for the last three years see “Item 4. Information on the Company—B. Business Overview—Research and Development.” For a description of our intellectual property, see “Item 4. Information on the Company—B. Business Overview—Intellectual Property.”

D. Trend Information

For a discussion of trend information, see “Item 5. Operating and Financial Review and Prospects.”

E. Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB. Some of the accounting methods and policies used in preparing the financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the circumstances concerned. The actual value of our assets, liabilities and shareholders’ equity and of our earnings could differ from the value derived from these estimates if conditions changed and these changes had an impact on the assumptions adopted.

Our significant accounting policies that we believe to be critical to the judgments and estimates used in the preparation of our financial statements are included in “Note 2.2—Going concern, Note 6—Accounting judgments and estimates” and “Note 21—Share-based payments” to our consolidated financial statements as of and for the year ended December 31, 2022.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Board Structure

We have a two-tier board structure consisting of a management board (*bestuur*) and a separate supervisory board (*raad van commissarissen*).

Management Board

Our management board consists of three members, who we refer to as our managing directors (and who are also our executive officers). Each managing director of Centogene N.V. holds office for the term set by our general meeting of shareholders (as set forth in the table below), except in the case of earlier death, resignation or removal. Our managing directors do not have a retirement age requirement under our articles of association.

Our managing directors are responsible for the management and representation of our company. We have a strong centralized management team led by our CEO, with broad experience in strategy, operations, finance, information technology, sales, communications and training.

The following table lists the current members of our management board, as well as the year of expiration of their terms as management board members of Centogene N.V. We consider all persons named in the table below key executive officers.

<u>Name</u>	<u>Position</u>	<u>Age</u>	<u>Year of Expiration of Term</u>
Kim Stratton	Chief Executive Officer	60	2026
Miguel Coego Ríos	Chief Financial Officer	49	2026
Prof. Peter Bauer, M.D.	Chief Medical and Genomic Officer ⁽¹⁾	53	-

(1) On January 24, 2023, Prof. Peter Bauer, M.D. was appointed as a temporary managing director (Chief Medical and Genomic Officer to the Management Board of Centogene N.V.), until his proposed formal appointment at the Company’s upcoming general meeting of shareholders.

On May 3, 2022, Volkmar Weckesser stepped down from his role as Chief Information Officer and member of the management board.

Unless otherwise indicated, the current business address for our managing directors is Am Strande 7, 18055 Rostock, Germany.

Kim Stratton, was appointed as our managing director and Chief Executive Officer on February 1, 2022, after having served as interim managing director and Chief Executive Officer as of December 20, 2021. Mrs. Stratton has more than 25 years of global commercial expertise in the biopharmaceutical space, with significant experience across multiple geographies, including the United Kingdom, the United States, Europe, and emerging markets. Most recently, Mrs. Stratton was CEO of Orphazyme, a biopharmaceutical company dedicated to developing treatments for patients living with rare diseases. Prior to this role, she worked at Shire Pharmaceuticals, where she served as Head of International Commercial for Shire’s Specialty and Rare Diseases portfolio. Before Shire, Mrs. Stratton spent nearly 15 years at Novartis in a number of senior management roles, including global product development, commercial, marketing, general manager, and various global corporate functions, including government and external affairs. Mrs. Stratton is on the Board of Recordati S.p.A, Novozymes A/S and Vifor Pharma AG.

Miguel Coego Ríos, Mr. Coego Ríos was appointed as our Chief Financial Officer, Legal & IT on June 22, 2022, after having served as interim Chief Financial Officer, Legal & IT since April 1, 2022. Mr. Coego Ríos is an experienced senior executive with broad expertise in finance and commercial leadership roles in the pharmaceutical and biotech sectors. He has an extensive track record in achieving sales and expenses targets, team management and development, and steering multi-country projects. Most recently, he was Vice President & General Manager South Europe at Orphazyme A/S, a late-stage clinical biotech company. Before that he was Vice President & CFO EMEA at Mundipharma, a multinational pharmaceutical company. Earlier in his career, he served in several senior management positions at Shire Pharmaceuticals between 2011 and 2019, most recently as CFO LATAM and General Manager of the Andean region.

Prof. Peter Bauer, M.D. Prof. Bauer was appointed as temporary managing director to the management board as our Chief Medical and Genomic Officer on January 24, 2023, until his proposed formal appointment at the Company’s next general meeting of shareholders, after having served as our Chief Medical Officer since 2022 and Chief Genomic Officer since December 2019, prior to which he served as our Chief Scientific officer from January 2017 to November 2019 and Chief Operating officer since joining Centogene in 2016. Prof. Bauer is a professor of human genetics at the University of Tübingen and a board-certified human geneticist with expertise in molecular genetics, diagnostic testing, genetic counselling, functional validation of genetic variants and bioinformatics tools for medical interpretation of clinical sequencing. Prior to joining us, he headed of the diagnostic and research laboratory at the Institute of Medical Genetics and Applied Genomics, University Hospital Tübingen from 2001 to 2015. Prof. Bauer has been vice president of the German Society of Neurogenetics since 2004. Prof. Bauer received a degree in medicine from the Freie University Berlin and the approbation as physician (German official license to practice medicine) from the Board of Physicians in Berlin in 1998.

The following table lists those of our key executive officers as of December 31, 2022 who are not members of our management board:

Name	Position	Age	Year of Expiration of Term
Patrice P. Denèfle, Ph.D.	Chief Scientific Officer	63	—
Florian Vogel, Ph.D. ⁽¹⁾	Chief Process Officer	42	—
Bettina Goerner	Chief Data Officer	39	—

(1) Mr. Vogel who served as Centogene’s Chief Process Officer resigned his position at the end of February 2023.

Mr. Schmid who served as Centogene’s Chief Commercial Officer – Diagnostics resigned his position at the end of June 2022. Mr. Motz who served as Centogene’s Chief Commercial Officer – Pharmaceuticals resigned his position at the end of February 2022. Mrs. Daste who served as Centogene’s Chief Human Resources Officer resigned her position at the end of August 2022. Ian Rentsch joined Centogene on March 15, 2023, as Chief Commercial Officer and General Manager – Pharma, and now represents as a key executive officer.

Patrice P. Denèfle, Ph.D., Mr. Denèfle serves as Centogene’s Chief Scientific Officer. Within this role, he is responsible for overseeing the Company’s scientific activities to deliver on its vision and strategy, while driving value creation. Mr. Denèfle is a seasoned executive and scientific pioneer with over 35 years of experience at pharmaceutical and biotechnology companies in Europe and the U.S., spearheading translational R&D to deliver breakthrough treatments to patients. Prior to joining Centogene, Mr. Denèfle served as Chief Scientific Officer at 4P-Pharma, where he led the R&D drug repositioning strategy and operations towards potential full clinical demonstration and asset-value transfer to large pharmaceutical companies. Over the past three decades, he has held several leadership positions, including as the General Manager of the Roche Institute for Research and Translational Medicine, as well as other senior roles at Sanofi Aventis and Ipsen. Mr. Denèfle also served as CSO at Genethon, a biotech company dedicated to the development of gene therapy treatments for rare diseases. Mr. Denèfle received his Ph.D. in Molecular Biology and Biotechnology from the Pasteur Institute, Paris, completed his HDR (Habilitation) in Molecular Pharmacology at the University of Lille, graduated as Adjunct University Professor, and taught Biotechnology for 10 years at the University Paris-Descartes. Mr. Denèfle was also trained as a CEDEP fellow at INSEAD and has co-authored more than 150 scientific papers and patents.

Florian Vogel, Ph.D., Mr. Vogel served as our Chief Process Officer since 2021 and stepped down effective February 28, 2023. Within his role, he held disciplinary and budget responsibility for all five Diagnostic wet lab production departments in Rostock, Germany, and the CLIA and CAP lab processing facility in Cambridge, Massachusetts, United States. In addition, he was responsible for the Method & Process Development in Rostock. Before taking on this position, he served as Senior Director Research & Development from 2015-2018 at Centogene. Mr. Vogel has extensive experience in product development and streamlining of workflows for genetically based methods enabling the highest quality as well as high throughput testing. Mr. Vogel has more than ten years of know-how in molecular genetic assay design and international leadership in various industry sections. Prior to joining Centogene, he was living in South Korea to set up the local branch of a German university and labs for chemical and bioengineering as Head of the White Biotechnology department, including lab build out and starting industry collaborations. Mr. Vogel studied Biology at Friedrich-Alexander-University of Erlangen-Nurnberg and received his doctoral degree in Molecular Biology *summa cum laude*.

Bettina Goerner, Mrs. Goerner serves as our Chief Data Officer (CDO). Bringing 15 years of international industry experience and product-centricity, Mrs. Goerner is responsible for data management, enablement, and data partnerships for the CENTOGENE Biodatabank, which includes multiomic and clinical data, as well as biomaterial. Mrs. Goerner previously served as Managing Director of Data Products & Services at Springer Nature – overseeing data and product development, as well as commercialization of five data products for R&D, including the AdisInsight databases for drug development. While at Springer Nature, she built up new product lines, markets and business models. Mrs. Goerner holds a master’s degree in Molecular Biology from the International Max Planck Research School, including research at Harvard Institutes of Medicine. She started her career at McKinsey & Company and INSEAD Business School. She also holds board seats at Deepmatter Group Plc, a laboratory digitalization company focused on big data and experimental chemistry, as well as at Eagle Genomics Ltd., an innovator of data analysis software for life sciences and a Microsoft Genomics Partner.

Supervisory Board

Our supervisory board consists of nine members and one interim member. Each supervisory board member holds office for the term set by our general meeting of shareholders (as set forth in the table below), except in the case of his earlier death, resignation or removal. Our supervisory board members do not have a retirement age requirement under our articles of association.

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The following table presents the names of the current members of our supervisory board, as well as the year of expiration of their terms as supervisory board members of Centogene N.V.:

Name	Position	Age	Year of Expiration of Term
Peer M. Schatz	Chairman of the Supervisory Board	57	2023
Andreas Busch, Ph.D.	Member and Vice-Chairman of the Supervisory Board	59	2026
Flemming Ornskov, M.D.	Member of the Supervisory Board	65	2025
Jonathan G. Sheldon, Ph.D.	Member of the Supervisory Board	51	2025
Holger Friedrich	Member of the Supervisory Board	56	2025
Guido Prehn	Member of the Supervisory Board	45	2025
Eric Sou�tre, M.D.	Member of the Supervisory Board	67	2025
Berndt Modig ⁽¹⁾	Member of the Supervisory Board	64	2025
Hubert Birner, Ph.D.	Member of the Supervisory Board	56	2025
Mary Sheahan ⁽²⁾	Interim Member of the Supervisory Board	50	-

(1) On December 1, 2022, Mr. Modig stepped down from his role as audit committee chair and currently serves as audit committee member and member of the supervisory board from which positions he is expected to step down after the next general meeting of shareholders.

(2) Mrs. Sheahan has been nominated for appointment as supervisory director of the Company for an initial period of four years at the next general meeting. Effective from December 1, 2022 Mrs. Sheahan is serving as our new chairwoman of the audit committee.

Unless otherwise indicated, the current business address for our directors is Am Strande 7, 18055 Rostock, Germany.

Peer M. Schatz From January 1, 2021, Peer Schatz has served as Chairman of our supervisory board. Mr. Schatz joined the supervisory board of Centogene in March 2020 as interim member and interim Vice-Chairman of the supervisory board. His appointment was approved in the annual general meeting of shareholders in June 2020. He joined Centogene from his position as long-time Chief Executive Officer of QIAGEN N.V. (Nasdaq: QGEN; Frankfurt: QIA), a leading provider of molecular sample and assay technologies. From 1993 to 2019, he led QIAGEN's rapid expansion from a start-up company with \$2 million in sales into a global leader in molecular testing with over \$1.6 billion in revenues. Mr. Schatz also serves as member of the supervisory board of Siemens Healthineers AG and as Chairman of the board of Resolve Biosciences GmbH and as Managing Director of PS Capital Management GmbH. He also served as a founding member of the German Corporate Governance Commission and as a supervisory board member of Evotec AG (Frankfurt: EVT). Mr. Schatz graduated from the University of St. Gallen, Switzerland with a master's degree in Finance and from the University of Chicago Graduate School of Business with an MBA.

Andreas Busch, Ph.D., Dr. Busch was appointed member and Vice-Chairman of the supervisory board on February 18, 2022 and brings over 20 years of experience and leadership in the pharmaceutical industry. In April 2022, Dr. Busch transitioned from the board of directors at Absci, a leader in the protein drug creation revolution harnessing generative AI, to Absci's leadership team as Chief Innovation Officer. From 2019 to 2022, he served as Chief Innovation Officer and Chief Scientific Officer at Cycleron Therapeutics, Inc. (Nasdaq: CYCN), a clinical-stage biopharmaceutical company on a mission to develop treatments that restore cognitive function. Prior to this, Dr. Busch served as Head of R&D and CSO at Shire plc., a global biotechnology leader serving patients with rare diseases. Previously, he held a variety of senior leadership positions in his 13-year tenure at Bayer group, most recently as Head of Drug Discovery and a member of the Executive Committee for the Pharmaceuticals division of Bayer. Prior to joining Bayer, Dr. Busch was Global Head of Cardiovascular Research at Hoechst and Sanofi-Aventis. Dr. Busch has served as a member of numerous Supervisory and Scientific Boards of research institutions and companies, including the German Cancer Research Center, the University of T bingen, the Max Delbr ck Center, and the Max Planck Institute of Molecular Genetics, as well as Takeda and start-up companies, such as Omeicos and BerlinCures. He also holds the title of Extraordinary Professor of Pharmacology at the Johann Wolfgang Goethe-University in Frankfurt, Germany. Dr. Busch received his license to practice Pharmacy and Ph.D. in Pharmacology from the Johann-Wolfgang-Goethe-University, Frankfurt. He is the author of over 400 publications and abstracts and received the prestigious Sir Bernard Katz and Franz Volhard Awards for his work on renal and cardiac ion channels and transporters.

Flemming Ornskov, M.D., MPH, MBA. Dr. Ornskov has served as a member of our supervisory board since April 2019. From April 2019 until December 31, 2020, he also served as the Chairman of the supervisory board. He has served as the Chief Executive Officer of Galderma S.A. since October 2019. He currently also serves as the Chairman of the Board of Director of Waters Corporation. Dr. Ornskov was the Chief Executive Officer and a member of the board of directors of Shire Plc from April 2013 to January 2019, when Shire was acquired by Takeda. Earlier in his career, Dr. Ornskov worked in executive roles at Bayer, Novartis and Merck & Co. Dr. Ornskov received his M.D. from the University of Copenhagen, MBA from INSEAD, and Master of Public Health from Harvard University.

Jonathan G. Sheldon, PhD. Dr. Sheldon joined our supervisory board as an interim member on November 10, 2020, and his appointment was approved by the shareholders in the extraordinary general meeting of shareholders on December 18, 2020. Mr. Sheldon has an extensive track record in the life science and healthcare industry – having spearheaded growth and strategy development of multiple global companies. He serves as Senior Vice President of the Digital Insights Business Area and member of the Executive Committee at QIAGEN N.V., a leading provider of molecular sample and assay technologies. Prior to joining QIAGEN, Jonathan served as the Global Vice President of Oracle Health Services – further positioning the Company’s product portfolio, defining its healthcare strategy, and its convergence with Life Sciences. Previously, he was the Head of Bioinformatics at Roche Pharmaceutical, where he established the Company’s first bioinformatics department in the UK as well as providing leadership to a variety of software and data companies serving both the life science and healthcare sectors. From 2019 to 2021, Mr. Sheldon was a Board Member of the Drug Information Association (DIA) and served on the board of the American College of Medical Genetics Foundation. He completed his B.Sc. in Biochemistry and Molecular Biology at the University of Manchester, and went on to receive his Ph.D. in Biochemistry and Molecular Biology from the University of Cambridge.

Holger Friedrich. Mr. Friedrich has been a member of our supervisory board since 2017. Since 2010, Mr. Friedrich has been the Managing Director of the consulting division of CORE SE (acquired by EPAM). Prior to that, he was Chairman of SPM Technologies (acquired by SAP) from 1993 to 2003 and Senior Vice President, IT Architecture, at SAP from 2003 to 2005. From 2005 to 2008, he was a partner at McKinsey, responsible for IT Enterprise Architecture in Europe. From 2009 to 2010, he was a member of the Executive Board at Software AG. Friedrich studied computer science and German language and literature.

Guido Prehn. Mr. Prehn joined our supervisory board as a member in 2019. Mr. Prehn has over 15 years of experience in the private equity industry. He currently serves on the boards of OmniaMed Holding GmbH, Calvias GmbH, Everest TopCo B.V., Auerbach Holding AG, VTU Group GmbH, FinCo GmbH, B plus L Group Holding GmbH, M-Personal Protection Holding GmbH and M-Personal Protection Management GmbH. Mr. Prehn is a managing director of DPE Deutsche Private Equity which he joined in 2010, shortly after its foundation. Between 2002 and 2009, he worked in various positions at Allianz Capital Partners, TPG Capital and Merrill Lynch. Mr. Prehn studied business administration at the European Business School, Oestrich-Winkel, De Paul University Chicago and Universidad Argentina de la Empresa, Buenos Aires.

Eric Sou tre, M.D. Dr. Sou tre joined our supervisory board as a member in 2017. After various research positions at National Institute of Mental Health, Dr. Sou tre founded “BENEFIT” in 1990, a research and consulting company in health economics (subsequently acquired by QUINTILES Inc. (USA) in 1995). He then served as a board member at QUINTILES Inc., where he was responsible for the global consulting function. In 2003, Dr. Sou tre co-founded LABCO - a network of clinical laboratories - and led the company to a European leadership as chairman and CEO until late 2010. He remained as an active board member until LABCO was sold to CINVEN in 2015. Dr. Sou tre has since co-founded a private equity fund, Careventures, focused on pan European healthcare service ventures. He currently serves on the board of OPERA SA. Dr. Sou tre holds a Ph.D. in neurosciences by the Marseille University, an M.D. by the Medical University of Nice and an MBA from HEC school of Paris.

Berndt Modig, MBA. Mr. Modig joined our supervisory board as a member in April 2018 and will step down from his role after the 2023 Annual General Meeting. He is the Chief Executive Officer and Co-Founder of Pharvaris N.V. and brings more than 25 years of experience in working with biotech companies. He served as Chief Financial Officer of Prosensa Holding N.V., a public pharmaceutical company, from March 2010 until its acquisition by BioMarin Pharmaceutical Inc. in January 2015. From October 2003 to November 2008, Mr. Modig was Chief Financial Officer at Jerini AG where he directed private financing rounds, its IPO in 2005, and its acquisition by Shire Plc in 2008. Before that, Mr. Modig served as Chief Financial Officer at Surplex AG from 2001 to 2003 and as Finance Director Europe of U.S.-based Hayward Industrial Products Inc. from 1999 to 2001. In previous positions, Mr. Modig was a partner in the Brussels-based private equity firm, Agra Industria, from 1994 to 1999 and a senior manager in the Financial Services Industry Group of Price Waterhouse LLP in New York from 1991 to 1994. In addition, until April 2021 he served as Vice-Chairman of the supervisory board and Chairman of the audit committee of Kiadis Pharma N.V., all of which are publicly held pharmaceutical companies, and he was a Director of Mobile Loyalty plc from 2012 to 2013. Mr. Modig received a bachelor’s degree in business administration, economics and German language from the University of Lund, Sweden, and an MBA from INSEAD, Fontainebleau, France. He is a certified public accountant (inactive).

Hubert Birner, Ph.D. Dr. Birner joined our supervisory board as chairman from July 2017 to March 30, 2019, and as vice-chairman from April 1, 2019, to March 16, 2020. Dr. Birner is responsible for TVM Capital Life Science's overall investment strategy and global fund operations in Europe and North America. He currently serves as Chairman of the board of directors of Leon-nanodrugs GmbH and AL-S Pharma AG. Dr. Birner previously served on the board of Acer Therapeutics, Argos Therapeutic, Horizon Pharma, Inc., Bioxell SA, Evotec AG, Jerini AG, Noxxon Pharma, Probiodrugs AG, Proteon Therapeutics Inc. and SpePharm Holdings BV. Prior to his current tenure, he was Head of Business Development Europe and Director of Marketing for Germany at Zeneca Agrochemicals. Dr. Birner joined Zeneca from McKinsey & Company's European Health Care and Pharmaceutical practice and as Assistant Professor for biochemistry at the Ludwig-Maximilian-University ("LMU"), following his summa cum laude doctoral degree in biochemistry at LMU; his doctoral thesis was honored with the Hoffmann-La Roche prize for outstanding basic research in metabolic diseases. Dr. Birner also holds an MBA from Harvard Business School.

Mary Sheahan. Mrs. Sheahan has been appointed as an interim supervisory director effective as of December 31, 2022, until her proposed formal appointment at the Company's next general meeting of shareholders. Mrs. Sheahan brings over 20 years of experience in private and publicly listed international pharmaceutical and life science companies, including as an executive at Avillion, Perrigo, and Elan Corporation, as well as a non-executive director at Venn Life Sciences. Throughout her career, she has held significant financial and other management roles and supported value creation across a wide range of areas, including supporting development, approval, and launch of products for neurology and immunology indications. Mrs. Sheahan currently serves as CFO of Avillion LLP, a private equity-backed life sciences company focused on the co-development and financing of pharmaceutical products. In this role, she is also responsible for supporting Avillion's partnerships with multinational pharmaceutical companies. Mrs. Sheahan is also a qualified chartered accountant and has worked as an auditor with KPMG.

B. Compensation

Compensation of Managing Directors, Supervisory Board Members and Officers

We are a foreign private issuer. As a result, in accordance with Nasdaq listing requirements, we are complying with home country compensation requirements and certain exemptions thereunder rather than with Nasdaq compensation requirements. Dutch law does not provide for limitations with respect to the aggregate annual compensation paid to members of our management board or supervisory board, provided that such compensation is consistent with our compensation policy. Such compensation policy requires approval by our general meeting of shareholders. The supervisory board determines the remuneration of individual managing directors with due observance of the remuneration policy. A proposal with respect to remuneration schemes in the form of shares or rights to shares in which managing directors may participate is subject to approval by our general meeting of shareholders. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to the managing directors and the criteria for granting or amendment. The compensation for our supervisory board members is set by the general meeting of shareholders.

The compensation, including benefits in kind, accrued or paid to our managing directors and supervisory board members with respect to the year ended December 31, 2022, for services in all capacities is shown below on an individual basis. Further details for the compensation for our managing directors and supervisory board members are provided in note 26 to our consolidated financial statements as of and for the year ended December 31, 2022.

Directors Compensation 2022

Supervisory Board Members

On June 22, 2022, at the general meeting of the Company, our shareholders approved changes to the cash remuneration payable to members of our supervisory board. Pursuant to the new cash remuneration scheme, each member of the supervisory board will receive a fixed cash fee of €20,000 (gross) per annum. The Chairman of the supervisory board will receive an additional fixed cash fee of €15,000 (gross) per annum as of the financial year 2022, and the Vice-Chairman of the supervisory board will receive an additional fixed cash fee of €10,000 (gross) per annum as of the financial year 2022. The Chairman of the audit committee will receive an additional fixed cash fee of €10,000 (gross) per annum, and the Chairman of the compensation committee will receive an additional fixed cash fee of €2,000 (gross) per annum. If a supervisory board member serves for only part of a financial year, the fixed cash fees referred to above payable to such member will be adjusted and, if already paid, will be reimbursed by such member to us on a pro rata basis.

	<u>P. Schatz</u>	<u>A. Busch</u>	<u>F. Ornskov</u>	<u>H. Birner</u>	<u>J. Sheldon</u>	<u>H. Friedrich</u>	<u>G. Prehn</u>	<u>E. Souêtre</u>	<u>B. Modig</u>	<u>M. Sheahan</u>
	(in € thousands)									
Periodically paid compensation	35	27	20	22	20	20	20	20	30	2
Total cash compensation	35	27	20	22	20	20	20	20	30	2
2019 Equity Incentive Plan ⁽¹⁾	949	97	153	—	27	33	—	—	112	19
Total share-based payment compensation	949	97	153	—	27	33	—	—	112	19

(1) This amount represents the portion of the grant date fair value of the option and RSU (as defined herein) awards recognized as an expense in 2022 under the provisions of IFRS 2.

Managing Directors

	<u>K. Stratton</u>	<u>M. Coego</u>	<u>P. Bauer⁽¹⁾</u>	<u>A. Oswald⁽²⁾</u>	<u>R. Just⁽³⁾</u>	<u>V. Weckesser⁽⁴⁾</u>
	(in € thousands)					
Periodically paid compensation	861	299	172	146	159	232
Bonuses	—	—	—	184	451	180
Termination benefits	—	—	—	541	—	138
Total cash compensation	861	299	172	871	610	550
2019 Equity Incentive Plan ⁽⁵⁾	666	122	2	—	—	—
Total share-based payment compensation	666	122	2	—	—	—

(1) On January 24, 2023, Prof. Peter Bauer, M.D. was appointed as temporary managing director (Chief Medical and Genomic Officer and member of the management board of Centogene N.V.), until his proposed formal appointment at the Company's next general meeting of shareholders.

(2) On February 1, 2022, Andrin Oswald stepped down from the management board and his role as our Chief Executive Officer.

(3) On March 31, 2022, René Just stepped down from the management board and his role as our Chief Financial Officer.

(4) On May 3, 2022, Volkmar Weckesser stepped down from the management board and his role as our Chief Information Officer.

(5) This amount represents grant date fair value of the RSUs and option awards granted in 2022 under the 2019 Plan (as defined and discussed below), recognized in 2022 under the provisions of IFRS 2.

For the year ended December 31, 2022, our performance-based compensation programs are described below.

2019 Equity Incentive Plan

In conjunction with the consummation of our IPO, we have established a new long-term incentive plan (our “2019 Plan”) with the purpose of advancing the interests of our shareholders and other stakeholders by enhancing our ability to attract, retain and motivate individuals who are expected to make important contributions to us. The 2019 Plan governs issuances of equity and equity-based incentive awards from and after the consummation of our IPO. The maximum number of common shares underlying awards that may be granted pursuant to the 2019 Plan (other than replacement awards) will not exceed 13% of the Company’s issued share capital immediately following our IPO. Such maximum number has been increased on January 1, 2020, and will be increased on January 1 of each calendar year thereafter, by an additional number of common shares equal to 3% of the Company’s issued share capital on such date (or a lower number of common shares as determined by the management board or supervisory board, where appropriate on the basis of a recommendation of the compensation committee (as the case may be, as prescribed by the 2019 Plan and, collectively, the “Committee”). On November 1, 2022, the 2019 Plan was modified to reflect the leaver arrangements described under “Termination of Service” below.

Plan Administration. The 2019 Plan is administered by the Committee.

Eligibility. Awards under the 2019 Plan may be granted to our employees, the members of our management board and supervisory board, consultants or other advisors.

Awards. Awards under the 2019 Plan may be granted in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, other share-based awards or a combination of the foregoing. The Committee may condition the right of an individual to exercise his or her awards upon the achievement or satisfaction of performance criteria.

Vesting. The vesting conditions for awards under the 2019 Plan are determined by the Committee and are set forth in the applicable award documentation.

Termination of Service. In the event of a good leaver’s (as defined in the 2019 Plan) termination of employment or service, all vested awards will be exercised or settled in accordance with their terms within a 6-month period as otherwise specified by the Committee and all unvested awards will be cancelled automatically unless decided otherwise by the Committee. In the event of a bad leaver’s (as defined in the 2019 Plan) termination of employment or service, all vested and unvested awards will be cancelled automatically without compensation. Pursuant to an amendment to the 2019 Plan applicable to awards granted in the period between September 11, 2020 and November 25, 2020, unless otherwise determined by the Committee, in the event of a good leaver’s termination of employment or service, all unvested awards will vest in full and all vested awards that have not yet been exercised or settled must be exercised or settled in accordance with their terms within a period specified by the Committee. If those awards are not exercised or settled within such period, they will be cancelled automatically without compensation.

Change in Control. In the event of a change in control of the Company (as defined in the 2019 Plan), outstanding awards that will be substituted or exchanged for equivalent replacement awards, in connection with the change in control will be cancelled. Outstanding rewards that are not substituted or exchanged for equivalent replacement awards, in connection with the change in control will immediately vest and settle in full, unless otherwise decided by the Committee.

During the year ended December 31, 2022, the following options were granted under 2019 Plan:

Equity Share Option – Replacement (2017 Plan)

In 2017, the Group established a virtual share option program (the “2017 Plan”) that entitled the management board to grant virtual share options to individuals, in regard to services they provide and their continuous commitment to the Group. As part of the corporate reorganization, in connection with the IPO, the options granted under the 2017 Plan of Centogene AG were converted into option awards under the 2019 Plan exercisable for common shares of Centogene N.V. immediately prior to the completion of our IPO in 2019. For further details of this plan, please see note 21(iii) to our consolidated financial statements as of and for the year ended December 31, 2022.

The following table shows the options outstanding as of December 31, 2022, held by our managing directors under the 2019 Plan to replace their options under the 2017 Plan:

Beneficiary ⁽¹⁾	Grant Date	Number of Options	Exercise Price EUR	Expiration Date
Volkmar Weckesser	November 9, 2019	33,773	0.12	October 31, 2029
Total		33,773		

(1) On May 3, 2022, Volkmar Weckesser stepped down from the management board and his role as our Chief Information Officer.

Equity Share Option (ESOP 2019) to Flemming Ornskov

In connection with his appointment as a member of the supervisory board, the Company entered into an agreement with Flemming Ornskov, pursuant to which Mr. Ornskov was granted a total of 396,522 options, with each option representing the right to acquire one common share with an exercise price equaling the IPO price, which was €12.58 per share on the date of our IPO.

On December 18, 2020, in an extraordinary general meeting of shareholders of the Company, the shareholders approved the grant of 300,000 restricted stock units (“RSUs”) to Mr. Ornskov under the 2019 Plan, which replaced the ESOP 2019 and pursuant to which Mr. Ornskov will forfeit the options granted to him thereunder in exchange for the RSUs granted to him. The RSUs will expire after ten years, will not be subject to any other performance criteria, will have no exercise price and will be settled in shares. With respect to the RSUs granted 33% vested immediately and the remaining 67% will vest in two equal annual instalments on each anniversary of October 1 following the date of grant. All of the 300,000 RSUs have been settled in 2022. For further details of this plan, please see note 21(iv) to our consolidated financial statements as of and for the year ended December 31, 2022.

2022 Grants to Employees, Management Board and Selected Consultants

Under the 2019 Plan, we granted 1,295,015 RSUs to our employees, management board members and select consultants in 2022. Apart from one award that has performance vesting only, two awards will vest in full upon a change of control of the Company, all other awards referred to above will vest in four equal tranches in each year following the grant date. Four awards will continue to time-vest for 12 months after termination in 12 equal monthly instalments equal to 1/12 of one annual instalment under the original vesting schedule. In the event of a termination of employment or service, all other vested awards will be exercised or settled in accordance with their terms and all unvested awards will be cancelled automatically.

The following table shows the options and RSUs granted to the members of the management board in 2022 and outstanding as of December 31, 2022, under the 2019 Plan:

Beneficiary	Grant Date	Number of Options	Exercise Price USD	Number of RSUs	Exercise Price USD	Expiration Date
Kim Stratton	February 1, 2022	—	—	166,667	—	February 1, 2032
Kim Stratton	February 1, 2022	—	—	87,197	12	January 1, 2024
Kim Stratton	February 1, 2022	—	—	87,197	15	January 1, 2024
Kim Stratton	February 1, 2022	—	—	275,000	15	February 1, 2032
Miguel Coego Ríos	February 2, 2022	—	—	30,995	—	February 2, 2032
Miguel Coego Ríos	May 27, 2022	—	—	55,556	—	May 27, 2032
Miguel Coego Ríos	May 27, 2022	—	—	29,066	12	February 1, 2024
Miguel Coego Ríos	May 27, 2022	—	—	29,066	15	February 1, 2024
Miguel Coego Ríos	May 27, 2022	—	—	91,667	15	May 27, 2032
Total		—		852,411		

(1) On May 3, 2022, Volkmar Weckesser stepped down from the management board and his role as our Chief Information Officer. As a result, his 30,000 RSUs vested in full.

For further details of this plan, please see note 21(vi) to our consolidated financial statements as of and for the year ended December 31, 2022.

2020 Grants to Dr. Andrin Oswald

In 2020, the Company and Andrin Oswald entered into an award agreement under the 2019 Plan pursuant to which a total of 324,000 RSUs were granted to Mr. Oswald on December 1, 2020, subject to the purchase of ordinary shares of the Company on the open market in the amount of CHF 1,000,000 after the grant date. The RSUs had no exercise price and would have vested in four equal annual installments following December 1, 2020, subject to the CEO's continued service with the Company and continued ownership of a number of shares equal or higher than the number of purchased shares. This award agreement was amended on September 5, 2021, for the following points; the RSUs will vest in 14 equal quarterly installments following July 30, 2021 with final vesting date on December 1, 2024, subject to the purchase of ordinary shares of the Company on the open market in the amount of CHF 1,000,000 by June 30, 2022. Further, under the award agreement, the RSUs will vest pro rata to the number of shares actually purchased up to the full investment amount of CHF 1,000,000 on each quarterly installment prior to the share purchase deadline and are subject to the continued ownership of a number of shares equal or higher than the pro rata number of shares actually purchased on each applicable vesting date or share purchase deadline. The amendment did not result in incremental fair value of the award. The grant date fair value of the award will be recognized in the statement of comprehensive loss over the remaining vesting period based on the modified vesting schedule using the graded approach.

Additionally, a total of 500,000 performance-based vesting RSUs were granted to Mr. Oswald on December 1, 2020, subject to the following conditions:

1. 200,000 RSUs will vest if the applicable volume-weighted average stock price of the Company equals or exceeds USD 24 in any consecutive three-month period prior to January 1, 2023 (for these RSUs the "Initial Vesting Date"). To the extent that this hurdle will not be met, these RSUs will be forfeited in their entirety.
2. 300,000 RSUs will vest if the applicable volume-weighted average stock price of the Company equals or exceeds USD 33 in any consecutive three-month period prior to January 1, 2024 (for these RSUs the "Initial Vesting Date"). To the extent that this hurdle will not be met, these RSUs will be forfeited in their entirety.

Pursuant to the award agreement, all of these RSUs will vest in four equal annual installments following the relevant Initial Vesting Date, if the applicable performance hurdles are met, and subject to Mr. Oswald's continued service with the Company as of the vesting date. The contractual term of the RSUs is ten years from the respective grant dates. The RSUs issued are equity-settled. On February 1, 2022, the Group announced the resignation of Dr. Andrin Oswald as CEO, effective immediately, due to his prolonged medical leave and entered into a separation agreement with him. Pursuant to his separation agreement, all unvested RSUs held by Mr. Oswald under the Company's LTIP continued to vest in accordance with their terms through the date of his termination on April 30, 2022, however; the number of RSUs shall not exceed 62,284 RSUs. As a result, unvested RSUs granted to Mr. Oswald shall be forfeited as of January 31, 2022 when Mr. Oswald stopped rendering services for the Group. Total RSUs in the amount of EUR 1,358 thousand that was recognized in the financial statements in the previous periods were derecognized in 2022 financial year and additional RSUs in the amount of EUR 201k were recognized in 2022 financial statements to match 62,284 RSUs granted to Mr. Oswald.

2022 Supervisory Board Incentive Compensation Scheme

In the Company's annual general meeting of shareholders on June 22, 2022, shareholders approved a new incentive compensation scheme for supervisory board members which is designed to attract and incentivize such members.

Pursuant to this scheme, certain members of the supervisory board will annually receive an award of options and RSUs for ordinary shares of the Company under the 2019 Plan with a value of EUR 140,000 multiplied by the LTI factor. For each award, RSUs will constitute 75% of the value of the award while options will constitute the remaining 25% of the value of the award. The LTI factor will be 100% or less based on the volume-weighted average stock price of our shares over a 60-trading day period preceding December 31 of the relevant financial year. Furthermore, the chairman and vice-chairman of the supervisory board, will each annually receive an additional award with a value of EUR 105,000 and EUR 70,000, respectively, multiplied by the LTI factor; the chairman of the audit committee and chairman of the compensation committee will each annually receive an additional award with a value of EUR 70,000 and EUR 14,000, respectively, multiplied by the LTI factor. The awards will be granted retrospectively for the preceding financial year following the audit of the Company's annual accounts over such financial year. The LTI factor for 2021 with respect of the 2020 financial year was set to 100% which resulted in a grant of 9,427 RSUs to Mr. Berndt Modig and 878 RSUs to Mr. Jonathan Sheldon. In the same respect 4,713 share options were granted to Mr. Modig and 439 share options were granted to Mr. Sheldon, each with a strike price of USD 9.92. The awards will vest in four equal annual instalments on each relevant anniversary of the grant date and will vest in full upon a change in control of the Company (provided that the holder remains an eligible participant on the date of the change in control). The awards will expire on the ten-year anniversary of the grant date, are not subject to any performance criteria and will be settled in shares.

In connection to our initial public offering, 10,000 share options have been granted as an extraordinary incentive to Mr. Modig as approved in the annual general meeting of shareholders on June 24, 2021. The options have a strike price of USD 14 and will vest in four equal installments following the grant date. The total amount of Supervisory Board Incentive Compensation expense recognized in 2022 financial statements is EUR 1,390k. For further details of the 2022 Supervisory Board incentive compensation scheme, please see note 21(viii) to our consolidated financial statements as of and for the year ended December 31, 2022.

C. Board Practices

Date of expiration

For the year of expiration of the current term of the supervisory and management board members of Centogene N.V. see “—A. Directors and Senior Management.”

Service Agreements

As of the consummation of our IPO, we entered into service agreements with all of the managing directors and supervisory board members of the Company. All of these agreements provide for notice of termination periods after certain minimum appointment periods and all of them include restrictive covenants.

Committees

Audit Committee

The audit committee, which consists of Mary Sheahan, Peer Schatz and Jonathan G. Sheldon, assists the supervisory board in overseeing our accounting and financial reporting processes and the audits of our financial statements. In addition, the audit committee is responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our supervisory board has determined that Mary Sheahan, Peer Schatz and Jonathan G. Sheldon each satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act and Mary Sheahan qualifies as an “audit committee financial expert,” as such term is defined in the rules of the SEC. The composition of our audit committee is consistent with the best practice provisions of the DCGC. The audit committee is governed by a charter that is available on our website.

The audit committee's responsibilities include:

- monitoring the management board with respect to (i) the relations with, and the compliance with recommendations and follow-up of comments made by, the Company's internal audit function and the Dutch independent auditor, (ii) the Company's funding, (iii) the application of information and communication technology by the Company, including risks relating to cybersecurity and (iv) the Company's tax policy;
- issuing recommendations concerning the appointment and the dismissal of the head of the Company's internal audit function;

- reviewing and discussing the performance of the Company’s internal audit function;
- the Company’s compliance with applicable legal and regulatory requirements;
- the operation of the Company’s code of conduct and ethics and its other internal policies;
- reviewing and discussing the Company’s audit plan, including with the Dutch independent auditor and the internal audit function;
- reviewing and discussing the essence of the audit results, including (i) flaws in the effectiveness of the internal controls, (ii) findings and observations with a material impact on the Company’s risk profile and (iii) failings in the follow-up of recommendations made previously by the internal audit function;
- receiving from the Dutch independent auditor a formal written statement at least annually delineating all relationships between the Dutch independent auditor and the Company consistent with applicable requirements of the Public Company Accounting Oversight Board (PCAOB) regarding the communications of the Dutch independent auditor with the Audit Committee concerning independence;
- reviewing and discussing with the Dutch independent auditor, at least annually (i) the scope and materiality of the Company’s audit plan and the principal risks of the Company’s annual financial reporting identified in such audit plan, (ii) the findings and outcome of the Dutch independent auditor’s audit of the Company’s financial statements and the management letter and (iii) significant findings from the audit and any problems or difficulties encountered, including restrictions on the scope of the Dutch independent auditor’s activities or on access to requested information, as well as significant disagreements with the Company’s management;
- determining whether and, if so, how the Dutch independent auditor should be involved in the content and publication of financial reports other than the Company’s financial statements;
- resolving disagreements between management and the Dutch independent auditor regarding the Company’s financial reporting;
- reviewing and discussing with the Dutch independent auditor any audit problems or difficulties and the response of the Company’s management thereto, including those matters required to be discussed with the Audit Committee by the Dutch independent auditor pursuant to established auditing standards, such as (i) restrictions on the scope of the activities of the Dutch independent auditor or on access to requested information, (ii) accounting adjustments that were noted or proposed by the Dutch independent auditor but were “passed” (as immaterial or otherwise), (iii) communications between the audit team and the audit firm’s national office regarding auditing or accounting issues presented by the engagement and (iv) management or internal control letters issued, or proposed to be issued, by the Dutch independent auditor;
- reviewing and discussing the effectiveness of the design and operation of the internal controls with the management board, the Chief Executive Officer and the Chief Financial Officer, as appropriate, including identified material failings, deficiencies or material weaknesses in the internal controls and material changes made to, and material improvements planned for, the internal controls;
- assisting the Company in preparing the disclosure to be included in the Company’s applicable filings as required by the Securities Act, the Exchange Act and their related rules;
- advising the management board regarding the Dutch independent auditor’s nomination for (re)appointment or dismissal (including confirmation and evaluation on the rotation of the audit partners on the audit engagement team as required by applicable laws) and preparing the selection of the Dutch independent auditor for such purpose, as relevant;

- reviewing and discussing the terms of engagement of the Dutch independent auditor to audit the Company's financial statements, to prepare or issue an audit report, or to perform other audit, review or attest services, including the scope of the audit, the materiality standard to be applied, and causing the Company, without further action, to pay the compensation of the Dutch independent auditor as approved by the audit committee;
- engagement of such independent legal, accounting and other advisors as the audit committee deems necessary or appropriate to carry out its responsibilities, including causing the Company, without further action, to pay the reasonable compensation of such advisors as approved by the audit committee;
- causing the Company to pay, without further action, the ordinary administrative expenses of the audit committee that are necessary or appropriate in carrying out its duties;
- preparing the audit committee report that the SEC rules require to be included in the Company's annual proxy statement (if and when the Company would become subject to those rules);
- establishing policies for the Company's hiring of current or former employees of the Dutch independent auditor;
- establishing procedures for (i) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and (ii) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters;
- reviewing potential conflicts of interest involving managing or supervisory board members, including whether they may take part in the deliberations in the decision-making process on any issue as to which there may be a conflict; and
- developing and recommending to the supervisory board the Company's related person transaction policy.

Compensation Committee

The compensation committee consists of Hubert Birner, Guido Prehn and Eric Sou tre. The compensation committee assists the supervisory board in determining compensation for our executive officers and the members of our management board and supervisory board. The composition of our compensation committee is consistent with the best practice provisions of the DCGC.

The compensation committee's responsibilities include:

- reviewing and evaluating the Company's compensation policy and benefits policies generally, including the review and recommendation of incentive-compensation and equity-based plans of the Company that are subject to approval of the supervisory board, as well as the compensation of the chief executive officer and the Company's other executive officers
- submitting proposals to the supervisory board concerning changes to the Company's compensation policies, as relevant;
- submitting proposals to the supervisory board concerning the compensation of individual managing directors and the Company's other executive officers, covering at least (i) the compensation structure, (ii) the amount of the fixed and variable compensation components, (iii) the applicable performance criteria, (iv) the scenario analyses that have been carried out, (v) the pay ratios within the Company's peer group, (vi) the views of any managing director with regard to the amount and structure of his own compensation and (vii) if considered appropriate by the management board or the compensation committee, the views of any executive officer with regard to the amount and structure of his own compensation;
- submitting proposals to the supervisory board concerning the compensation of individual supervisory board members;
- reviewing and assessing of risks arising from the Company's compensation policies and practices and whether any such risks are reasonably likely to have a material adverse effect on the Company;
- preparing of the Company's compensation report for the supervisory board;

- preparing of the compensation committee report required by SEC rules or the rules of any other regulatory body; and
- retaining of or obtaining advice from a compensation consultant, legal counsel or other advisor as the compensation committee deems necessary or appropriate to carry out its responsibilities, including the appointment of such consultant, counsel or advisor and the ability to cause the Company, without further approval, to pay with Company funds the reasonable compensation of such consultant, counsel or advisor as approved by the compensation committee, provided, however, that (i) in retaining or obtaining the advice of such consultant, counsel or advisor, other than in-house legal counsel, the compensation committee shall take into consideration the factors affecting independence required by applicable SEC rules and Nasdaq rules and (ii) the compensation committee will be responsible for the oversight of the work of any such consultant, counsel or advisor.

Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard director fees. As permitted by the listing requirements of Nasdaq, we have opted out of Nasdaq Listing Rule 5605(d), which requires that a compensation committee consist entirely of independent directors. The compensation committee is governed by a charter that is available on our website.

Nomination and Corporate Governance Committee

The nomination and corporate governance committee consists of Eric Sou tre, Peer Schatz, Guido Prehn and Hubert Birner. The nomination and corporate governance committee assists our supervisory board in identifying individuals qualified to become members of our management board or supervisory board consistent with criteria established by us and in developing our code of business conduct and ethics. The composition of our nomination and corporate governance committee is consistent with the best practice provisions of the DCGC.

The nomination and corporate governance committee’s responsibilities include:

- drawing up selection criteria and appointment procedures for the managing directors and supervisory board members;
- reviewing the size and composition of the management board and the supervisory board and submitting proposals for the composition profile of the supervisory board;
- making recommendations to the supervisory board as to determinations of supervisory board members independence;
- reviewing the functioning of individual managing directors and supervisory board members and reporting on such review to the supervisory board;
- drawing up a plan for the succession of managing directors and supervisory board members;
- submitting proposals for (re)appointment of managing directors and supervisory board members;
- supervising the policy of the management board regarding the selection criteria and appointment procedures for the Company’s executive officers;
- overseeing the self-evaluation of the management board and the supervisory board to determine whether it and its committees are functioning effectively; and
- developing and recommending to the management board the code of conduct and ethics and overseeing compliance with the code of conduct and ethics, including - at least annually - reviewing and reassessing the adequacy of the code of conduct and ethics and recommending any proposed changes to the management board.

As permitted by the listing requirements of Nasdaq, we have opted out of Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations. The nomination and corporate governance committee is governed by a charter that is available on our website.

D. Employees

As of December 31, 2022, we employed approximately 517 highly qualified personnel (including consultants) from 59 nationalities. All of our employees are engaged in either operations, sales, research and development, or corporate and other supporting functions. None of our employees are covered by collective bargaining agreements. The following tables provide breakdowns of our full-time equivalent employees as of December 31, 2022, by function and by region:

	As of December 31, 2022
Diagnostics Operations	204
Pharmaceutical Operations	16
Sales and Marketing	72
Pharmaceutical Business Development	22
Research and Development	79
Corporate and other supporting functions	124
Total employees (including consultants and apprentices)	517

	As of December 31, 2022
Germany	412
United States	20
India	12
Consultants (located mainly in Europe, Asia, Middle East and Latin America)	73
Total employees (including consultants and apprentices)	517

E. Share Ownership

See “Item 7. Major Shareholders and Related Party Transactions—A. Major Shareholders.”

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

As of the date of this Annual Report, our authorized share capital was €9,480,000, consisting of 79,000,000 common shares, par value €0.12 per share. Each of our common shares entitles its holder to one vote. The following table presents information relating to the beneficial ownership of our common shares as of the date of this Annual Report by:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding shares;
- each member of our management board and supervisory board; and

- all members of our management board and supervisory board as a group

Shareholder	Number of Common Shares beneficially owned	
	Number	Percentage
>5% Shareholders:		
Entities affiliated with DPE Deutsche Private Equity GmbH(1)	7,739,658	28.0 %
Careventures Fund II S.C.Sp(2)	4,261,460	15.4 %
Entities affiliated with TVM Life Science Innovation I, L.P.(3)	3,125,635	11.3 %
Platinum Asset Management Ltd.(4)	2,377,150	8.6 %
Management Board Members and Key Officers:		
Kim Stratton	—	—
Miguel Coego Ríos	—	—
Florian Vogel	—	—
Peter Bauer	11,654	*
Patrice P. Denèfle	—	—
Bettina Goerner	—	—
Supervisory Board Members:		
Guido Prehn(7)	7,739,658	28.0 %
Eric Souëtre(8)	4,261,460	15.4 %
Hubert Birner(5)	3,125,635	11.3 %
Holger Friedrich(6)	350,145	1.3 %
Flemming Ornskov	300,000	1.1 %
Peer Schatz(9)	100,100	*
Berndt Modig	—	—
Jonathan G. Sheldon	—	—
Andreas Busch	—	—
Mary Sheahan (Ad Interim Member)	—	—

* Less than 1% ownership.

- (1) The 7,739,658 common shares held by entities affiliated with DPE Deutsche Private Equity GmbH consist of (a) 5,086,022 common shares held by DPE Deutschland II A GmbH & Co. KG (“DPE II A”) and (b) 2,653,636 common shares held by DPE Deutschland II B GmbH & Co. KG (“DPE II B”). DPE Deutsche Private Equity GmbH is the managing limited partner of DPE II A and DPE II B and may be deemed to beneficially own the common shares held by such entities, but disclaims beneficial ownership of such shares. Marc Thiery is the managing director of DPE Deutsche Private Equity GmbH and has sole power to vote the common shares beneficially owned by DPE Deutsche Private Equity GmbH. Guido Prehn has decision-making power over the common shares beneficially owned by DPE Deutsche Private Equity GmbH but disclaims beneficial ownership of such shares. The address for DPE Deutsche Private Equity GmbH, DPE II A and DPE II B is Ludwigstrasse 7, 80539 Munich, Germany.
- (2) Careventures Fund II S.C.Sp (“Careventures II”) is managed by its general partner Careventures Fund II GP Sarl (“General Partner”), and Eric Souëtre, being a founder and shareholder of General Partner, participates in the collective decisions of the shareholders in relation to the General Partner. The registered address of Careventures II and the General Partner is 42-44, Avenue de la Gare, 1610 Luxembourg, Luxembourg.
- (3) The 3,125,635 common shares held by entities affiliated with TVM Life Science Innovation I, L.P. consist of (a) 1,632,606 common shares held by TVM Life Science Innovation I, L.P and (b) 1,493,029 common shares held by TVM Life Science Innovation II SCSp. The governance, investment strategy and decision-making with respect to investments held by TVM Life Science Innovation I, L.P. is directed by TVM Life Science Innovation I (GP) Limited, whose directors are Reshenthia Beeby, Hubert Birner and Gary Leatt, and who have shared power to vote the common shares beneficially owned by TVM Life Science Innovation I, L.P. As a result, each may be deemed to beneficially own the shares beneficially owned by TVM Life Science Innovation I, L.P. The address for TVM Life Science Innovation I, L.P. is 500-1 Place Ville-Marie, Montréal (Québec) H3B 1R1, Canada. The governance, investment strategy and decision-making process with respect to investments held by TVM Life Science Innovation II, SCSp. is directed by TVM Life Science Innovation II (GP) S.à r.l., whose directors are Monica Morsch, Ganash Lokanathen and Jens Hoellermann, and who have shared power to vote the common shares beneficially owned by TVM Life Science Innovation II SCSp. As a result, each may be deemed to beneficially own the shares beneficially owned by TVM Life Science Innovation II SCSp. The address for TVM Life Science Innovation II SCSp is 8 rue Lou Hemmer, L-1748, Senningerberg, Grand Duchy of Luxembourg.
- (4) Platinum Investment Management Limited (“Platinum”) is a Sydney, Australia-based investment advisory firm founded by Kerr Neilson and Andrew Clifford in 1994. Platinum is a fully owned subsidiary of Platinum Asset Management Limited (ABN 13 050 064 287), a company listed on the Australian Securities Exchange. The firm caters to retail and institutional investors. The address for Platinum is Level 8, 7 Macquarie Place, Sydney NSW 2000, Australia.
- (5) Hubert Birner beneficially owns common shares through his indirect ownership of interests in TVM Life Science Innovation I, L.P and TVM Life Science Innovation II (GP) S.à r.l.
- (6) Common shares are held by CCG-Commercial Coordination Germany GmbH and are beneficially owned by Holger Friedrich. The address for CCG-Commercial Coordination Germany GmbH is Mauerstraße 78, 10117 Berlin, Germany.

- (7) Guido Prehn has decision-making power over the common shares beneficially owned by DPE Deutsche Private Equity GmbH but disclaims beneficial ownership of such shares.
- (8) Eric Sou tre beneficially owns common shares through his indirect ownership of interests in Careventures Fund.
- (9) The 25,100 Common shares are held by PS Capital Management GmbH and are beneficially owned by Peer Schatz.

Each of our shareholders is entitled to one vote per common share. None of the holders of our shares have different voting rights from other holders of shares. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Our common shares are held through the book-entry system provided by The Depository Trust Company (“DTC”) and are registered in the register of shareholders in the name of Cede & Co., as DTC’s nominee. We are, therefore, not aware of the identity of our beneficial owners, the number of common shares they hold, nor where such beneficial owners reside.

B. Related Party Transactions

The following is a description of related party transactions we have entered into since January 1, 2022 with any of our officers, directors and the holders of more than 5% of our voting securities, or any member of the immediate family of any of the foregoing persons.

Transaction with Shareholders

On January 31, 2022, pursuant to the Securities Purchase Agreement and the Warrant Agreement, each signed with certain Investors, each of whom is (or is affiliated with) a significant shareholder of the Company, the Group received €15.0 million in exchange for the issuance of an aggregate of 4,479,088 common shares at a price per share of USD 3.73 and Warrants initially exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares at an initial exercise price per common share of USD 7.72. The Warrants are exercisable immediately as of the date of issuance and will expire on December 31, 2026.

See “Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources—Private Placement of Common Shares and Warrants” for more information.

Transactions Involving Members of Our Supervisory Board, Management Board and Other Related Parties

The Company purchased supplies used for genetic testing from an entity related to a member of the supervisory board. Expenses totaling €170 thousand were charged to profit and loss related to the period of service of the board member.

For the year ended December 31, 2022, no revenues were recognized in profit and loss in relation performance of genetic testing services for entities related to members of the supervisory board.

On January 31, 2022 (the “Closing Date”), the Company, Centogene GmbH, CentoSafe B.V. and Centogene US, LLC (together, the “Borrowers”), entered into the Loan and Security Agreement with Oxford Finance LLC and the other financial institutions or entities from time to time parties to the Loan and Security Agreement (collectively, referred to as “Lenders”) and Oxford, in its capacity as collateral agent for itself and the Lenders (in such capacity, “Agent”). Under the Loan and Security Agreement, the Lenders agreed to make available to the Borrowers certain term loans in an aggregate principal amount of up to \$45.0 million, subject to funding in two tranches as follows: (a) on the Closing Date, a loan in the aggregate principal amount of \$25.0 million (the “Term A Loan”) and (b) on and after the Term B Milestone (as defined below) until the earlier of 60 days thereafter and July 31, 2023, a loan in the aggregate principal amount of USD 20.0 million (the “Term B Loan” and collectively with the Term A Loan, the “Term Loans”). The obligations of the Lenders to fund the Term B Loan are subject to our achievement of product revenues from our diagnostics and pharmaceutical services segments of at least USD 50.0 million calculated on a trailing twelve month basis as of the last day of any fiscal month (such achievement, the “Term B Milestone”). As security for the Borrowers’ obligations under the Loan and Security Agreement, the Borrowers granted the Lenders a first priority security interest on the Borrowers’ assets.

The maturity date of the Term Loans is January 29, 2027, with amortized payments commencing March 1, 2025 in 24 equal monthly payments. The Term Loans bear an interest rate of 7.93% per annum plus the 1-month CME Term SOFR reference rate as published by the CME Group Benchmark Administration Limited (subject to a floor of 0.07% and 4.13% for Term A Loan and Term B Loan, respectively), based on a year consisting of 360 days.

At any time following the Closing Date, the Borrowers may prepay an amount of not less than all of the then outstanding principal balance and all accrued and unpaid interest on the Term Loans, subject to at least fifteen days' prior written notice to the Agent and the payment of a prepayment fee equal to (x) if made on or prior to the first anniversary of the Closing Date, 3.0% of the principal amount being prepaid, (y) if made after the first anniversary of the Closing Date but on or prior to the second anniversary of the Closing Date, 2.0% of the principal amount being prepaid and (z) otherwise, 1.0%.

The Loan and Security Agreement contains customary affirmative covenants, negative covenants and events of default, including covenants and restrictions that, among other things, require the Borrowers to satisfy a financial covenant, restrict Borrowers' ability to transfer cash to their subsidiaries, and in certain circumstances restrict the ability of the Borrowers to incur liens, incur additional indebtedness, engage in mergers and acquisitions, make distributions or make asset sales without the prior written consent of Lenders. A failure to comply with these covenants could permit the Lenders to declare the Borrowers' obligations under the Loan and Security Agreement, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination, as described above.

In connection with the foregoing, Borrowers have agreed to pay certain fees to Oxford that are customary for facilities of this type. See "Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources—Loan and Security Agreement" for more information.

On July 28, 2022, we amended the Loan Agreement to expand the scope of Permitted Indebtedness and Permitted Liens thereunder and each as defined therein. Later that year, we achieved the Term B Milestone and became eligible to draw down the outstanding \$20.0 million of commitments under the Term B Loan. On December 22, 2022, we borrowed the Term B Loan and received a net disbursement under the Oxford Facility of \$19,697,253.22 after accounting for fees, expenses and accrued interest.

We amended the Loan Agreement for a second time on April 30, 2023 to permit (i) the delivery of our audited consolidated financial statements for the fiscal year ended December 31, 2022 thirty days later than is otherwise required and (ii) the listing of our common shares on NASDAQ Capital Market. The Second Amendment introduced new requirements that (i) we prepay any outstanding loans under the Loan and Security Agreement in an amount of \$5.0 million (plus fees, interest and expenses, in each case, pursuant to the terms of the Loan and Security Agreement) upon the first new business development or financing transaction we enter and (ii) we maintain at least €9.1 million in unrestricted cash on deposit in collateral accounts subject to Oxford's perfected security interest granted under the Loan and Security Agreement.

Insurance and Indemnification Agreements

Our current and future managing directors and supervisory board members (and such other officer or employee as designated by our management board) have the benefit of indemnification provisions in our articles of association. These provisions give the indemnified persons the right to recover from us amounts, including but not limited to litigation expenses, and any damages they are ordered to pay, in relation to acts or omissions in the performance of their duties, subject to certain exceptions. In particular, there is no entitlement to indemnification for acts or omissions which have been determined to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person. In addition, we have entered into agreements with our managing directors and supervisory board members to indemnify them against expenses and liabilities to the fullest extent permitted by law. These agreements also provide, subject to certain exceptions, for indemnification for related expenses including, among others, attorneys' fees, judgments, penalties, fines and settlement amounts incurred by any of these individuals in any action or proceeding. In addition to such indemnification, we provide our managing directors and supervisory board members with directors' and officers' liability insurance.

Registration Rights Agreement

In connection with our initial public offering which closed on November 12, 2019, we entered into a registration rights agreement with certain of our existing shareholders pursuant to which we agreed under certain circumstances to file a registration statement to register the resale of the shares held by such holders, subject to certain exceptions, as well as to cooperate in certain public offerings of such shares. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. For more details, see the Form of Our Registration Rights Agreement attached as Exhibit 4.1 to our Registration Statement on Form F-1 filed with the SEC on October 11, 2019. On June 18, 2020, the Registration Rights Agreement was amended in accordance with its terms.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

See “Item 18. Financial Statements”, which contains our audited financial statements prepared in accordance with IFRS.

Legal Proceedings

Sanofi has filed an opposition proceeding in the EPO against the ‘725 Patent, (EP 2,718,725) a European patent that we own relating to our biomarker for Gaucher disease. The EPO opposition proceeding challenges the patentability of the ‘725 Patent in its entirety. The EPO rejected the opposition in the first instance in the oral proceedings on February 4, 2020. Sanofi has appealed the opposition decision. The Board of Appeal of the EPO has summoned to oral proceedings on September 26, 2023. We cannot predict the outcome of the proceedings. If the Board of Appeal does not uphold the opposition decision, the ‘725 Patent may still be revoked or maintained in amended form, in whole or in part, which could materially harm our business.

On April 15, 2021, Sanofi filed an opposition proceeding in the EPO against EP 3,318,881 (the “‘881 Patent”), a European patent that we own relating to our biomarker for Gaucher disease. Oral proceedings concerning the European patent took place before the opposition division of the EPO on May 04, 2022. The Opposition Division (as first instance) of the European Patent Office decided in the oral proceedings to maintain the patent in amended form. Sanofi has appealed the opposition decision. We have also appealed the opposition decision. The ‘881 Patent may still be revoked or maintained in amended, also further limited form, in whole or in part, which could materially harm our business. For more information regarding risks related to intellectual property, including this opposition proceeding, see “Item 3. Key Information—D. Risk Factors—Intellectual Property Risks Related to Our Business.”

In May 2016, we were informed in writing by the Universitair Medisch Centrum Utrecht (“UMCU”) that a claim had been initiated against UMCU regarding a prenatal diagnostic test that we conducted at UMCU’s request which failed to identify a specific mutation present in a patient. On October 1, 2018, the UMCU and Neon Underwriting Limited brought an action at the Regional Court of Rostock (Landgericht Rostock), Germany against us for damages, alleging that our negligence in performing the test resulted in the misdiagnosis of the patient. With the action, UMCU is seeking recovery for compensatory damages as a result of the alleged misdiagnosis. By court order of November 8, 2018, the Regional Court of Rostock set the amount in dispute at €880 thousand and opened the written preliminary proceedings against the Company. On November 12, 2018, we submitted a notice to the Regional Court of Rostock of our intention to defend against the claim. On January 3, 2019 we filed a motion to dismiss in which we denied the merits of the claim. UMCU and Neon Underwriting Limited responded to this motion on March 15, 2019 with a statement of reply, and the parties made several court filings setting out their arguments since. By order dated June 3, 2019, the Regional Court of Rostock provided a first set of questions to be answered by an expert witness. Following a request by the Court, the Director of the Institute of Genetics at the University of Bonn recommended a professor for human genetics from the University of Aachen to be appointed as such expert witness in this case. We agreed to such recommendation. As of December 31, 2020, the amount in dispute was €1.3 million. The matter was assigned to a new judge, due to the illness of the prior judge, and the decision to appoint the recommended expert witness is still pending. Since then, several potential experts were approached by the court, but eventually declined to prepare an expert witness report due to the possibility of bias. With its letter dated February 4, 2022, the court identified an expert witness to prepare a statement, which he delivered to the court on July 4, 2022. UMCU and Centogene were given four weeks to respond to the witness report. Based on the comments of both parties to the expert witness report, the court has asked the expert witness to answer additional questions in an additional report. The court has not set a date for such additional report. For more information regarding risks related to liability claims, including this proceeding, see “Item 3. Key Information-D. Risk Factors-We may become subject to substantial product liability or professional liability claims that could exceed our resources.”

Dividends and Dividend Policy

Under Dutch law, we may only pay dividends and other distributions from our reserves to the extent our shareholders’ equity (*eigen vermogen*) exceeds the sum of the paid-in and called-up share capital plus the reserves we must maintain under Dutch law or by our articles of association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by our general meeting from which it appears that such dividend distribution is allowed. Subject to those restrictions, any future determination to pay dividends or other distributions from our reserves will be at the discretion of our management board with the approval of our

supervisory board and will depend on many factors, including our results of operations, financial condition, cash requirements, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors we deem relevant. We have not adopted a formal dividend policy with respect to future dividends. We may adopt such a policy in the future, in which case we intend either to place a discussion of such policy on the agenda for our annual general meetings of shareholders, consistent with the DCGC, or to disclose a deviation from the DCGC in this respect in our statutory annual report.

Under our articles of association, our management board may decide that all or part of the profits shown in our adopted statutory annual accounts will be added to our reserves. After reservation of any such profits, any remaining profits will be at the disposal of the general meeting at the proposal of our management board, with the approval of our supervisory board, for distribution on our ordinary shares, subject to applicable restrictions of Dutch law. Our management board, with the approval of our supervisory board, is permitted, subject to certain requirements and applicable restrictions of Dutch law, to declare interim dividends without the approval of our general meeting. Dividends and other distributions shall be made payable no later than a date determined by us. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

B. Significant Changes

Except as disclosed in this Annual Report, there have been no other significant changes to our business since December 31, 2022.

Item 9. The Offer and Listing

A. Offer and Listing Details

Our common shares, with a par value of €0.12 per share, have traded on Nasdaq under the symbol “CNTG” since November 7, 2019.

B. Plan of Distribution

Not applicable.

C. Markets

For a description of our publicly traded common shares, see “—A. Offer and Listing Details.”

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

We incorporate by reference into this Annual Report our articles of association included as Exhibit 3.1 to Amendment No. 1 (File No. 333-234177) filed with the SEC on October 28, 2019. Such description sets forth an English translation of the official Dutch version of our articles of association as currently in effect. We also incorporate by reference into this Annual Report the section “Description of Share Capital and Articles of Association” included in our F-1 registration statement (File No. 333-239735) filed with the SEC on July 7, 2020.

C. Material Contracts

Shire/Takeda

We have entered into a strategic collaboration with Shire International GmbH (“Shire”), now a subsidiary of Takeda Pharmaceutical Company Limited, pursuant to a global master services agreement originally entered into in January 2015, as subsequently amended and further extended in December 2019, a supply agreement with Shire Pharmaceuticals Ireland Ltd. originally entered into in December 2013, as subsequently amended and further extended in December 2019, and two project services agreements with Shire, respectively, each as described below.

Global Master Services Agreement

Under the global master services agreement with Takeda Pharmaceutical Company Limited, the parent company of Shire International GmbH, we provide diagnostic services to Takeda and its affiliates. Takeda makes an annual fee payment to us for performance of an unlimited number of diagnostic tests for Morbus Fabry, Morbus Gaucher, Morbus Hunter, MPS1, MPS2, MPS3, MPS4, MPS6 and MPS7. Tests for some of these diseases are eligible for incremental payments from Takeda upon meeting a minimum quantity threshold. Pursuant to the December 2019 amendment and the most recent amendment in March 2021, the annual fee payable to us was increased and the minimum quantity threshold for the tests of some diseases was removed. In December 2021, we extended our Global Master Service Agreement with Takeda to March 2023. This continuous partnership allows us to continue diagnosing and connecting rare disease patients globally.

Supply Agreement

Under the supply agreement with Takeda, we develop, manufacture and supply customized CentoCard filter cards and kits for use in approximately 50 countries as requested by Takeda. These kits are language-specific and include a filter-card with requested patient/clinician information, self-addressed and labeled envelopes, barcode/tracking stickers, an informed consent form and instructions. Payments are calculated at fixed and variable rates, including fixed rates per newly designed language-specific kits and related storage and quality control fees. Kits are then billed at variable rates based on volumes, with minimum order requirements. We granted Takeda and its affiliates a non-exclusive license to use any intellectual property in our existing kits or these custom-developed kits as necessary to distribute and provide the kits pursuant to the agreement. The supply agreement has been extended together with the extension of the Global Master Services Agreement.

Project Services Agreement

We have also entered into a project services agreement with Shire, now a subsidiary of Takeda, dated March 2018 for a collaborative research project on HAE DBS-based diagnostic testing screening algorithm. All charges under the agreement are to be paid by Takeda. We and Takeda have granted each other the limited right to use each other’s data and intellectual property related to such testing and screening for the sole purpose of performing research under the agreement. Any subsequent research results and inventions achieved under the agreement will be co-owned by us and Takeda, and Takeda has the exclusive right, for six months after our delivery of a research report, to negotiate with us to purchase ownership of or a license to our rights in any research results or inventions on commercially reasonable terms. This study was finalized in April 2022.

In July 2019, we entered into a collaborative research agreement with Shire, now a subsidiary of Takeda, related to HAE Kininogen assay mass spectrometry testing and screening. We and Takeda granted each other the limited right to use each other’s data and intellectual property related to such testing and screening for the sole purpose of performing research under the agreement. Any subsequent research results and inventions achieved under the agreement will be co-owned by us and Takeda, and Takeda has the exclusive right, for six months following the delivery of our research report, to negotiate with us to purchase ownership of or a license

to our rights in any such research results or inventions on commercially reasonable terms. This project described under the agreement is funded by Takeda and finalized in 2022.

Pfizer

Global Master Scientific Services Agreement

In July 2019, we entered into a strategic collaboration with Pfizer Inc. (“Pfizer”), pursuant to a global master scientific services agreement (“MSSA”). Further to the MSSA, we entered into a statement of work (“SOW”) in November 2019 to provide sequencing services to Pfizer, for patients in the United States or Puerto Rico with transthyretin amyloid cardiomyopathy (“ATTR-CM”), patients suspected of having ATTR-CM, or individuals with a confirmed family history of hereditary ATTR-CM. Pfizer made an annual flat-fee payment to us for performance of a limited number of diagnostic tests. In addition, CentoCard filter cards and kits were delivered to qualified healthcare providers for sample collection. These were billed at a fixed rate per kit to Pfizer and the fee included access to CentoPortal. The number of diagnostic tests covered in SOW was further increased under an amended SOW entered into as of December 2019, as well as another SOW for the customization and manufacturing of CentoCard filter cards. This collaboration has ended in September 2022.

Data access and collaboration

In October 2019, we entered into a DACA with Pfizer, pursuant to which we granted Pfizer access to our data repository, which may be used in the discovery and validation of novel genetic and biochemical targets for the potential development of new therapies for rare diseases. This agreement ended in October 2022. See “Item 4. Information on the Company—B. Business Overview—Key Partnerships.”

Denali

Master Agreement on Patient Recruitment Activities and Laboratory Services and Statement of Work 2.

In 2018, we entered a strategic collaboration with Denali Therapeutics for the targeted global identification of PD patients with genetic variations in the LRRK2 gene. This collaboration has been known as the Rostock International Parkinson’s disease (ROPAD) Study. In December 2022 the amendment to SOW was signed, extending the study, in order to recruit and genetically test additional patients on a monthly basis over the next few years. Based on initial findings of the more than 12,500 participants already recruited and genetically tested, the study will now focus its efforts on 48 sites across 10 countries, consisting of Argentina, Belgium, Brazil, Germany, Israel, Italy, Portugal, Spain, the U.K., and the U.S. Denali will reimburse us for the actual costs to conduct the activities for the ROPAD Study, inclusive of the costs for the tests kits, genotyping, Centogene’s labor on an FTE basis, investigator costs, etc. We have granted to Denali a non-exclusive royalty-free, irrevocable, transferable license, unlimited in time and purpose, to use (but not disclose) our data for its own research and development purposes with respect to the Parkinson’s disease.

D. Exchange Controls

Under Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company, subject to applicable restrictions under sanctions and measures, including those concerning export control, pursuant to European Union regulations, the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation, applicable anti-boycott regulations, applicable anti-money-laundering regulations and similar rules and provided that, under certain circumstances, payments of such dividends or other distributions must be reported to the Dutch Central Bank at their request for statistical purposes. There are no special restrictions in the articles of association or Dutch law that limit the rights of shareholders who are not citizens or residents of the Netherlands to hold or vote shares.

However, we are present in some countries, and could become elsewhere, subject to strict restrictions on the movement of cash and the exchange of foreign currencies, which limits our ability to use this cash across our global operations. We also face risks related to the collection of payments due to us from our major pharmaceutical partners or clients that are located in certain geographical regions with foreign currency or international monetary controls. This risk could increase as we continue our geographic expansion. In particular, for the years ended December 31, 2022 and 2021, we derived 42.0% and 38.9%, respectively, of our total revenues from our Middle East region. Certain Middle East economies have adopted or been subject to international restrictions on the ability to transfer funds out of the country and convert local currencies into euros. This may increase our costs and limit our ability to convert local currency into euros and transfer funds out of certain countries. Any shortages or restrictions may impede our ability to

convert these currencies into euros and to transfer funds, including for the payment of dividends or interest or principal on our outstanding debt.

E. Taxation

The following summary contains a description of certain U.S. federal, Dutch and German income tax consequences of the acquisition, ownership and disposition of common shares, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase common shares. The summary is based upon the tax laws of the United States and regulations thereunder, the tax laws of the Netherlands and regulations thereunder and the tax laws of Germany and regulations thereunder as of the date hereof, which are subject to change.

Material U.S. Federal Income Tax Considerations for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders, described below, of owning and disposing of our common shares. It does not set forth all tax considerations that may be relevant to a particular person's decision to own or dispose of our common shares.

This section applies only to a U.S. Holder that holds our common shares as capital assets for U.S. federal income tax purposes. In addition, it does not set forth all of the U.S. federal income tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including alternative minimum tax consequences, the potential application of the provisions of the Code known as the Medicare contribution tax and tax consequences applicable to U.S. persons subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding our common shares as part of a hedging transaction, straddle, wash sale, conversion transaction or other integrated transaction or persons entering into a constructive sale with respect to our common shares;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities classified as partnerships for U.S. federal income tax purposes;
- tax-exempt entities, "individual retirement accounts" or "Roth IRAs";
- persons who acquired our common shares pursuant to the exercise of an employee stock option or otherwise as compensation;
- persons that own or are deemed to own 10% or more of our shares (by vote or value); or
- persons holding our common shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds our common shares, the U.S. federal income tax treatment of a partner will depend on the status of the partner and the activities of the partnership. Partnerships holding our common shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of our common shares.

This section is based on the Internal Revenue Code of 1986, as amended (the "Code"), administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the income tax treaty between Germany and the United States (the "Treaty") all as of the date hereof, any of which is subject to change or differing interpretations, possibly with retroactive effect.

A "U.S. Holder" is a holder who is, for U.S. federal income tax purposes, a beneficial owner of our common shares and:

- a citizen or individual resident of the United States;

- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or
- an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

This discussion assumes that our position as to us being tax resident solely in Germany is respected. U.S. Holders should consult their own tax advisers regarding any tax consequences that may arise if we were also treated as a tax resident of the Netherlands.

This discussion does not address the effects of any state, local or non-U.S. tax laws, or any U.S. federal tax laws other than income tax laws (such as U.S. federal estate or gift tax laws). U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of our common shares in their particular circumstances.

Taxation of Distributions

This discussion is subject to the discussion under “*Passive Foreign Investment Company Rules*” below.

Distributions of cash or other property, if any, that are made on our common shares, other than certain pro rata distributions of our common shares, will be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). For so long as our common shares continue to be listed on Nasdaq or another established securities market in the United States or we are eligible for benefits under the Treaty, subject to applicable limitations (that depend on a U.S. Holder’s particular circumstances) dividends paid to certain non-corporate U.S. Holders will be eligible for taxation as “qualified dividend income,” which is taxable at the rates applicable to long-term capital gains. Non-corporate U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends in their particular circumstances. The amount of a dividend will include any amounts withheld by us in respect of German income taxes. Dividends will not be eligible for the dividends-received deduction available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder’s income on the date of the U.S. Holder’s receipt of the dividend. The amount of any dividend income paid in euros will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Dividends will be foreign-source income to U.S. Holders. German income taxes withheld from dividends on our common shares at a rate not exceeding the rate provided by the Treaty will be eligible for credit against the U.S. Holder’s U.S. federal income tax liability. German taxes withheld in excess of the rate applicable under the Treaty or that are otherwise refundable under German tax law will not be eligible for credit against a U.S. Holder’s federal income tax liability. The rules governing foreign tax credits are complex. For example, Treasury regulations provide that, in the absence of an election to apply the benefits of an applicable income tax treaty, in order for non-U.S. income taxes to be creditable the relevant non-U.S. income tax rules must be consistent with certain U.S. federal income tax principles, and we have not determined whether the German income tax system meets these requirements. U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may elect to deduct non-U.S. taxes, including any German income tax, in computing their taxable income. An election to deduct non-U.S. taxes instead of claiming foreign tax credits applies to all creditable non-U.S. taxes paid or accrued in the taxable year. If Dutch income taxes are withheld from dividends paid to U.S. Holders, U.S. Holders are urged to consult their tax advisers regarding the creditability or deductibility of such Dutch income taxes against their U.S. federal income tax liabilities. See “Item 3. Key Information—D. Risk factors—Certain Factors Relating to Our Common Shares—If we do pay dividends, we may need to withhold tax on such dividends payable to holders of our shares in both Germany and the Netherlands.”

Sale or Other Disposition of Common Shares

This discussion is subject to the discussion under “*Passive Foreign Investment Company Rules*” below.

Gain or loss realized on the sale or other disposition of our common shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held our common shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder’s tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. Any gain or loss generally will be treated as U.S.-source gain or loss. German taxes on disposition gains (if any) generally will not be creditable or deductible for U.S. federal income tax purposes. The deductibility of capital losses is subject to limitations.

Passive Foreign Investment Company Rules

Under the Code, we will be a passive foreign investment company (“PFIC”) for any taxable year in which, after the application of certain “look-through” rules with respect to our subsidiaries, either (i) 75% or more of our gross income consists of “passive income” or (ii) 50% or more of the average value of our assets (generally determined on a quarterly basis) consists of assets that produce, or are held for the production of, “passive income.” For purposes of the above calculations, we will be treated as if we hold our proportionate share of the assets of, and receive directly our proportionate share of the income of, any other corporation in which we directly or indirectly own at least 25%, by value, of the shares of such corporation. Passive income includes, among other things, dividends, interest, certain non-active rents and royalties and investment gains. For these purposes cash is generally a passive asset. Goodwill is generally an active asset to the extent associated with business activities that produce active income.

Based on our current operations and composition of our income and assets, and certain estimates as to the value of our assets, we do not believe that we were a PFIC for our 2022 taxable year. However, there can be no assurance that the IRS will agree with our conclusion. In addition, whether we will be a PFIC in 2023 or any future taxable year is uncertain because, among other things, (i) we currently own, and expect to continue to own, a substantial amount of passive assets, including cash, (ii) the value of our assets that generate non-passive income for PFIC purposes, including our goodwill and other intangible assets, is uncertain and may vary substantially over time (and may be determined, in large part, by reference to our market capitalization, which has been, and may continue to be, volatile) and (iii) the composition of our income may vary substantially over time. Accordingly, there can be no assurance that we will not be a PFIC for any taxable year. For example, if we raise additional cash, or if our market capitalization continues to decline or fluctuate (and the value of our assets were determined in part by reference to our market capitalization), then there is a significant risk that we could be a PFIC for 2023, depending on the composition and average value of our assets for 2023 (which cannot be determined until after 2023).

If we are a PFIC for any taxable year and any entity in which it owned equity interests is also a PFIC (a “Lower-tier PFIC”), a U.S. Holder will be deemed to own a proportionate amount (by value) of the shares of each Lower-tier PFIC and will be subject to U.S. federal income tax according to the rules described in the next paragraph on (i) certain distributions by the Lower-tier PFIC and (ii) dispositions of shares of the Lower-tier PFIC, in each case as if the U.S. Holder held such shares directly, even though the U.S. Holder will not receive any proceeds of those distributions or dispositions.

In general, if we are a PFIC for any taxable year during which a U.S. Holder holds our common shares (assuming such U.S. Holder has not made a timely mark-to-market election, as described below), gain recognized by a U.S. Holder on a sale or other disposition (including certain pledges) of our common shares will be allocated ratably over the U.S. Holder’s holding period for our common shares. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC will be taxed as ordinary income. The amount allocated to each other taxable year will be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an additional tax representing a deferred interest charge will be imposed on the amount allocated to that taxable year. Further, to the extent that distributions received by a U.S. Holder on our common shares in any taxable year exceed 125% of the average of the annual distributions on our common shares received during the preceding three taxable years or the U.S. Holder’s holding period, whichever is shorter, the excess distribution will be subject to taxation in the same manner as gain, described immediately above. If we are a PFIC for any taxable year during which a U.S. Holder owns our common shares, we will continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder owns the common shares, even if we cease to meet the threshold requirements for PFIC status, unless the U.S. Holder makes a valid “deemed sale election” under the applicable Treasury regulations with respect to our common shares (and pays any tax resulting from that election).

If we are a PFIC for any taxable year, a U.S. Holder can avoid the adverse rules described in the preceding paragraph by making a timely mark-to-market election with respect to our common shares, provided that our common shares are “marketable.” Our common shares will be marketable if they are “regularly traded” on a “qualified exchange” or other market within the meaning of applicable Treasury regulations. The Nasdaq is a qualified exchange for this purpose, but there is no assurance that our common shares will continue to be listed on the Nasdaq, or that they will be regularly traded for any period. If a U.S. Holder makes the mark-to-market election, it will recognize as ordinary income any excess of the fair market value of our common shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of our common shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder’s tax basis in our common shares will be adjusted to reflect the amount of income or loss that is recognized. Any gain recognized on the sale or other disposition of our common shares in a taxable year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election, with any excess treated as a capital loss). U.S. Holders should consult their tax advisers regarding the availability and advisability of

making a mark-to-market election in their particular circumstances. In particular, U.S. Holders should consider the impact of a mark-to-market election with respect to their common shares given that we may have Lower-tier PFICs, and there is no provision in the Code, Treasury regulations or other official guidance that would give U.S. Holders the right to make a mark-to-market election with respect to any Lower-tier PFIC the shares of which are not regularly traded.

In addition, in order to avoid the application of the foregoing rules, a United States person that owns stock in a PFIC for U.S. federal income tax purposes may make a qualified electing fund (“QEF”) election with respect to such PFIC that results in a tax treatment different from the treatment described above. We do not intend to provide information necessary for U.S. Holders to make QEF elections and therefore these elections will not be available.

If we are a PFIC or, with respect to a particular U.S. Holder, are treated as a PFIC for the taxable year in which we paid a dividend or for the prior taxable year, the preferential dividend rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders will not apply.

If a U.S. Holder owns our common shares during any taxable year in which we are a PFIC, subject to certain exceptions, the U.S. Holder must file annual reports on IRS Form 8621 (or any successor form) with respect to us.

U.S. Holders should consult their tax advisers concerning our potential PFIC status and the potential application of the PFIC rules.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder’s U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Reporting With Respect to Foreign Financial Assets

Certain U.S. Holders who are individuals and certain entities may be required to report information relating to an interest in our common shares by filing a Form 8398 with their U.S. federal income tax return, subject to certain exceptions (including an exception for our common shares held in accounts maintained by certain U.S. financial institutions). Failure to file a Form 8398 where required can result in monetary penalties and the extension of the relevant statute of limitations with respect to all or a part of the relevant U.S. tax return. U.S. Holders should consult their tax advisers regarding this reporting requirement.

Material Dutch Tax Considerations

The following is a summary of certain material Dutch tax consequences of the acquisition, holding and disposal of common shares. This summary does not purport to describe all possible tax considerations or consequences that may be relevant to a holder or prospective holder of common shares and does not purport to deal with the tax consequences applicable to all categories of investors, some of which (such as trusts or similar arrangements) may be subject to special rules. In view of its general nature, this summary should be treated with corresponding caution.

For the purposes of this discussion, we assume that we are a tax resident of Germany under German national tax laws since we intended to have, from our incorporation and on a continuous basis, our place of effective management in Germany. See “Item 3. Key Information—D. Risk Factors—We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us.” Except as otherwise indicated, this summary is based on the tax laws of the Netherlands, published regulations thereunder and published authoritative case law, all as in effect on the date hereof, and all of which are subject to change, possibly with retroactive effect. Where the summary refers to “the Netherlands” or “Dutch” it refers only to the part of the Kingdom of the Netherlands located in Europe. The applicable tax laws or interpretations thereof may change, or the relevant facts and circumstances may change, and such changes may affect the contents of this section, which will not be up-dated to reflect any such changes.

This discussion is for general information purposes only and is not Dutch tax advice or a complete description of all Dutch tax consequences relating to the acquisition, holding and disposal of the common shares. Holders or prospective holders of common shares should consult their own tax advisors regarding the Dutch tax consequences relating to the acquisition, holding and disposal of the common shares in light of their particular circumstances.

Please note that the summary does not describe the Dutch tax consequences for:

(i) holders of common shares if such holders, and in the case of individuals, such holder's partner or certain of its relatives by blood or marriage in the direct line (including foster children), have a substantial interest (*aanmerkelijk belang*) or deemed substantial interest (*fictief aanmerkelijk belang*) in us under the Dutch Income Tax Act 2001 (*Wet inkomstenbelasting 2001*). A holder of securities in a company is considered to hold a substantial interest in such company, if such holder alone or, in the case of individuals, together with such holder's partner (as defined in the Dutch Income Tax Act 2001), directly or indirectly, holds (i) an interest of 5% or more of the total issued and outstanding capital of that company or of 5% or more of the issued and outstanding capital of a certain class of shares of that company; or (ii) rights to acquire, directly or indirectly, such interest; or (iii) certain profit sharing rights in that company that relate to 5% or more of the company's annual profits or to 5% or more of the company's liquidation proceeds. A deemed substantial interest may arise if a substantial interest (or part thereof) in a company has been disposed of, or is deemed to have been disposed of, on a non-recognition basis;

(ii) holders of common shares, if the common shares held by such holders qualify or qualified as a participation (*deelneming*) for purposes of the Dutch Corporate Income Tax Act 1969 (*Wet op de vennootschapsbelasting 1969*). Generally, a holder's shareholding of 5% or more in a company's nominal paid-up share capital qualifies as a participation. A holder may also have a participation if such holder does not have a shareholding of 5% or more but a related entity (statutorily defined term) has a participation or if the company in which the shares are held is a related entity (statutorily defined term).

(iii) pension funds, investment institutions (*fiscale beleggingsinstellingen*) and tax exempt investment institutions (*vrijgestelde beleggingsinstellingen*) (each as defined in the Dutch Corporate Income Tax Act 1969) and other entities that are, in whole or in part, not subject to or exempt from Dutch corporate income tax, entities that have a function comparable to an investment institution or a tax exempt investment institution, as well as entities that are exempt from corporate income tax in their country of residence, such country of residence being another state of the European Union, Norway, Liechtenstein, Iceland or any other state with which the Netherlands has agreed to exchange information in line with international standards;

(iv) holders of common shares who are individuals for whom the common shares or any benefit derived from the common shares are a remuneration or deemed to be a remuneration for activities performed by such holders or certain individuals related to such holders (as defined in the Dutch Income Tax Act 2001); and

(v) a holder of our common shares which is or who is entitled to the dividend withholding tax exemption (*inhoudingsvrijstelling*) with respect to any income (*opbrengst*) derived from the common shares (as defined in Article 4 of the Dutch Dividend Withholding Tax Act 1965 (*Wet op de dividendbelasting*)). Generally, a holder of common shares may be entitled or required to apply, subject to certain other requirements, the dividend withholding tax exemption if it is an entity and holds an interest of 5% or more in our nominal paid-up share capital.

Dividend Withholding tax

We are incorporated under the laws of the Netherlands, and therefore a Dutch tax resident for Dutch domestic tax law purposes, including the Dutch Dividend Withholding Tax Act 1969. As such, we are required to withhold Dutch dividend withholding tax at a rate of 15% from dividends distributed by us (which withholding tax will not be borne by us, but will be withheld by us from the gross dividends paid on the common shares). We are, however, also treated as a German tax resident for German domestic tax law purposes, since our place of effective management is located in Germany. As long as we continue to have our place of effective management in Germany, and not in the Netherlands, under the convention between the Federal Republic of Germany and the Netherlands for the avoidance of double taxation with respect to taxes on income of 2012, we will be considered to be exclusively tax resident in Germany. Consequently, the Netherlands will be restricted to impose Dutch dividend withholding tax on dividends distributed by us (and we will not be required to withhold Dutch dividend withholding tax). This exemption from withholding does not apply to dividends distributed by us to a holder of our common shares who is resident or deemed to be resident in the Netherlands for Dutch income tax purposes or Dutch corporate income tax purposes or to holders of common shares that are neither resident nor

deemed to be resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such non-resident holder, in which events the following applies. See “Item 3. Key Information—D. Risk Factors—If we do pay dividends, we may need to withhold tax on such dividends payable to holders of our shares in both Germany and the Netherlands”.

Dividends distributed by us to individuals and corporate legal entities who are resident or deemed to be resident in the Netherlands for Dutch (corporate) income tax purposes (“Dutch Resident Individuals” and “Dutch Resident Entities,” as the case may be) or to holders of our common shares that are neither resident nor deemed to be resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such non-resident holder are subject to Dutch dividend withholding tax at a rate of 15%.

The expression “dividends distributed” includes, among other things:

- distributions in cash or in kind, deemed and constructive distributions and repayments of paid-in capital not recognized for Dutch dividend withholding tax purposes;
- liquidation proceeds, proceeds of redemption of shares, or proceeds of the repurchase of shares by us or one of our subsidiaries or other affiliated entities to the extent such proceeds exceed the average paid-in capital of those shares as recognized for purposes of Dutch dividend withholding tax;
- an amount equal to the par value of shares issued or an increase of the par value of shares, to the extent that it does not appear that a contribution, recognized for purposes of Dutch dividend withholding tax, has been made or will be made; and
- partial repayment of the paid-in capital, recognized for purposes of Dutch dividend withholding tax, if and to the extent that we have net profits (*zuivere winst*), unless (i) the general meeting has resolved in advance to make such repayment and (ii) the par value of the shares concerned has been reduced by an equal amount by way of an amendment to our articles of association. The term “net profits” includes anticipated profits that have yet to be realized.

Dutch Resident Individuals and Dutch Resident Entities can generally credit the Dutch dividend withholding tax against their income tax or corporate income tax liability and to a refund of any residual Dutch dividend withholding tax. The same generally applies to holders of our common shares that are neither resident nor deemed to be resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such non-resident holder.

Pursuant to legislation to counteract “dividend stripping”, a reduction, exemption, credit or refund of Dutch dividend withholding tax is denied if the recipient of the dividend is not the beneficial owner as described in the Dutch Dividend Withholding Tax Act 1965 (*Wet op de dividendbelasting 1965*). This legislation generally targets situations in which a shareholder retains its economic interest in shares but reduces the withholding tax costs on dividends by a transaction with another party. It is not required for these rules to apply that the recipient of the dividends is aware that a dividend stripping transaction took place. The Dutch State Secretary of Finance takes the position that the definition of beneficial ownership introduced by this legislation will also be applied in the context of a double taxation convention.

Conditional withholding tax on dividends (as of January 1, 2024)

In addition to the above, it cannot be excluded that dividends distributed by us to certain related entities which are not resident in the Netherlands for Dutch tax purposes will become subject to a Dutch conditional withholding tax in certain specific situations (see below), irrespectively of the fact that we have our place of effective management in Germany and, therefore, are a tax resident of Germany under German national tax laws. As of January 1, 2024, a Dutch conditional withholding tax will be imposed on dividends distributed by us to related (*gelieerd*) entities (within the meaning of the Dutch Withholding Tax Act 2021; *Wet bronbelasting 2021*), if such related entity:

- is considered to be resident (*gevestigd*) in a jurisdiction that is listed in the yearly updated Dutch Regulation on low-taxing states and non-cooperative jurisdictions for tax purposes (*Regeling laagbelastende staten en niet-coöperatieve rechtsgebieden voor belastingdoeleinden*) (a “Listed Jurisdiction”); or
- has a permanent establishment located in a Listed Jurisdiction to which the ordinary shares are attributable; or

- holds the ordinary shares for the main purpose or one of the main purposes to avoid taxation for another person or entity and there is an artificial arrangement or transaction or a series of artificial arrangements or transactions; or
- is not considered to be the beneficial owner of the ordinary shares in its jurisdiction of residence because such jurisdiction treats another entity as the beneficial owner of the ordinary shares (a hybrid mismatch); or
- is not resident in any jurisdiction (also a hybrid mismatch); or
- is a reverse hybrid (within the meaning of Article 2(12) of the Dutch Corporate Income Tax Act 1969), if and to the extent (x) there is a participant in the reverse hybrid which is related (*gelieerd*) to the reverse hybrid, (y) the jurisdiction of residence of such participant treats the reverse hybrid as transparent for tax purposes and (z) such participant would have been subject to the Dutch conditional withholding tax in respect of dividends distributed by the Company without the interposition of the reverse hybrid,

all within the meaning of the Dutch Withholding Tax Act 2021.

The Dutch conditional withholding tax on dividends will be imposed at the highest Dutch corporate income tax rate in effect at the time of the distribution (currently 25.8%). The Dutch conditional withholding tax on dividends will be reduced, but not below zero, by any regular Dutch dividend withholding tax withheld in respect of the same dividend distribution. As such, based on the currently applicable rates, the overall effective tax rate of withholding the regular Dutch dividend withholding tax (as described above) and the Dutch conditional withholding tax on dividends will not exceed the highest corporate income tax rate in effect at the time of the distribution (currently 25.8%).

Taxes on income and capital gains

Dutch Resident Entities

Any benefit derived or deemed to be derived from the shares held by a Dutch Resident Entity, including any capital gains realized on the disposal thereof, will generally be subject to Dutch corporate income tax at a rate of 19 percent with respect to taxable profits up to €200,000 and 25.8 percent with respect to taxable profits in excess of that amount (rates and brackets for 2023).

Dutch Resident Individuals

If a holder of common shares is a Dutch Resident Individual, any benefit derived or deemed to be derived from the common shares is taxable at the progressive Dutch income tax rates (with a maximum of 49.50% in 2023), if:

- (i) the common shares are attributable to an enterprise from which the holder of common shares derives a share of the profit, whether as an entrepreneur (*ondernemer*) or as a person who has a co-entitlement to the net worth (*medegerechtigd tot het vermogen*) of such enterprise without being an entrepreneur or a shareholder in such enterprise (as defined in the Dutch Income Tax Act 2001); or
- (ii) the holder of shares is considered to perform activities with respect to the common shares that go beyond ordinary asset management (*normaal, actief vermogensbeheer*) or derives benefits from the common shares that are taxable as benefits from other activities (*resultaat uit overige werkzaamheden*).

Taxation of savings and investments

If the above-mentioned conditions (i) and (ii) do not apply to a Dutch Resident Individual, the common shares will be subject to an annual Dutch income tax under the regime for savings and investments (*inkomen uit sparen en beleggen*). Taxation only occurs insofar the Dutch Resident Individual's net investment assets for the year exceed a statutory threshold (*heffingvrij vermogen*). The net investment assets for the year are the fair market value of the investment assets less the fair market value of the liabilities on 1 January of the relevant calendar year (reference date; *peildatum*). The common shares are included as investment assets. The taxable benefit for the year (*voordeel uit sparen en beleggen*) is taxed at a flat rate of 32% (rate for 2023). Actual income or capital gains realized in respect of the common shares are as such not subject to Dutch income tax.

The taxable benefit for the year is calculated as follows:

- (i) The Dutch Resident Individual's assets and liabilities taxed under this regime, including the common shares, are allocated over the following three categories: (a) bank savings, (b) other investments, including the common shares, and (c) liabilities.
- (ii) The return (*rendement*) in respect of these assets and liabilities is calculated as follows (the return is at a minimum nihil):
 - a. a deemed return on the fair market value of the actual amount of bank savings and cash on January 1 of the relevant calendar year; plus
 - b. a deemed return on the fair market value of the actual amount of other investments, including the common shares, on January 1 of the relevant calendar year; minus
 - c. a deemed return on the sum of the fair market value of the actual amount of liabilities on January 1 of the relevant calendar year less the statutory threshold for liabilities (*drempe*l).
- (iii) The return percentage (%) (*rendementspercentage*) is calculated as follows:
 - a. by dividing the return calculated under (ii) above by the net investment assets for the year of the Dutch Resident Individual; multiplied by
 - b. 100.
- (iv) The taxable base (*grondslag sparen en beleggen*) is calculated as follows:
 - a. the net investment assets for the year of the Dutch Resident Individual; minus
 - b. the applicable statutory threshold.
- (v) The taxable benefit for the year is equal to the taxable base calculated under (iv) above multiplied by the return percentage calculated under (iii) above.

For the calendar year 2023, the deemed returns for the investment categories mentioned under (ii) (a) and (c) above have been temporarily set at 0.36% and 2.57%, respectively. The definitive percentages for these investment categories for the year 2023 will be published in the first months of 2024 and will have retroactive effect to January 1, 2023. The deemed return applicable to the other investments (mentioned under (ii)(b) above), including the common shares is set at 6.17% for the calendar year 2023. Transactions in the three-month period before and after January 1 of the relevant calendar year implemented to arbitrate between the deemed return percentages applicable to bank savings, other investments and liabilities will for this purpose be ignored if the holder of common shares cannot sufficiently demonstrate that such transactions are implemented for other than tax reasons.

Non-residents of the Netherlands

A holder of common shares that is neither a Dutch Resident Entity nor a Dutch Resident Individual will not be subject to Dutch corporate income tax in respect of income derived or deemed to be derived from the common shares or in respect of any gain or loss realized on the disposal or deemed disposal of the common shares, provided that:

- (i) such holder does not have an interest in an enterprise or a deemed enterprise (as defined in the Dutch Income Tax Act 2001 and the Dutch Corporate Income Tax Act 1969) which, in whole or in part, is either effectively managed in the Netherlands or is carried out on through a permanent establishment, a deemed permanent establishment or a permanent representative in the Netherlands and to which enterprise or part of an enterprise the common shares are attributable; and

(ii) in the event such holder is an individual, such holder does not carry out any activities in the Netherlands with respect to the common shares that go beyond ordinary asset management and does not derive benefits from the shares that are taxable as benefits from other activities in the Netherlands.

Gift and inheritance taxes

Residents of the Netherlands

Gift or inheritance taxes will arise in the Netherlands with respect to a transfer of common shares by way of a gift by, or on the death of, a holder of such common shares who is resident or deemed resident of the Netherlands at the time of the gift or the holder's death.

Non-residents of the Netherlands

No gift or inheritance taxes will arise in the Netherlands with respect to a transfer of the shares by way of gift by, or on the death of, a holder of common shares who is neither resident nor deemed to be resident of the Netherlands, unless:

(i) in the case of a gift of common shares by an individual who at the date of the gift was neither resident nor deemed to be resident of the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident of the Netherlands; or

(ii) the transfer is otherwise construed as a gift or inheritance made by, or on behalf of, a person who, at the time of the gift or death, is or is deemed to be resident of the Netherlands.

For purposes of Dutch gift and inheritance taxes, amongst others, a person that holds the Dutch nationality will be deemed to be resident of the Netherlands if such person has been resident in the Netherlands at any time during the ten years preceding the date of the gift or the holder's death. Additionally, for purposes of Dutch gift tax, amongst others, a person not holding the Dutch nationality will be deemed to be resident of the Netherlands if such person has been resident in the Netherlands at any time during the twelve months preceding the date of the gift. Applicable tax treaties may override deemed residency.

Value added tax (VAT)

No Dutch VAT will be payable by a holder of common shares in respect of any payment in consideration for the holding or disposal of the common shares.

Other taxes and duties

No Dutch registration tax, stamp duty or any other similar documentary tax or duty will be payable by a holder of common shares in respect of any payment in consideration for the holding or disposal of the common shares.

Material German Tax Considerations

The following is a summary of certain material German tax considerations of the acquisition, holding and disposal the Company's common shares. For the purposes of this discussion, we assume that we are a tax resident of Germany under German national tax laws since we intended to have, from our incorporation and on a continuous basis, our place of effective management in Germany. See "Item 3. Key Information—D. Risk Factors—We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us." This section does not set forth all German tax aspects that may be relevant for shareholders. The section is based on the German tax law applicable as of the date of this Annual Report. It should be noted that the law may change following the issuance of this Prospectus and that such changes may have retroactive effect.

The material German tax principles of purchasing, owning and transferring of shares are set forth in the following. This section does not purport to be a comprehensive or complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of shares and does not set forth all tax considerations that may be relevant to a particular person's decision to acquire common shares. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences set forth below. This section does not refer to any U.S. Foreign Account Tax Compliance Act aspects.

Shareholders are advised to consult their own tax advisers with regard to the application of German tax law to their particular situations, in particular with respect to the procedure to be complied with to obtain a relief of withholding tax on dividends and on capital gains (*Kapitalertragsteuer*) and with respect to the influence of double tax treaty provisions, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction. For German tax purposes, a shareholder may include an individual who or an entity that does not have the legal title to the shares, but to whom nevertheless the shares are attributed, based either on such individual or entity owning a beneficial interest in the shares or based on specific statutory provisions.

This section does not constitute a particular tax advice. Potential purchasers of the Company's shares are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of shares in light of their particular circumstances.

Taxation of Dividends

Withholding Tax on Dividends

Dividends distributed from a company to its shareholders are subject to withholding tax, subject to certain exemptions (for example, repayments of capital from the tax equity account (*steuerliches Einlagekonto*)), as described in the following. The withholding tax rate is 25% plus 5.5% solidarity surcharge (*Solidaritätszuschlag*) thereon (in total 26.375% plus, in the case of individuals as shareholders, church tax if applicable subject to further prerequisites) of the gross dividend approved by the ordinary shareholders' meeting. Withholding tax is to be withheld and passed on for the account of the shareholders by a domestic branch of a domestic or foreign credit or financial services institution (*Kredit- und Finanzdienstleistungsinstitut*), by the domestic securities trading company (*inländisches Wertpapierhandelsunternehmen*) or a domestic securities trading bank (*inländische Wertpapierhandelsbank*) which keeps and administers the shares and disburses or credits the dividends or disburses the dividends to a foreign agent, or by the securities custodian bank (*Wertpapiersammelbank*) to which the shares were entrusted for collective custody if the dividends are distributed to a foreign agent by such securities custodian bank (which is referred to as the "Dividend Paying Agent"). In case the shares are not held in collective deposit with a Dividend Paying Agent, the Company is responsible for withholding and remitting the tax to the competent tax office.

Such withholding tax is levied and withheld irrespective of whether and to what extent the dividend distribution is taxable at the level of the shareholder and whether the shareholder is a person residing in Germany or in a foreign country.

In the case of dividends distributed to a company within the meaning of Art. 2 of the amended EU Directive 2011/96/EU of the Council of November 30, 2011 (the "EU Parent Subsidiary Directive") domiciled in another Member State of the European Union, an exemption from withholding tax will be granted upon request if further prerequisites are satisfied (*Freistellung im Steuerabzugsverfahren*). This also applies to dividends distributed to a permanent establishment located in another Member State of the European Union of such a parent company or of a parent company tax resident in Germany if the participation in the Company is effectively connected with this permanent establishment. The key prerequisite for the application of the EU Parent Subsidiary Directive is that the shareholder has held a direct participation in the share capital of the Company of at least 10% for at least one year.

The withholding tax on distributions to other foreign resident shareholders can be reduced in accordance with a double taxation treaty (subject to domestic anti-treaty shopping rules or specific anti-abuse provisions in an applicable treaty, please see below) if Germany has concluded such double taxation treaty with the country of residence of the shareholder and if the shareholder does not hold his shares either as part of the assets of a permanent establishment or a fixed place of business in Germany or as business assets for which a permanent representative has been appointed in Germany. The reduction of the withholding tax is procedurally granted in such a manner that the difference between the total amount withheld, including the solidarity surcharge, and the tax liability determined on the basis of the tax rate set forth in the applicable double taxation treaty (generally 15% under German tax treaties providing for a dividend article in line with the OECD Model Treaty, or a lower rate subject to further prerequisites being met) is refunded by the German tax administration upon request (Federal Central Office for Taxes (*Bundeszentralamt für Steuern*), main office in Bonn-Beuel, An der Kuppe 1, 53225 Bonn, Germany).

In the case of dividends received by corporations whose statutory seat and effective place of management are not located in Germany and who are therefore not tax resident in Germany, two-fifths of the withholding tax deducted and remitted are refunded without the need to fulfill all prerequisites required for such refund under the EU Parent Subsidiary Directive or under a double taxation treaty or if no double taxation treaty has been concluded between the state of residence of the shareholder (but subject to domestic anti-abuse rules such as substance requirements, please see below).

In order to receive a refund pursuant to a double taxation treaty or the aforementioned option for foreign corporations, the shareholder has to submit a completed form for refund (available at the Federal Central Office for Taxes (<http://www.bzst.de>) as well as at the German embassies and consulates) together with a withholding tax certificate (*Kapitalertragsteuerbescheinigung*) issued by the institution that withheld the tax.

The exemption from withholding tax in accordance with the EU Parent Subsidiary Directive or a double tax treaty and the aforementioned options for a refund of the withholding tax (with or without protection under a double taxation treaty) depend on whether certain additional prerequisites (in particular so-called substance requirements) are fulfilled. The applicable withholding tax relief will only be granted if the preconditions of the German anti avoidance rules (so called Directive Override or Treaty Override), in particular Section 50d, paragraph 3, German Income Tax Act (*Einkommensteuergesetz*) are fulfilled.

The aforementioned reductions of (or exemptions from) withholding tax are further restricted if (i) the applicable double taxation treaty provides for a tax reduction resulting in an applicable tax rate of less than 15% and (ii) the shareholder is not a corporation that directly holds at least 10% in the equity capital of the Company and is subject to tax on its income and profits in its state of residence without being exempt. In this case, the reduction of (or exemption from) withholding tax is subject to the following three cumulative prerequisites: (i) the shareholder must qualify as beneficial owner of the shares in the Company for a minimum holding period of 45 consecutive days occurring within a period of 45 days prior and 45 days after the due date of the dividends, (ii) the shareholder has to bear at least 70% of the change in value risk related to the shares in the Company during the minimum holding period without being directly or indirectly hedged and (iii) the shareholder must not be required to fully or largely compensate directly or indirectly the dividends to third parties. However, these further prerequisites do not apply if the shareholder has been the beneficial owner of the shares in the Company for at least one uninterrupted year upon receipt of the dividends.

For individual or corporate shareholders tax resident outside Germany not holding the shares through a permanent establishment (*Betriebsstätte*) in Germany or as business assets (*Betriebsvermögen*) for which a permanent representative (*ständiger Vertreter*) has been appointed in Germany, the remaining and paid withholding tax (if any) is final (i.e., not refundable) and settles the shareholder's limited tax liability in Germany. For individual or corporate shareholders tax resident in Germany (that are, for example, shareholders whose residence, domicile, registered office or place of management is located in Germany) holding their shares as business assets, as well as for shareholders tax resident outside of Germany holding their shares through a permanent establishment in Germany or as business assets for which a permanent representative has been appointed in Germany, the withholding tax withheld (including solidarity surcharge) can be credited against the shareholder's personal income tax or corporate income tax liability in Germany. Any withholding tax (including solidarity surcharge) in excess of such tax liability is refunded. For individual shareholders tax resident in Germany holding the Company's shares as private assets, the withholding tax is a final tax (*Abgeltungsteuer*), subject to the exceptions described in the following section.

Pursuant to special rules on the restriction of withholding tax credit, the credit of withholding tax is subject to the following three cumulative prerequisites: (i) the shareholder must qualify as beneficial owner of the shares in the Company for a minimum holding period of 45 consecutive days occurring within a period of 45 days prior and 45 days after the due date of the dividends, (ii) the shareholder has to bear at least 70% of the change in value risk related to the shares in the Company during the minimum holding period without being directly or indirectly hedged and (iii) the shareholder must not be required to fully or largely compensate directly or indirectly the dividends to third parties. Absent the fulfillment of all of the three prerequisites, three-fifths of the withholding tax imposed on the dividends must not be credited against the shareholder's (corporate) income tax liability, but may, upon application, be deducted from the shareholder's tax base for the relevant assessment period. A shareholder that has received gross dividends without any deduction of withholding tax due to a tax exemption without qualifying for a full tax credit has to notify the competent local tax office accordingly and has to make a payment in the amount of the omitted withholding tax deduction. The special rules on the restriction of withholding tax credit do not apply to a shareholder whose overall dividend earnings within an assessment period do not exceed €20,000 or that has been the beneficial owner of the shares in the Company for at least one uninterrupted year upon receipt of the dividends.

Taxation of dividend income of shareholders tax resident in Germany holding the Company's shares as private assets

For individual shareholders (individuals) resident in Germany holding the Company's shares as private assets, dividends are subject to a flat tax rate which is satisfied by the withholding tax actually withheld (*Abgeltungsteuer*). Accordingly, dividend income will be taxed at a flat tax rate of 25% plus 5.5% solidarity surcharge thereon (in total 26.375%) and church tax (*Kirchensteuer*) in case the shareholder is subject to church tax because of his individual circumstances. An automatic procedure for deduction of church tax by way of withholding will apply to shareholders being subject to church tax unless the shareholder has filed a blocking notice (*Sperrvermerk*) with the German Federal Tax Office (details related to the computation of the concrete tax rate including church tax are to be discussed with the individual tax adviser of the relevant shareholder). Except for an annual lump sum savings allowance (*Sparer-Pauschbetrag*) of up to €801 (for individual filers) or up to €1,602 (for married couples and for partners in accordance with the registered partnership law (*Gesetz über die Eingetragene Lebenspartnerschaft*) filing jointly), private individual shareholders will not be entitled to deduct expenses incurred in connection with the capital investment from their dividend income.

The income tax owed for the dividend income is satisfied by the withholding tax withheld by the Dividend Paying Agent. However, if the flat tax results in a higher tax burden as opposed to the private shareholder's individual tax rate, the private shareholder can opt for taxation at his individual personal income tax rate. In that case, the final withholding tax will be credited against the income tax. However, pursuant to the German tax authorities and a court ruling, private shareholders are nevertheless not entitled to deduct expenses incurred in connection with the capital investment from their income. The option can be exercised only for all capital income from capital investments received in the relevant assessment period uniformly, and married couples as well as partners in accordance with the registered partnership law filing jointly may only jointly exercise the option.

Exceptions from the flat tax rate (satisfied by withholding at source) (*Abgeltungsteuer*) may apply—that is, only upon application—for shareholders who have a shareholding of at least 25% in a company and for shareholders who have a shareholding of at least 1% in the Company and work for the Company in a professional capacity. In such a case, the same rules apply as for sole proprietors holding the shares as business assets. See “—Taxation of dividend income of shareholders tax resident in Germany holding the Company's shares as business assets—Sole proprietors.”

Taxation of dividend income of shareholders tax resident in Germany holding the Company's shares as business assets

If a shareholder holds the Company's shares as business assets, the taxation of the dividend income depends on whether the respective shareholder is a corporation, a sole proprietor or a partnership.

Corporations

Dividend income of corporate shareholders is exempt from corporate income tax, provided that the incorporated entity holds a direct participation of at least 10% in the share capital of a company at the beginning of the calendar year in which the dividends are paid. The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the purpose of this rule. Participations in the share capital of the Company which a corporate shareholder holds through a partnership, including co-entrepreneurships (*Mitunternehmenschaften*), are attributable to such corporate shareholder only on a pro rata basis at the ratio of the interest share of the corporate shareholder in the assets of the relevant partnership. However, 5% of the tax exempt dividends are deemed to be non-deductible business expenses for tax purposes and therefore are subject to corporate income tax (plus solidarity surcharge) and trade tax, i.e., tax exemption of 95%. Business expenses incurred in connection with the dividends received are entirely tax-deductible.

For trade tax purposes the entire dividend income is subject to trade tax (i.e., the tax-exempt dividends must be added back when determining the trade taxable income), unless the corporation shareholder holds at least 15% of the Company's registered share capital at the beginning of the relevant tax assessment period (*Erhebungszeitraum*). In case of an indirect participation via a partnership please refer to the section “Partnerships” below.

If the shareholding is below 10% in the share capital, dividends are taxable at the applicable corporate income tax rate of 15% plus 5.5% solidarity surcharge thereon and trade tax (the rate of which depends on the municipalities the corporate shareholder resides in).

Special regulations apply which abolish the 95% tax exemption if the Company's shares are held as trading portfolio assets in the meaning of Section 340e of the German commercial code (*Handelsgesetzbuch*) by (i) a credit institution (*Kreditinstitut*), (ii) a financial service institution (*Finanzdienstleistungsinstitut*) or (iii) a financial enterprise within the meaning of the German Banking Act (*Kreditwesengesetz*), in case more than 50% of the shares of such financial enterprise are held directly or indirectly by a credit institution or a financial service institution, as well as by a life insurance company, a health insurance company or a pension fund in case the shares are attributable to the capital investments, resulting in fully taxable income.

Sole proprietors

For sole proprietors (individuals) resident in Germany holding shares as business assets dividends are subject to the partial income rule (*Teileinkünfteverfahren*). Accordingly, only (i) 60% of the dividend income will be taxed at his/her individual personal income tax rate plus 5.5% solidarity surcharge thereon and church tax (if applicable) and (ii) 60% of the business expenses related to the dividend income are deductible for tax purposes. In addition, the dividend income is entirely subject to trade tax if the shares are held as business assets of a permanent establishment in Germany within the meaning of the German Trade Tax Act (*Gewerbesteuer*gesetz), unless the shareholder holds at least 15% of the Company's registered share capital at the beginning of the relevant assessment period. The trade tax levied will be eligible for credit against the shareholder's personal income tax liability based on the applicable municipal trade tax rate and the individual tax situation of the shareholder.

Partnerships

In case shares are held by a partnership, the partnership itself is not subject to corporate income tax or personal income tax. In this regard, corporate income tax or personal income tax (and church tax, if applicable) as well as solidarity surcharge, are levied only at the level of the partner with respect to their relevant part of the profit and depending on their individual circumstances.

If the partner is a corporation, the dividend income will be subject to corporate income tax plus solidarity surcharge. See “—Corporations.”

If the partner is a sole proprietor (individual), the dividend income will be subject to the partial income rule. See “—Sole Proprietors.”

The dividend income is subject to trade tax at the level of the partnership (provided that the partnership is liable to trade tax), unless the partnership holds at least 15% of a company's registered share capital at the beginning of the relevant assessment period, in which case the dividend income is exempt from trade tax. In the case of dividends received by a corporate shareholder of the partnership. However, trade tax will be levied on 5% of the dividends to the extent they are attributable to the shares of such corporate partners to whom at least 10% of the shares of the Company are attributable on a look-through basis, since such portion of the dividends will be deemed to be non-deductible business expenses.

If a partner is an individual, depending on the applicable municipal trade tax rate and the individual tax situation, the trade tax paid at the level of the partnership is partly or entirely be credited against the partner's personal income tax liability.

In case of a corporation being a partner, special regulations will apply with respect to trading portfolio assets of credit institutions, financial service institutions or financial enterprises within the meaning of the German Banking Act (*Kreditwesengesetz*) or life insurance companies, health insurance companies or pension funds. See “—Corporations.”

Thus, the actual trade tax charge, if any, at the level of the partnership depends on the shareholding quota of the partnership and the nature of the partners (e.g., individual or corporation).

Taxation of dividend income of shareholders tax resident outside of Germany

For foreign individual or corporate shareholders tax resident outside of Germany not holding the shares through a permanent establishment in Germany or as business assets for which a permanent representative has been appointed in Germany, the deducted withholding tax (possibly reduced by way of a tax relief under a double tax treaty or domestic tax law, such as in connection with the EU Parent Subsidiary Directive) is final (that is, not refundable) and settles the shareholder's limited tax liability in Germany, unless the shareholder is entitled to apply for a withholding tax refund or exemption.

In contrast, individual or corporate shareholders tax resident outside of Germany holding the Company's shares through a permanent establishment in Germany or as business assets for which a permanent representative has been appointed in Germany are subject to the same rules as applicable (and described above) to shareholders resident in Germany holding the shares as business assets. The withholding tax withheld (including solidarity surcharge) is credited against the shareholder's personal income tax or corporate income tax liability in Germany.

Taxation of Capital Gains

Withholding tax on capital gains

Capital gains realized on the disposal of shares are only subject to withholding tax if a German branch of a German or foreign credit or financial institution, a German securities trading Company or a German securities trading bank holds in safe custody or administers the shares or carries out the sale of the shares and pays or credits the capital gains in its capacity as disbursing agent. In those cases, the disbursing agent (and not the company) is required to deduct the withholding tax at the time of payment for the account of the shareholder and has to pay the withholding tax to the competent tax authority. However, no withholding tax should be levied by the disbursing agent from capital gains realized on the disposal of the shares by a shareholder that is tax resident outside of Germany and not subject to German taxation (see below section "Taxation of capital gains realized by shareholders tax resident outside of Germany"). In case the shares in Centogene N.V. are held (i) as business assets by a sole proprietor, a partnership or a corporation and such shares are attributable to a German business or (ii) in case of a corporation being subject to unlimited corporate income tax liability in Germany, the capital gains are not subject to withholding tax. In case of clause (i), the withholding tax exemption is subject to the condition that the paying agent has been notified by the beneficiary (*Gläubiger*) that the capital gains are exempt from withholding tax. The respective notification has to be filed by using the officially prescribed form.

Taxation of capital gains realized by shareholders tax resident in Germany holding shares as private assets

For individual shareholders (individuals) resident in Germany holding shares as private assets, capital gains realized on the disposal of shares are subject to final withholding tax. Accordingly, capital gains will be taxed at a flat tax rate of 25% plus a 5.5% solidarity surcharge thereon (in total 26.375%) and church tax, in case the shareholder is subject to church tax because of his individual circumstances. An automatic procedure for deduction of church tax by way of withholding will apply to shareholders being subject to church tax unless the shareholder has filed a blocking notice (*Sperrvermerk*) with the German Federal Tax Office (details related to the computation of the concrete tax rate including church tax are to be discussed with the individual tax adviser of the relevant shareholder). The taxable capital gain is calculated by deducting the acquisition costs of the shares and the expenses directly related to the disposal from the proceeds of the disposal. Apart from that, except for an annual lump sum savings allowance (*Sparer-Pauschbetrag*) of up to €801 (for individual filers) or up to €1,602 (for married couples and for partners in accordance with the registered partnership law (*Gesetz über die Eingetragene Lebenspartnerschaft*) filing jointly), private individual shareholders will not be entitled to deduct expenses incurred in connection with the capital investment from their capital gain.

In case the flat tax results in a higher tax burden as opposed to the private shareholder's individual tax rate, the private shareholder can opt for taxation at his individual personal income tax rate. In that case, the withholding tax (including solidarity surcharge) withheld will be credited against the income tax. However, pursuant to the German tax authorities the private shareholders are nevertheless not entitled to deduct expenses incurred in connection with the capital investment from their income. The option can be exercised only for all capital income from capital investments received in the relevant assessment period uniformly, and married couples as well as for partners in accordance with the registered partnership law filing jointly may only jointly exercise the option.

Capital losses arising from the sale of the shares can only be offset against other capital gains resulting from the disposition of the shares or shares in other stock corporations during the same calendar year. Offsetting of overall losses with other income (such as business or rental income) and other capital income is not possible. Such losses are to be carried forward and to be offset against positive capital gains deriving from the sale of shares in stock corporations in future years.

The final withholding tax will not apply if the seller of the shares or in case of gratuitous transfer, its legal predecessor has held, directly or indirectly, at least 1% of the Company's registered share capital at any time during the five years prior to the disposal. In that case capital gains are subject to the partial income rule. Accordingly, only (i) 60% of the capital gains will be taxed at his individual personal income tax rate plus a 5.5% solidarity surcharge thereon and church tax (if applicable) and (ii) 60% of the business expenses related to the capital gains are deductible for tax purposes. The withholding tax withheld (including solidarity surcharge) will be credited against the shareholder's personal income tax liability in Germany.

Taxation of capital gains realized by shareholders tax resident in Germany holding the Company's shares as business assets

If a shareholder holds shares as business assets, the taxation of capital gains realized on the disposal of such shares depends on whether the respective shareholder is a corporation, a sole proprietor or a partnership:

Corporations

Capital gains realized on the disposal of shares by a corporate shareholder are generally exempt from corporate income tax and trade tax. However, 5% of the tax-exempt capital gains are deemed to be non-deductible business expenses for tax purposes and therefore are subject to corporate income tax (plus solidarity surcharge) and trade tax, i.e., tax exemption of 95%.

Capital losses incurred upon the disposal of shares or other impairments of the share value are not tax-deductible. A reduction of profit is also defined as any losses incurred in connection with a loan or security in the event the loan or the security is granted by a shareholder or by a related party thereto or by a third person with the right of recourse against the before-mentioned persons, and the shareholder holds directly or indirectly more than 25% of the company's registered share capital.

Special regulations apply if the shares are held as trading portfolio assets by a credit institution, a financial service institution or a financial enterprise within the meaning of the German Banking Act (*Kreditwesengesetz*) as well as by a life insurance company, a health insurance company or a pension fund. See “—Corporations.”

Sole Proprietors

If the shares are held by a sole proprietor, capital gains realized on the disposal of the shares are subject to the partial income rule. Accordingly, only (i) 60% of the capital gains will be taxed at his/her individual personal income tax rate plus a 5.5% solidarity surcharge thereon and church tax (if applicable) and (ii) 60% of the business expenses related to the dividend income are deductible for tax purposes. In addition, 60% of the capital gains are subject to trade tax if the shares are held as business assets of a permanent establishment in Germany within the meaning of the German Trade Tax Act (*Gewerbesteuerengesetz*). The trade tax levied, depending on the applicable municipal trade tax rate and the individual tax situation, is partly or entirely credited against the shareholder's personal income tax liability.

Partnerships

In case the shares are held by a partnership, the partnership itself is not subject to corporate income tax or personal income tax as well as a solidarity surcharge (and church tax) since partnerships qualify as transparent for German tax purposes. In this regard, corporate income tax or personal income tax as well as a solidarity surcharge (and church tax, if applicable) are levied only at the level of the partner with respect to their relevant part of the profit and depending on their individual circumstances.

If the partner is a corporation, the capital gains will be subject to corporate income tax plus a solidarity surcharge. See “—Corporations.” Trade tax will be levied additionally at the level of the partner insofar as the relevant profit of the partnership is not subject to trade tax at the level of the partnership. However, with respect to both corporate income and trade tax, the 95% exemption rule as described above applies.

If the partner is a sole proprietor (individual), the capital gains are subject to the partial income rule. See “—Sole Proprietors.”

In addition, if the partnership is liable to trade tax, 60% of the capital gains are subject to trade tax at the level of the partnership, to the extent the partners are individuals, and 5% of the capital gains are subject to trade tax, to the extent the partners are corporations. However, if a partner is an individual, depending on the applicable municipal trade tax rate and the individual tax situation, the trade tax paid at the level of the partnership is credited against the partner's personal income tax liability.

With regard to corporate partners, special regulations apply if they are held as trading portfolio assets by credit institutions, financial service institutions or financial enterprises within the meaning of the German Banking Act or life insurance companies, health insurance companies or pension funds, as described above.

Taxation of capital gains realized by shareholders tax resident outside of Germany

Capital gains realized on the disposal of the shares by a shareholder tax resident outside of Germany are subject to German taxation provided that (i) the Company's shares are held as business assets of a permanent establishment or as business assets for which a permanent representative has been appointed in Germany, or (ii) the shareholder or, in case of a gratuitous transfer, its legal predecessor has held, directly or indirectly, at least 1% of the company's shares capital at any time during a five-year period prior to the disposal. In these cases, capital gains are generally subject to the same rules as described above for shareholders resident in Germany. However, in case the shares are not attributable to a German permanent establishment or permanent representative the 5% taxation (see "—Corporations—Taxation of capital gains realized by shareholders tax resident in Germany holding the Company's shares as business assets") should not apply and the capital gains are fully exempt from German tax.

However, except for the cases referred to in clause (i) above, some of the double tax treaties concluded with Germany (including the German-U.S. tax treaty) provide for a full exemption from German taxation.

Inheritance and Gift Tax

The transfer of the Company's shares to another person by way of succession or donation is subject to German inheritance and gift tax (*Erbschaft- und Schenkungsteuer*) if:

- (i) the decedent, the donor, the heir, the donee or any other beneficiary has his/her/its residence, domicile, registered office or place of management in Germany at the time of the transfer, or is a German citizen who has not stayed abroad for more than five consecutive years without having a residence in Germany; or
- (ii) (irrespective of the personal circumstances) the shares are held by the decedent or donor as business assets for which a permanent establishment in Germany is maintained or a permanent representative is appointed in Germany; or
- (iii) (irrespective of the personal circumstances) at least 10% of the shares are held, directly or indirectly by, the decedent or person making the gift, himself or together with a related party in terms of Section 6 Foreign Tax Act.

Special regulations apply to qualified German citizens who maintain neither a residence nor their domicile in Germany but in a low tax jurisdiction, and to former German citizens, also resulting in inheritance and gift tax. The few double tax treaties on inheritance and gift tax which Germany has entered into provide that German inheritance and gift tax is levied only in case of (i) and, with certain restrictions, in case of (ii).

Imposition of Solidarity Surcharge

With effect as from the assessment period 2021, the solidarity surcharge has been partially abolished for certain individuals. The solidarity surcharge shall, however, continue to apply for capital investment and, thus, on withholding taxes levied. If the individual income tax burden for an individual shareholder is lower than 25%, the shareholder can apply for his/her capital investment income to be assessed at his/her individual tariff-based income tax rate, in which case the solidarity surcharge would be refunded.

Other Taxes

No German capital transfer tax (*Kapitalverkehrsteuer*), value-added tax (*Umsatzsteuer*), stamp duty (*Stempelgebühr*) or similar taxes are levied when acquiring, holding or transferring the Company's shares. No value-added tax will be levied unless the shareholder validly opts for it. Net wealth tax (*Vermögensteuer*) is currently not levied in Germany.

On February 14, 2013, the EU Commission adopted a proposal for a Council Directive (the "Draft Directive") on a common financial transaction tax ("FTT") to be implemented in Austria, Belgium, France, Germany, Greece, Italy, Portugal, Spain, Slovakia, and Slovenia (the "Participating Member States"). Estonia has stated in 2015 that it will not participate in implementing the proposed FTT.

The Draft Directive has a very broad scope and could, if introduced, apply to certain dealings in the shares or subscription rights (including secondary market transactions) in certain circumstances. The Draft Directive focused on levying a FTT on financial transactions (as defined in the Draft Directive), including the purchase, sale and exchange of financial instruments. Under the Draft Directive, the rate of the FTT would not be lower than 0.1% (0.01% for derivatives), generally based on the amount of the paid or owed consideration or in case of derivatives, the notional amount referred to in the derivatives contract at the time of the financial transaction. The issuance and subscription of shares should, however, be exempt.

Since the date of the publication of the Draft Directive, discussions have taken place between the Participating Member States. According to a statement of the German Federal Ministry of Finance (*Bundesministerium der Finanzen*) dated May 25, 2020, the work on the legal framework for the FTT was expected to be finalized in the second half of the calendar year 2020 based on the model of the existing French FTT legislation. Accordingly, the scope of application of the FTT to be levied at a rate of 0.2%, if enacted at all, could be confined to secondary market acquisitions of shares in domestic companies with a market capitalization of more than EUR 1 billion, while initial public offerings, market making and intraday trading should not be within the scope of taxation.

Nevertheless, the FTT remains subject to negotiation between the Participating Member States and was (and most probably will be) the subject of legal challenge. It may still be altered prior to its adoption. Moreover, once any directive has been adopted, it will need to be implemented into the respective domestic laws of the participating member states, and the domestic provisions implementing the directive might deviate from the directive itself. Finally, additional EU member states may decide to participate in or to dismiss the implementation.

A joint statement issued by 10 of the 11 participating EU member states in October 2016 reaffirmed the intention to introduce FTT. However, at the moment not many details are available. Thus, it is not known to what extent the elements of the European Commission's proposal outlined in the preceding paragraph will be followed in relation to the taxation of shares. The FTT proposal remains subject to negotiation between the participating Member States and is subject to political discussion. It may, therefore, be altered prior to the implementation, the timing of which remains unclear. Additional EU member states may decide to participate.

Prospective holders of the shares are advised to monitor future developments closely and to seek their own professional advice in relation to FTT.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

We also make available on our website, free of charge, our Annual Report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is www.centogene.com. The information contained on our website is not incorporated by reference in this Annual Report and our website address is included in this Annual Report as an inactive textual reference only.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

In the ordinary course of the business activities, the Group is exposed to various risks that are beyond its control, including credit risk, liquidity risk, currency risk and interest rate risk. Refer to Note 22 to our consolidated financial statements as of December 31, 2022, for further details.

Item 12. Description of Securities Other Than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

On January 31, 2022, pursuant to a securities purchase agreement and a warrant agreement, each signed with certain investors, the Group received EUR 15.0 million in exchange for the issuance of an aggregate of 4,479,088 common shares at a price per share of USD 3.73 (EUR 3.35) and warrants initially exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares at an initial exercise price per common share of USD 7.72. The warrants are exercisable immediately as of the date of issuance and will expire on December 31, 2026. Based on the fair value per share at the issuance date, the Group recognized the warrants as liabilities in the amount of USD 3.2 million (EUR 2.8 million). The fair value of warrants decreased from EUR 2.11 per warrant as of January 31, 2022 to EUR 0.19 per warrant as of December 31, 2022. The result is a decrease in fair value of warrant liabilities of EUR 2,574k for the period ended December 31, 2022.

C. Other Securities

Not applicable.

D. American Depositary Shares

Not applicable.

PART TWO

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

A. Material Modifications to Instruments

Not applicable.

B. Material Modifications to Rights

Not applicable.

C. Withdrawal or Substitution of Assets

Not applicable.

D. Changes in Trustees or Paying Agents

Not applicable.

E. Use of Proceeds

Not applicable.

Item 15. Controls and Procedures

A. Disclosure Controls and Procedures

As required by Rule 13a-15 under the Exchange Act, management, including our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding our required disclosures.

Based on the foregoing, including the material weaknesses noted below, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2022, the design and operation of our disclosure controls and procedures were not effective at the reasonable assurance level.

B. Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections or any evaluation or effectiveness for future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As part of our continued risk assessment and implementation of controls, we identified three material weaknesses related to ensuring the amounts in each financial statement account are complete and accurate. These relate to a lack of effectively designed review and monitoring financial statement close process controls for routine and non-routine transactions, including the inability of our business to timely and appropriately communicate non-routine transactions to the finance function, together with the lack of accounting policies to enable timely and appropriate technical assessment of the related accounting implications of non-routine transactions; a lack of an effectively designed and operating general IT controls framework (including system interfaces); and a lack of controls over the work performed by third-party suppliers.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022, using the criteria established in “Internal Control - Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation and the criteria issued by COSO, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2022, our internal control over financial reporting was not effective because of the material weaknesses related to the design and maintenance of effective controls described above, which has not been remediated.

With the oversight of the Management Board and our Audit Committee, our management has been and is actively undertaking remediation efforts to address the material weaknesses identified above through the following actions:

- Designing and formalizing policies and procedures to ensure routine transactions and judgmental and complex areas of the financial statement close process are sufficiently technical analyzed and assessed against the requirements of IFRS and our corporate governance standards, and that contemporaneous documentation is prepared and reviewed in a timely manner. In particular, we intend to continue hiring additional finance and accounting personnel with appropriate training to support the financial statement closing process and further developing and documenting our accounting policies and financial reporting procedures.
- Performing risk assessments to identify relevant financial risks and designing and implementing a formalized IT controls framework (including system interfaces and reasonable master data governance), based on the “Internal Control - Integrated Framework (2013)” issued by COSO, to reasonably address those risks. In addition, designing and formalizing IT General Control policies and procedures.
- Performing additional reviews by management to exercise preventive controls over the information processed and reported by third party suppliers and implementing contracting guidelines for the selection of these third-party suppliers.
- We shall finalize the design of the internal control framework in 2023, including the implementation and monitoring of effectiveness of internal controls over financial reporting and disclosure related to risk assessment, compliance, and oversight of the Company’s businesses.

These remediation efforts will be time consuming, costly and might place significant demands on our financial and operational resources. Because the reliability of the internal controls process requires repeatable execution, the successful remediation of the material weaknesses will require review and evidence of effectiveness prior to management concluding that the Company’s internal controls over financial reporting are effective. As management continues to evaluate and improve the Company’s internal controls over financial reporting, it may take additional measures to address control deficiencies or to modify the remediation plan described above.

During 2023, management shall test and evaluate the implementation of these internal controls to ascertain whether they are designed and operating effectively in order to provide reasonable assurance that they will prevent or detect a material misstatement in the Company’s consolidated financial statements. If our efforts to remediate these material weaknesses are not successful, the material weaknesses may reoccur, or other material weaknesses could occur in the future.

Notwithstanding the identified material weaknesses, our management believes that the financial statements and related notes thereto included in this annual report on Form 20-F fairly present, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in accordance with IFRS.

C. Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to a transition period established by rules of the SEC for emerging growth companies. We will cease to qualify as an emerging growth company on November 6, 2024. As a result, we will be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act for the year ending December 31, 2024.

D. Changes in Internal Control Over Financial Reporting

Our management is committed to improving the internal control over financial reporting and will undertake consistent improvements or enhancements on an ongoing basis, in addition to the remediation plans noted above. During the period covered by this annual report our management has taken steps toward improving our internal controls over financial reporting and remediating the identified material weaknesses. However, the changes during the period covered by this annual report have not yet comprehensively remediated the material weaknesses or our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our supervisory board has determined that Mary Sheahan, Peer Schatz and Jonathan G. Sheldon each satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act and Mary Sheahan qualifies as an “audit committee financial expert,” as such term is defined in the rules of the SEC. For more information see “Item 6. Directors, Senior Management and Employees—C. Board Practices—Committees—Audit Committee.”

Item 16B. Code of Ethics

We adopted a Code of Business Conduct and Ethics (the “Code”) applicable to our management board, our supervisory board, and company personnel, which is a code of ethics as defined in Item 16B of Form 20-F promulgated by the SEC. The full text of the Code can be found on our website at www.centogene.com. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report and is not incorporated by reference herein. If we make any amendment to the Code or grant any waivers, including any implicit waiver, from a provision of the Code, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC.

Item 16C. Principal Accountant Fees and Services

Our financial statements have been prepared in accordance with IFRS and are audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft (“Ernst & Young”), our independent registered public accounting firm registered with the Public Company Accounting Oversight Board in the United States.

Ernst & Young has served as our independent registered public accounting firm for each of the three years ended December 31, 2022, 2021 and 2020, for which audited financial statements appear in this Annual Report.

	For the year ended December 31,	
	2022	2021
	(in thousands)	
Audit	1,342	1,050
Audit-related fees	—	—
Tax fees	—	—
All other fees	—	—
Total	1,342	1,050

Audit fees relate to (i) audit services, (ii) certain procedures on our quarterly results, and (iii) services related to our statutory and regulatory filings for certain of our subsidiaries, including Centogene GmbH.

Audit Committee’s Pre-Approval Policies and Procedures

The audit committee is responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm.

The Audit Committee evaluates the qualifications, independence and performance of the independent registered public accounting firm as well as pre-approves and reviews the audit and non-audit services to be performed by the independent registered public accounting firm. The external audit plan and fees for professional audit services and other services rendered by Ernst & Young for the years ended December 31, 2022 and 2021 were approved by the Audit Committee.

The Audit Committee monitors compliance with the German, Dutch and U.S. rules on non-audit services provided by an independent registered public accounting firm.

Audit Work Performed by Persons Other Than Principal Accountant if Greater than 50%

Not applicable.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any affiliated purchaser has purchased any shares or other units of any class of our equity securities registered pursuant to Section 12 of the Exchange Act during the fiscal year ended December 31, 2022.

Item 16F. Change in Registrant’s Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

As a “foreign private issuer”, as defined by the SEC, we are permitted to rely on home country governance requirements and certain exemptions thereunder rather than on the corporate governance requirements of Nasdaq. For example, in accordance with Dutch law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice varies from the requirement of Nasdaq Listing Rule 5620(b). As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(d), which requires, among other things, an issuer to have a compensation committee that consists entirely of independent directors, Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations, and Nasdaq Listing Rule 5605(b)(1), which requires an issuer to have a majority of independent directors on its board. In addition, we have opted out of shareholder approval requirements, as included in the Nasdaq Listing Rules, for the issuance of securities in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of the Company and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Miscellaneous. Disclosure under Iran Threat Reduction and Syria Human Rights Act of 2012 (ITRA)

Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012 added Section 13(r) to the Exchange Act. Section 13(r) requires an issuer to disclose in its annual or quarterly reports, as applicable, whether it or any of its affiliates knowingly engaged in certain activities, transactions or dealings relating to Iran or with designated natural persons or entities sanctioned under programs relating to terrorism or the proliferation of weapons of mass destruction. Disclosure is required even where the activities, transactions or dealings are conducted outside the US by non-US affiliates in compliance with applicable law, and whether or not the activities are sanctionable under US law.

As of the date of this Annual Report, we are not aware of any activity, transaction or dealing by us during the financial year ended December 31, 2022 that is disclosable under Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012 and Section 13(r) of the Exchange Act, except as set forth below. This information is to the best of our knowledge.

Centogene N.V., which is not a U.S. person and is not owned or controlled by U.S. persons, does not have any branches or subsidiaries based in Iran. However, we have contracts with several laboratories and one distributor in Iran through which we provide diagnostic tests to patients in Iran, primarily NIPT for pregnant women. These laboratories and our third-party distributor are not owned or controlled by the Iranian government and we do not have any agreements, commercial arrangements, or other contracts with the Iranian government. Moreover, neither our distributor nor we have entered into any arrangements with or sold any products to persons included on the Specially Designated Nationals and Blocked Persons List maintained by the U.S. Department of the Treasury's Office of Foreign Asset Control.

In the year ended December 31, 2022, our gross revenues from activities in Iran amounted to €0, which represented 0% of our total gross revenues. We did not generate any net profits for the year ended December 31, 2022, from activities in Iran.

We do not receive information regarding the identity of our distributor's downstream customers and intermediaries in Iran, and it is possible that these parties include entities, such as government-owned hospitals and pharmacies, that are owned directly or indirectly by the Iranian government or by persons or entities sanctioned in connection with terrorism or proliferation activities. As a result, we cannot establish the proportion of gross revenue or sales potentially attributable to entities affiliated with the Iranian government or parties sanctioned for disclosable activities.

We believe that our business with Iranian parties is conducted in compliance with all applicable sanctions and export controls and that such activities, which involve providing genetic testing services to patients, are not sanctionable under U.S. secondary sanctions targeting Iran. For further information, see "Item 3. Key Information—D. Risk Factors—Transactions involving Iran or other countries or parties that are targets of U.S. or other economic sanctions could expose us to certain risks and may lead some potential customers and investors to avoid doing business with us or investing in our securities."

As of the date of this Annual Report, our management does not anticipate any change in our activities in Iran that would result in a material impact on Centogene.

PART THREE

Item 17. Financial Statements

We have responded to Item 18 in lieu of this item.

Item 18. Financial Statements

Our audited consolidated financial statements are included in this Annual Report beginning at Page F-1.

Item 19. Exhibits

<u>Exhibit no.</u>	<u>Description</u>
1.1	Form of Articles of Association of Centogene N.V. (incorporated into this Annual Report on Form 20-F by reference to Exhibit 3.1 to Amendment No. 1 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 28, 2019).
2.1	Form of Registration Rights Agreement (incorporated into this Annual Report on Form 20-F by reference to Exhibit 4.1 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).
2.2	Amendment No. 1 to Registration Rights Agreement (incorporated into this Annual Report on Form 20-F by reference to Exhibit 4.2 to our Registration Statement on Form F-1 (File No. 333-239735), filed with the SEC on July 7, 2020).
2.3	Description of the rights of each class of securities registered under Section 12 of the Securities Exchange Act of 1934 as of December 31, 2021. (incorporated into this Annual Report on Form 20-F by reference to Exhibit 2.2 to our Annual Report on Form 20-F for the year ended December 31, 2020 (File No. 001-39124), filed with the SEC on April 15, 2021).
4.1	Global Master Services Agreement between Centogene AG and Shire International GmbH, dated January 1, 2015 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 10.1 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).†
4.2	Supply Agreement between Centogene AG and Shire Pharmaceuticals Ireland Ltd, dated January 1, 2016 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 10.2 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).†
4.3	Amendment to the Global Master Services Agreement and Supply Agreement among Centogene AG, Shire International GmbH and Shire Pharmaceuticals Ireland Ltd., dated May 3, 2017 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 10.3 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).†
4.4	Amendment to the Global Master Services Agreement and Supply Agreement among Centogene AG, Shire International GmbH and Shire Pharmaceuticals Ireland Ltd., dated July 2, 2018 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 10.4 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).†
4.5	Amendment to the Global Master Services Agreement and Supply Agreement among Centogene AG, Shire International GmbH and Shire Pharmaceuticals Ireland Ltd., dated December 10, 2019 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 4.5 to our Annual Report on Form 20-F for the year ended December 31, 2019 (File No. 001-39124), filed with the SEC on April 23, 2020).†
4.6	Amendment to the Global Master Services Agreement and Supply Agreement among Centogene AG, Shire International, dated March 17, 2021. (incorporated into this Annual Report on Form 20-F by reference to Exhibit 4.6 to our Annual Report on Form 20-F for the year ended December 31, 2020 (File No. 001-39124), filed with the SEC on April 15, 2021).†
4.7	Form of Long Term Incentive Plan of Centogene N.V. (incorporated into this Annual Report on Form 20-F by reference to Exhibit 10.5 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).
4.8	Form of indemnification agreement between Centogene N.V. and members of the Supervisory Board or Management Board (incorporated into this Annual Report on Form 20-F by reference to Exhibit 10.6 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).
4.9	English summary of the Property Sale Agreement between Centogene AG and Ludewig-Wasserbau- und Werft- GmbH, dated June 28, 2019 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 10.7 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).
4.10	English summary of the Lease Agreement between Centogene AG and Ludewig-Wasserbau- und Werft- GmbH, dated June 28, 2019 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 10.8 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).
4.11	English summary of the Securities Sale Agreement between Centogene AG and K&L Immobilien GmbH and F&G IT GmbH, dated July 22, 2019 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 10.9 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).

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<u>Exhibit no.</u>	<u>Description</u>
4.12	English summary of the Service Agreement between Centogene GmbH and the Free State of Bavaria, Germany, represented by the Bavarian State Office for Health and Food Safety, dated April 29, 2021 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 4.12 to our Annual Report on Form 20-F for the year ended December 31, 2021 (File No. 001-39124), filed with the SEC on March 31, 2022).
4.13	English summary of the Cooperation Agreement between Centogene GmbH and Dr. Bauer Laboratoriums GmbH, dated June 25, 2020. (incorporated into this Annual Report on Form 20-F by reference to Exhibit 4.17 to our Annual Report on Form 20-F for the year ended December 31, 2020 (File No. 001-39124), filed with the SEC on April 15, 2021).†
4.14	Framework Agreement between Centogene GmbH and 21Dx GmbH (as main contractor to the state of Berlin), dated June 25, 2021 (incorporated into this Annual Report on Form 20-F by reference to Exhibit 4.14 to our Annual Report on Form 20-F for the year ended December 31, 2021 (File No. 001-39124), filed with the SEC on March 31, 2022).
4.15	Securities Purchase Agreement, dated January 31, 2022, by and among Centogene N.V. and the Investors identified on Schedule 1 attached thereto, incorporated into this Annual Report on Form 20-F by reference to our Report on Form 6-K filed with the SEC on February 1, 2022 (File No. 001-39124).
4.16	Warrant Agreement, dated January 31, 2022, by and among Centogene N.V. and the Investors identified on Schedule 1 attached thereto, incorporated into this Annual Report on Form 20-F by reference to our Report on Form 6-K filed with the SEC on February 1, 2022 (File No. 001-39124).
4.17	Loan and Security Agreement dated as of January 31, 2022 between Centogene N.V., Oxford Finance LLC, as Collateral Agent, and the Lenders named in Schedule 1.1 attached thereto, incorporated into this Annual Report on Form 20-F by reference to our Report on Form 6-K filed with the SEC on February 1, 2022 (File No. 001-39124).
4.18	Second Amendment to the Loan and Security Agreement dated as of January 31, 2022 between Centogene N.V., Oxford Finance LLC, as Collateral Agent, and the Lenders named in Schedule 1.1 attached thereto, incorporated into this Annual Report on Form 20-F by reference to our Report on Form 6-K filed with the SEC on May 4, 2023 (File No. 001-39124).
4.19	Global Master Supply and Services Agreement between Centogene GmbH and Takeda Pharmaceuticals International GmbH, dated March 31, 2023, replacing the Global Master Services Agreement dated January 1, 2015 as well as the Supply Agreement dated January 1, 2016, each as amended*†
4.20	Amendment to the Long Term Incentive Plan of Centogene N.V. dated as of November 1, 2022*
8.1	List of subsidiaries.*
11.1	Code of Business Conduct and Ethics of Centogene N.V. (incorporated into this Annual Report on Form 20-F by reference to Exhibit 14.1 to our Registration Statement on Form F-1 (File No. 333-234177), filed with the SEC on October 11, 2019).
12.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
12.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
13.1	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
13.2	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
15.1	Consent of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft.*
101	The following materials from this Annual Report on Form 20-F formatted in iXBRL (Inline Extensible Business Reporting Language) are furnished herewith: (i) the Report of Independent Registered Public Accounting Firm, (ii) the consolidated statements of comprehensive loss data, (iii) the consolidated statements of financial position, (iv) the consolidated statements of cash flows, (v) the consolidated statements of changes in equity, and (vi) the notes to consolidated financial statements, in each case tagged as blocks of text and in detail.**
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

* Filed herewith.

** Furnished herewith.

† Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

SIGNATURE

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

CEN TOGENE N.V.

By: /s/ KIM STRATTON

Name: Kim Stratton

Title: *Chief Executive Officer*

Date: May 16, 2023

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Supervisory Board of Centogene N.V.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Centogene N.V. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2.2 to the consolidated financial statements, the Company has suffered recurring losses from operations since inception and has stated that significant doubt exists about the Company’s ability to continue as a going concern. Management’s evaluation of the events and conditions and management’s plans regarding these matters are also described in Note 2.2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Restatement of Previously Issued Financial Statements

As discussed in Note 2.4 to the consolidated financial statements, the 2021 and 2020 consolidated financial statements have been restated to correct misstatements.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company’s auditor since 2010.

Berlin, Germany
May 16, 2023

Centogene N.V.

Consolidated statements of comprehensive loss for the years ended December 31, 2022, 2021 and 2020

(in EUR k)

	Note	2022	2021* Restated	2020* Restated
Revenue	7	47,473	42,234	38,453
Cost of sales		27,712	28,735	35,286
Gross profit		19,761	13,499	3,167
Research and development expenses		17,488	19,297	14,935
General administrative expenses		32,587	43,480	37,665
Selling expenses		9,924	9,326	7,580
Impairment of financial assets	22.2	—	827	3,636
Gain on reversal of financial asset impairment		432	—	—
Other operating income	8.1	3,774	2,894	2,392
Other operating expenses	8.2	741	86	182
Operating loss		(36,773)	(56,623)	(58,439)
Changes in fair value of warrants	8.3	2,574	—	—
Interest and similar income		512	3	6
Interest and similar expenses		4,909	802	1,381
Financial costs, net	8.3	(1,823)	(799)	(1,375)
Loss before taxes from continuing operations		(38,596)	(57,422)	(59,814)
Income taxes expenses	10	107	(70)	224
Loss for the year from continuing operations		(38,703)	(57,352)	(60,038)
Net income from discontinued operations, net of tax	9	6,862	11,106	38,052
Loss for the period		(31,841)	(46,246)	(21,986)
Other comprehensive income/(loss), all attributable to equity holders of the parent		(76)	543	(48)
Total comprehensive loss		(31,917)	(45,703)	(22,034)
Attributable to:				
Equity holders of the parent		(31,917)	(45,801)	(22,094)
Non-controlling interests from continuing operations	24	—	98	60
Non-controlling interests from discontinued operations		—	—	—
		<u>(31,917)</u>	<u>(45,703)</u>	<u>(22,034)</u>
Net loss per share - Basic and diluted from (in EUR)				
Continuing operations	11	(1.45)	(2.53)	(2.87)
Loss attributable to parent	11	(1.19)	(2.04)	(1.05)

*The comparative numbers have been re-presented as a result of the discontinued operations. Refer to Note 9 – Discontinued Operations.

The accompanying notes form an integral part of these consolidated financial statements

Centogene N.V.

Consolidated statements of financial position as of December 31, 2022 and 2021

(in EUR k)

Assets	Note	Dec 31, 2022	Dec 31, 2021 Restated*	Jan 1, 2021 Restated*
Non-current assets				
Intangible assets	12	7,400	9,194	12,407
Property, plant and equipment	13	6,808	9,464	16,590
Right-of-use assets	14	15,351	18,904	22,120
Derivatives assets	22	510	—	—
Other assets	16	2,911	2,972	1,967
		32,980	40,534	53,084
Current assets				
Inventories	15	1,819	3,869	11,405
Trade receivables and contract assets	16	16,548	23,462	28,988
Other assets	16	5,514	5,453	8,286
Cash and cash equivalents	17	35,951	17,818	48,156
		59,832	50,602	96,835
		92,812	91,136	149,919
Equity and liabilities				
Equity	Note	Dec 31, 2022	Dec 31, 2021	Jan 1, 2021
Issued capital	18	3,307	2,708	2,654
Capital reserve	18	145,369	133,897	125,916
Accumulated deficit and other reserves		(141,265)	(109,540)	(63,739)
Non-controlling interests		—	193	95
		7,411	27,258	64,926
Non-current liabilities				
Non-current loans	20.1	40,051	—	401
Lease liabilities	20.1	13,125	15,394	17,677
Deferred tax liabilities		35	79	207
Government grants	20.2	6,687	8,028	8,950
Derivative liabilities	22	376	—	—
Warrant liability	22	260	—	—
Other liabilities	20.2, 21	202	960	640
		60,736	24,461	27,875
Current liabilities				
Government grants	20.2	1,263	1,368	1,342
Current loans	20.1	4,635	3,815	2,492
Lease liabilities	20.1	2,311	3,330	3,528
Liabilities from income taxes	10	89	178	58
Trade payables	20.2	6,317	11,252	31,736
Other liabilities	20.2, 21	10,050	19,474	17,962
		24,665	39,417	57,118
		92,812	91,136	149,919

*Property, plant and equipment and lease liabilities as of December 31, 2021, and Trade receivables and contract assets and other liabilities as of December 31, 2021, and January 1, 2021, have been restated. Refer to Note 2.4 – Restatement of selected assets and liabilities in the consolidated statements of financial position and selected income and expenses in the consolidated statements of comprehensive loss.

The accompanying notes form an integral part of these consolidated financial statements

Centogene N.V.

Consolidated statements of cash flows for the years ended December 31, 2022, 2021 and 2020

(in EUR k)

	Note	2022	2021* (Restated)	2020* (Restated)
Operating activities				
Loss before taxes from continuing operations		(38,596)	(57,422)	(59,814)
Income before taxes from discontinued operations	9	6,875	11,152	38,110
Loss before taxes		(31,721)	(46,270)	(21,704)
Adjustments to reconcile earnings to cash flow from operating activities				
Amortization (including impairments) and depreciation	12,13,14	10,378	19,974	15,128
Inventory write-off		—	1,795	—
Interest income	8.3	—	(3)	(6)
Interest expense	8.3	4,909	851	1,400
Gain on the disposal of non-current assets		(754)	(18)	—
Expected credit loss allowances on trade receivables and contract assets	2.4	—	827	3,636
Share-based payment expenses	21	(16)	8,035	5,658
Tax expense		(89)	—	—
Fair value adjustments of warrants	8.3	(2,574)	—	—
Other non-cash items		(1,430)	(821)	(814)
Net foreign exchange differences		963	—	—
Changes in operating assets and liabilities:				
Inventories	15	2,050	5,741	(9,596)
Trade receivables and contract assets	16	6,914	4,855	(16,172)
Other assets	16	—	1,828	255
Trade payables	20.2	(4,935)	(20,484)	23,996
Other liabilities	28	(10,182)	1,952	6,681
Thereof cash flow (used in) continuing operating activities	28	(35,497)	(42,635)	(30,603)
Thereof cash flow from discontinued operating activities		9,009	20,897	39,065
Cash flow (used in)/from operating activities		(26,488)	(21,739)	8,462
Investing activities				
Cash paid for investments in intangible assets	12	(1,727)	(2,787)	(6,657)
Cash paid for investments in property, plant and equipment	13	(367)	(2,915)	(9,890)
Grants received for investment in property, plant and equipment	20.2	506	168	390
Grants refunded related to disposed property, plant and equipment	20.2	—	—	—
Cash received from disposals of property, plant and equipment		855	171	—
Interest received		—	3	6
Thereof cash flow (used in) continuing investing activities		(1,553)	(2,494)	(5,366)
Thereof cash flow from/(used in) discontinued investing activities		820	(2,866)	(10,785)
Cash flow (used in)/from investing activities		(733)	(5,360)	(16,151)
Financing activities				
Cash received from the issuance of shares	18	12,140	—	22,430
Cash received from issuance of warrants		2,833	—	—
Cash paid for acquisition of non-wholly owned subsidiary		(1)	—	(75)
Cash received from loans	20, 22.2	40,568	1,772	438
Cash repayments of loans	20, 22.2	—	(464)	(2,760)
Cash repayments of lease liabilities	20, 22.2	(4,314)	(4,244)	(5,018)
Interest paid	8.3	(4,909)	(267)	(173)
Thereof net cash flow from/(used in) continuing financing activities		46,798	(2,403)	13,561
Thereof net cash flow from/(used in) discontinued financing activities		(481)	(800)	1,281
Cash flow from financing activities		46,317	(3,203)	14,842
Changes in cash and cash equivalents		19,096	(30,302)	7,153
Cash and cash equivalents at the beginning of the period		17,818	48,156	41,095
Effect of movements in exchange rates on cash held		(963)	(36)	(92)
Cash and cash equivalents at the end of the period		<u>35,951</u>	<u>17,818</u>	<u>48,156</u>

*The comparative numbers have been re-presented as a result of the discontinued operations. Refer to Note 9- Discontinued Operations.

The accompanying notes form an integral part of these consolidated financial statements

Centogene N.V.

Consolidated statements of changes in equity for the years ended December 31, 2022, 2021 and 2020

in EUR k	Note	Attributable to the owners of the parent					Non-controlling interests	Total equity
		Issued capital	Capital reserve	Currency translation reserve	Accumulated deficit	Total		
As of December 31, 2019 (as previously reported)	1	2,383	98,099	-	(40,622)	59,860	(938)	58,922
Adjustments		-	-	-	(243)	(243)	-	(243)
As of December 31, 2019/ January 1, 2020 (as restated)		2,383	98,099	-	(40,865)	59,617	(938)	58,679
Loss for the year (restated)		-	-	-	(22,046)	(22,046)	60	(21,986)
Other comprehensive loss		-	-	(48)	-	(48)	-	(48)
Total comprehensive loss		-	-	(48)	(22,046)	(22,094)	60	(22,034)
Issuance of shares	18	240	22,969	-	-	23,209	-	23,209
Transaction costs	18	-	(780)	-	-	(780)	-	(780)
Share-based payments	21	-	5,658	-	-	5,658	-	5,658
Exercise of options		31	(31)	-	-	-	-	-
Disposal of non-wholly owned subsidiary		-	-	-	-	-	268	268
Acquisition of non-wholly owned subsidiary		-	-	-	(780)	(780)	705	(75)
As of December 31, 2020 (as restated)		2,654	125,916	(48)	(63,691)	64,831	95	64,926

in EUR k	Note	Attributable to the owners of the parent					Non-controlling interests	Total equity
		Issued capital	Capital reserve	Currency translation reserve	Accumulated deficit	Total		
As of December 31, 2020/ January 1, 2021 (as restated)	1	2,654	125,916	(48)	(63,691)	64,831	95	64,926
Loss for the year (restated)		-	-	-	(46,344)	(46,344)	98	(46,246)
Other comprehensive loss		-	-	543	-	543	-	543
Total comprehensive loss		-	-	543	(46,344)	(45,801)	98	(45,703)
Share-based payments	21	-	8,035	-	-	8,035	-	8,035
Exercise of options		54	(54)	-	-	-	-	-
As of December 31, 2021 (as restated)		2,708	133,897	495	(110,036)	27,064	193	27,258

in EUR k	Note	Attributable to the owners of the parent					Non-controlling interests	Total equity
		Issued capital	Capital reserve	Currency translation reserve	Accumulated deficit	Total		
As of January 1, 2022 (as restated)	1	2,708	133,897	495	(110,036)	27,064	193	27,258
Loss for the year		-	-	-	(31,841)	(31,841)	-	(31,841)
Other comprehensive loss		-	-	(76)	-	(76)	-	(76)
Total comprehensive loss		-	-	(76)	(31,841)	(31,917)	-	(31,917)
Issuance of shares	18	594	14,378	-	-	14,972	-	14,972
Share-based payments	21	-	(16)	-	-	(16)	-	(16)
Exercise of options	18	5	(5)	-	-	-	-	-
Warrant liability	18	-	(2,832)	-	-	(2,832)	-	(2,832)
Disposal of non-wholly owned subsidiary	24	-	(53)	-	193	140	(193)	(53)
As of December 31, 2022 (as restated)		3,307	145,369	419	(141,684)	7,411	-	7,411

The accompanying notes form an integral part of these consolidated financial statements

**Notes to the consolidated financial statements as of December 31, 2022 and 2021 and
for the three years ended December 31, 2022, 2021 and 2020**

1 General company information

Centogene N.V. (“the Company”) and its subsidiaries focus on providing data-driven answers to patients, physicians, and pharmaceutical companies for rare and neurodegenerative diseases. By integrating multiomic technologies with the CENTOGENE Biodatabank, we are able to provide dimensional analysis to guide the next generation of precision medicine. Our unique approach enables rapid and reliable diagnosis for patients, supports a more precise physician understanding of disease states, and accelerates and de-risks targeted pharmaceutical drug discovery, development, and commercialization.

On November 7, 2019, the Company completed an IPO and has since been listed on Nasdaq Global Market under stock code “CNTG”. We have historically conducted our business through Centogene AG (which is now known as Centogene GmbH), and therefore our historical financial statements present the results of operations and financial condition of Centogene AG and its controlled subsidiaries. In connection with our IPO, Centogene N.V. became the holding company of Centogene AG on November 12, 2019, and the historical consolidated financial statements of Centogene AG became the historical consolidated financial statements of Centogene N.V. Centogene N.V. is a public company with limited liability incorporated in the Netherlands, with registered office located at Am Strande 7 in 18055 Rostock, Germany and Dutch trade register number 72822872.

On March 5, 2020, the Company resolved that Centogene AG shall be converted into a German limited liability company and renamed Centogene GmbH. Such conversion became effective upon the registration in the German commercial register on June 29, 2020. Unless otherwise stated, “Centogene GmbH” also refers to the historical operations of Centogene AG throughout the notes.

In July 2020, the Company completed a follow-on public offering of 3,500,000 common shares of the Company (the “July 2020 Offering”), consisting of 2,000,000 common shares offered by the Company and 1,500,000 common shares offered by selling to shareholders at a price to the public of USD 14.00 per common share (i.e. EUR 12.71 per share). Aggregate offering proceeds, net of underwriting discounts, commissions and transaction costs, were EUR 22 million to the Company. On January 31, 2022, pursuant to a securities purchase agreement and a warrant agreement signed with certain investors, we received €15.0 million as consideration for the issuance by us of an aggregate of 4,479,088 common shares at a price per share of USD 3.73.

2 Basis of preparation

Unless otherwise specified, “the Company” refers to Centogene N.V. and Centogene GmbH throughout the remainder of these notes, while “the Group” refers to Centogene N.V., Centogene GmbH and its subsidiaries.

The consolidated financial statements of the Group were prepared in accordance with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board (the “IASB”). The accounting policies used in the fiscal year 2022 generally correspond to the policies applied in the prior year, except for the changes in presentation relating to discontinued operations (refer to Note 2.1– New significant accounting policies and accounting judgments and estimates and Note 9– Discontinued operations).

These consolidated financial statements are presented in euro, which is the Group’s functional currency. Unless otherwise specified, all financial information presented in euro is rounded to the nearest thousand (EUR k) in line with customary commercial practice.

2.1 New significant accounting policies and accounting judgments and estimates

Discontinued operations

A discontinued operation is a component of an entity that either has been disposed of, or that is classified as held for sale. It must either (i) represent a major separate line of business or geographical area of operations; (ii) be part of a single coordinated disposal plan; or (iii) be a subsidiary acquired exclusively with a view to resale. A component also qualifies for presentation as a discontinued operation when activities are ultimately ended (abandoned). Non-current assets and disposal groups are not classified as assets held for sale if their carrying amount is to be recovered through continuing use.

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In 2021, the Group decided to end its COVID-19 business activities in Q1 2022. The Group assessed that ending the activities of this operating segment would qualify as a discontinued operation. Therefore, the profit or loss related to the COVID-19 business is presented in a separate line item of the profit and loss section of the consolidated statements of comprehensive loss for the years ended December 31, 2022, 2021 and 2020. This also resulted in an accelerated depreciation of COVID-19 segment related property, plant and equipment and right of use assets through March 31, 2022. Since the operations were discontinued through winding-down of the COVID-19 business, no assets or liabilities were required to be disclosed separately on the statements of financial position. The segment reporting note and notes to the consolidated financial statements for the years ended December 31, 2022, 2021 and 2020 only represent continuing operations. For further details on the discontinued operations refer to Note 9 – Discontinued operations.

Warrants

Warrants are classified as equity to the extent that they confer the right to purchase a fixed number of shares for a fixed exercise price. In the event that the exercise price or the number of shares to be issued is not deemed to be fixed, the warrants are classified as a non-current derivative financial liability. Warrants entitle the holder to purchase one common share of the Company at an exercise price of USD 7.72 per share and can be settled for a fixed number of the Company's underlying common shares. Since the exercise price of the warrants is determined in US dollars which is different from the Company's functional currency, warrants are classified as liabilities. This liability is initially recognized at its fair value on the date the contract is entered into and subsequently accounted for at fair value through profit and loss (FVTPL) at each reporting date. As the warrants are classified as financial liabilities at FVTPL, transaction costs in the amount of EUR 68k were expensed in the consolidated statements of comprehensive loss for the year ended December 31, 2022. For more details, refer to Note 22 – Financial instruments - fair values and risk management.

2.2 Going Concern

As an early commercial-stage company, the Group is still in progress towards reaching break-even in its diagnostic and pharmaceutical businesses. The Group and Company are subject to a number of risks similar to those of other development and early commercial stage companies. These risks include, among other things, the failure to enter into and successfully execute further collaborations with pharmaceutical partners, the failure to generate revenue from the Company's development portfolio and risks associated with research, development, testing and obtaining related regulatory approvals in relation to our product candidates.

The Group's ongoing success and ultimately the attainment of profitable operations depends on future uncertain events which include, among other things, obtaining adequate financing to promote our commercial and development activities until the Group can generate sufficient revenues to support its operating cash requirements. The Group has incurred operating losses since inception. For the year ended December 31, 2022, the Group incurred a net comprehensive loss of EUR 31.9 million of which EUR 38.6 million is related to loss before taxes from continuing operations, resulting in net cash outflow from operating activities of EUR 26.5 million. As of December 31, 2022, the Group had generated an accumulated deficit of EUR 141.3 million and had an equity position of EUR 7.4 million.

Considering cash and cash equivalents as of December 31, 2022, of EUR 36.0 million with short term debt obligations of EUR 3.4 million, the Group has prepared cash flow forecasts and considered the cash flow requirement for the Company, principally focused on the twelve-month period from the date of the approval of these consolidated financial statements. Management updated their cash flow forecasts based on an amendment signed for the Group's Loan Facility (defined in Note 28) as of April 30, 2023. Accordingly, in addition to the short-term portion of the loan, the Group is also required to prepay USD 5.0 million of the loan upon the first new business development or financing transaction the Group will enter and to maintain at least EUR 9.1 million in unrestricted cash on deposit in collateral accounts (refer to Note 28). These forecasts show that further financings will be required during the course of the next 12 months assuming, among others, that development programs and other operating activities continue as currently planned. This requirement for additional financing represents a material uncertainty that raises significant doubt about our ability to continue as a going concern. Without such funding considered, the Group's current cash and cash equivalents will not be sufficient to fund its operations and meet all of its obligations as they fall due for at least one year from the date of the issuance of these consolidated financial statements.

Consequently, management plans to complete a significant financing primarily through private equity financing and/or convertible debt financing. The convertible debt financing discussions are at a progressed stage and aim to, not only, obtain a significant cash injection but also a long-term strategic collaboration in one of our key commercial regions. In parallel, management is

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in discussion with several private equity parties aiming to materialize a significant capital injection also with a suitable strategic fit for the company. Management has a reasonable level of confidence that one or more of the mentioned transactions should materialize in the next months improving the overall cash position and the mid-to-long-term sustainability of the Company.

As a third set of actions, which started in 2022, the company is in constant review of the cost structure, implementing several waves of efficiencies across the full organization aiming to improve our overall cash burn rate and reducing mainly our general and administrative expenses and research and development costs. Finally, the Group is seeking strategic collaborations and marketing, distribution or licensing arrangements, business and asset divestitures and grant funding among other things. Despite the Company's efforts to obtain the necessary funding and improve profitability of its operations, and despite management's expectation that these efforts will be successful, there can be no assurance of its success in doing so, or obtaining necessary funding on acceptable terms.

The accompanying consolidated financial statements for the year ended December 31, 2022, have been therefore prepared on a going concern basis contingent upon the successful implementation of the plans described above. This contemplates the Group will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities in the normal course of operations. The audited consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that would be necessary, was the Group unable to continue as a going concern.

2.3 COVID-19 Pandemic and Geopolitical Conditions

Worldwide economic and political disruptions as a result of COVID-19 and the conflict between Russia and Ukraine has resulted and is expected to further result in interruptions to business operations and supply chain disruption, affecting raw material and or intermediate supply or manufacturing capabilities.

COVID-19 vaccines being widely available, management updated its long-term outlook for the COVID-19 testing business at the end of the third quarter of 2021 and decided to wind-down all COVID-19 business related operations. Consequently, all COVID-19 testing site contracts expired, all COVID-19 operations at testing sites had ceased and the COVID-19 testing business was discontinued as of March 31, 2022. For Diagnostics and Pharmaceutical businesses, management expects that the impact of the pandemic would be minimal to none for the foreseeable future. However, it cannot be assured that the availability of supplies and equipment for the Group's laboratories, the availability of staff and the start dates and recruitment in clinical trials will not be impacted in the future.

Until today, the impact of geopolitical conditions has not been significant to the Group's operations. However, economic growth is expected to slow, including due to the recent surge in inflation and related actions by central banks, with a significant risk of recession in many parts of the world in the near term. This may also prolong tight credit markets and potentially cause such conditions to become more severe. These issues, along with the re-pricing of credit risk and the difficulties currently experienced by financial institutions, may make it difficult to obtain financing. Additionally, the Group may be affected by price increases or certain fiscal policy changes in Germany, such as new tax legislation, economic sanctions, and comparable measures, although at this point, management does not foresee any such macroeconomic changes.

2.4 Restatement of selected assets and liabilities in the consolidated statements of financial position and selected income and expenses in the consolidated statements of comprehensive loss

During the preparation of unaudited condensed consolidated financial statements as of and for the three months ended March 31, 2022, the Group identified unadjusted differences related to certain property, plant and equipment and lease liabilities balances on the consolidated statements of financial position and cost of sales and other operating income amounts in the statements of comprehensive loss as of and for the year ended December 31, 2021. These restated assets, liabilities, income and expenses are related to the COVID-19 segment which has been discontinued as of March 31, 2022. During Q2 2022, management identified the accelerated depreciation was over-stated with an amount of EUR 1,317k and a terminated lease contract in Q4 2021 with a EUR 273k lease liability balance which was not derecognized from the statement of financial position as of December 31, 2021. The lease liability is in relation to the closure of the Hamburg laboratory of which the right of use asset was completely written off in Q3 2021. To correct these differences, property, plant and equipment has been restated by EUR 1,317k with a corresponding decrease in depreciation expense under cost of sales and lease liabilities have been restated by EUR 273k with a corresponding increase in

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other operating income. All of these adjustments are related to discontinued operations. The net impact of this restatement has been disclosed under net income from discontinued operations, net of tax, in the amount of EUR 1,590k.

Additionally, during the preparation of the unaudited financial results for the second quarter ended June 30, 2022, the Group identified differences related to revenue recognized and impairment losses recognized on contract assets for the years ended December 31, 2021 and 2020 and trade receivables and contract assets outstanding as of December 31, 2021 and 2020 for the Diagnostic segment and COVID-19 segment. For the Diagnostic segment, these differences mainly resulted from the inappropriate usage of test codes for medical documentation submitted to insurance companies in the U.S. For the COVID-19 segment, the differences are related to inappropriate application of surveillance testing. Accordingly, to correct these differences, account receivables and contract assets has been restated by EUR 875k and EUR 211k and other liabilities has been restated by EUR 960k and EUR 640k as of December 31, 2021 and 2020, respectively. These restatements resulted in a decrease in revenue by EUR 1,355k and EUR 710k and a decrease in impairment of financial assets by EUR 313k and EUR 102k for the years ended December 31, 2021 and 2020, respectively. The impact of the correction of the differences on the accumulated deficit as of January 1, 2021 was EUR 851k. EUR 57k and EUR 127k of these adjustments corrected in trade receivables and revenue as of and for the years ended December 31, 2021 and 2020, respectively, are related to the COVID-19 business and included in discontinued operations. All of the remaining adjustments are related to the Diagnostic segment and included in continued operations.

The impact of the restatements on the consolidated statements of comprehensive income for the years ended December 31, 2021, and 2020 are as follows:

in EUR k	For the year ended Dec 31,			For the year ended Dec 31,		
	2021 (as previously reported)	Adjustments	2021 (as restated)*	2020 (as previously reported)	Adjustments	2020 (as restated)*
Revenue	189,923	(1,355)	188,568	128,381	(710)	127,671
Cost of sales	161,765	(1,317)	160,448	83,437	-	83,437
Gross profit	28,158	(38)	28,120	44,944	(710)	44,234
Research and development expenses	19,297	-	19,297	14,935	-	14,935
General administrative expenses	46,739	-	46,739	40,160	-	40,160
Selling expenses	9,860	-	9,860	8,026	-	8,026
Impairment of financial assets	1,140	(313)	827	3,738	(102)	3,636
Other operating income	2,936	331	3,267	2,394	-	2,394
Other operating expenses	86	-	86	182	-	182
Real estate transfer tax expenses	-	-	-	-	-	-
Operating loss	(46,028)	606	(45,422)	(19,703)	(608)	(20,311)
Loss for the period	(46,852)	606	(46,246)	(21,378)	(608)	(21,986)
Total comprehensive loss	(46,309)	606	(45,703)	(21,426)	(608)	(22,034)
Loss per share- Basic and diluted (in EUR)	(2.06)	0.02	(2.04)	(1.02)	(0.03)	(1.05)

*As restated consolidated statements of comprehensive income for the years ended December 31, 2021 and 2020 have not been re-presented as a result of discontinued operations. Refer to Note 9 – Discontinued Operations.

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The impact of the restatements on the consolidated statements of financial position as of December 31, 2021 and 2020, are as follows:

in EUR k	Dec 31, 2021	Adjustments	Dec 31, 2021	Dec 31, 2020	Adjustments	Dec 31, 2020
	(as previously reported)		(as restated)	(as previously reported)		(as restated)
Property, plant and equipment	8,147	1,317	9,464	16,590	-	16,590
Non-current assets	<u>39,217</u>	<u>1,317</u>	<u>40,534</u>	<u>53,084</u>	<u>-</u>	<u>53,084</u>
Trade receivables and contract assets	24,337	(875)	23,462	29,199	(211)	28,988
Current assets	<u>51,477</u>	<u>(875)</u>	<u>50,602</u>	<u>97,046</u>	<u>(211)</u>	<u>96,835</u>
Total Assets	<u>90,694</u>	<u>442</u>	<u>91,136</u>	<u>150,130</u>	<u>(211)</u>	<u>149,919</u>
Equity and liabilities						
Accumulated deficit and other reserves	(109,295)	(245)	(109,540)	(62,888)	(851)	(63,739)
Equity	<u>27,503</u>	<u>(245)</u>	<u>27,258</u>	<u>65,777</u>	<u>(851)</u>	<u>64,926</u>
Lease liabilities	15,588	(194)	15,394	17,677	-	17,677
Other liabilities	-	960	960	-	640	640
Non-current liabilities	<u>23,695</u>	<u>766</u>	<u>24,461</u>	<u>27,235</u>	<u>640</u>	<u>27,875</u>
Lease liabilities	3,409	(79)	3,330	3,528	-	3,528
Current liabilities	<u>39,496</u>	<u>(79)</u>	<u>39,417</u>	<u>57,118</u>	<u>-</u>	<u>57,118</u>
Total Equity and Liabilities	<u>90,694</u>	<u>442</u>	<u>91,136</u>	<u>150,130</u>	<u>(211)</u>	<u>149,919</u>

The impact of the restatements on the consolidated statements of cash flows for the years ended December 31, 2021 and 2020 are as follows:

in EUR k	For the year ended Dec 31,			For the year ended Dec 31,		
	2021 (as previously reported)	Adjustments	2021 (Restated)*	2020 (as previously reported)	Adjustments	2020 (Restated)*
Operating activities						
Loss before taxes	(46,876)	606	(46,270)	(21,097)	(607)	(21,704)
Adjustments to reconcile loss to cash flow from operating activities						
Amortization and depreciation	21,291	(1,317)	19,974	15,128	-	15,128
Expected credit loss allowances on trade receivable and contract liabilities	1,140	(313)	827	3,738	(102)	3,636
Other non-cash items	(862)	41	(821)	(915)	101	(814)
Changes in operating assets and liabilities						
Trade receivables and contract assets	4,191	664	4,855	(16,344)	172	(16,172)
Other liabilities	1,632	320	1,952	6,245	436	6,681
Net cash flow used in operating activities	<u>(21,739)</u>	<u>-</u>	<u>(21,739)</u>	<u>8,462</u>	<u>-</u>	<u>8,462</u>
Investing activities						
Cash flow used in investing activities	<u>(5,360)</u>	<u>-</u>	<u>(5,360)</u>	<u>(16,151)</u>	<u>-</u>	<u>(16,151)</u>
Financing activities						
Net cash flow from/ (used in) financing activities	<u>(3,203)</u>	<u>-</u>	<u>(3,203)</u>	<u>14,842</u>	<u>-</u>	<u>14,842</u>
Cash and cash equivalents at the end of the period	<u>17,818</u>	<u>-</u>	<u>17,818</u>	<u>48,156</u>	<u>-</u>	<u>48,156</u>

*As restated consolidated statements of comprehensive income for the years ended December 31, 2021 and 2020 have not been re-presented as a result of discontinued operations. Refer to Note 9 – Discontinued Operations.

The restatements above have no impact on the changes in cash, cash equivalents and net cash flows in operating, investing, and financing activities within the consolidated statements of cash flows for all periods presented.

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3 Effects of new accounting standards

(a) New standards adopted by the Group as of January 1, 2022

The following amendments and interpretations apply for the first time in 2022 and had no impact on the consolidated financial statements of the Group:

- Amendments to IFRS 3 - Business combinations.
- Amendments to IAS 16- Property, plant and equipment.
- Amendments to IAS 37- Provisions, contingent liabilities, and contingent assets.
- Amendments to IFRS 9 - Financial Instruments
- Amendments to Illustrative Examples accompanying IFRS 16

(b) New standards not yet effective

Furthermore, certain new and amended standards and interpretations have been published that are not mandatory for December 31, 2022, reporting periods and have not been early adopted by the Group. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective. The Group is currently evaluating the impact of these new or amended standards and interpretations that are issued and become effective for the 2023 annual reporting period.

4 Basis of consolidation

The basis of consolidation includes the entities over which Centogene N.V. has control within the meaning of IFRS 10 Consolidated Financial Statements. According to IFRS 10, Centogene N.V. has control of an investee when it has direct or indirect power over the investee, exposure, or rights to variable returns from its involvement with the investee and the ability to use its power over the investee to affect those returns. Control is established when it is possible to influence operating and financial policies of the investee, typically with a share in the voting rights or shareholding of more than 50% in the investee. An entity is included in the Group's basis of consolidation from the point in time when the Group obtains control of the entity and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated financial statements from the date the Group gains control until the date the Group ceases to control the subsidiary.

Profit or loss and each component of other comprehensive income are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full upon consolidation.

If the Group loses control over a subsidiary, it derecognizes the related assets, liabilities, non-controlling interest and other components of equity, while any resultant gain or loss is recognized in profit or loss.

In the third quarter of 2020, the Company entered into a collaboration agreement with Dr. Bauer Laboratoriums GmbH, Rostock (hereafter 'Dr. Bauer GmbH'). Dr. Bauer GmbH supported Centogene in certain areas of its COVID-19 testing business by providing the medical laboratory services to facilitate Centogene to perform its COVID-19 testing business activities. Dr. Bauer GmbH is wholly owned by a long-time employee of Centogene, who from a medical perspective and by observing the Medical Association's professional code of conduct continues to operate as an independent medical physician. As per the criteria in IFRS 10, Centogene assessed the control it had over Dr. Bauer GmbH and concluded to consolidate the activities of Dr. Bauer GmbH in the Group from the third quarter of 2020.

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At the end of the third quarter of 2021, management updated its long-term outlook for the COVID-19 testing business, which led to management’s decision to initiate a wind down process of relevant operations.

As of March 31, 2022, operations at all COVID-19 testing sites have ceased and the Group has abandoned the COVID-19 business line. Consequently, the Group is reporting its COVID-19 segment as a discontinued operation (Note 9). With the decision to cease COVID-19 operations as of March 31, 2022, Centogene terminated its cooperation agreement with Dr. Bauer GmbH with a separation agreement effective as of April 2, 2022 and signed on August 23, 2022 (the “Separation Agreement”). With the COVID-19 business being discontinued and the collaboration agreement being terminated, Centogene’s control over Dr. Bauer GmbH ceased; Centogene no longer meets the criteria of the control model under IFRS 10 as it no longer has exposure to variable returns and the ability to use power to affect returns through COVID-19 operations. Therefore, Centogene deconsolidated Dr. Bauer GmbH from its consolidated financial statements as of April 2, 2022 (“Deconsolidation Date”). The impact of the deconsolidation on the loss for the period and on the statement of cash flows is disclosed under Note 9 – Discontinued operations. The impact of the deconsolidation on the statement of financial position is disclosed under Note 26 – Related parties.

5 Significant accounting policies

The Group applied the following accounting policies consistently for all of the periods presented in these consolidated financial statements.

(a) Foreign currency and currency translation

The Group’s consolidated financial statements are presented based on the parent company’s functional currency. For each entity, the Group determines the functional currency and items included in the financial statements of each entity are measured using that functional currency. The Group uses the direct method of consolidation and on disposal of a foreign operation, the gain or loss that is reclassified to profit or loss reflects the amount that arises from using this method.

Transactions in foreign currency are translated into the respective entity’s functional currency at the spot rate prevailing on the date of the transaction.

The functional currency of each entity is the respective local currency, since the entities carry out their business activities independently from a financial, economic and organizational perspective.

Monetary assets and liabilities denominated in foreign currency are translated to the functional currency using the closing rate at the reporting date. Currency translation differences are recognized immediately through profit or loss. Non-monetary items denominated in a foreign currency that are measured at historical cost are not translated at the reporting date.

On consolidation, the assets and liabilities of foreign operations are translated into euros using the closing rate on the reporting date. Income and expenses of foreign operations are translated using the exchange rate prevailing on the date of the transaction or the annual average exchange rate. Equity is translated using historical rates until the entity is removed from the Group’s basis of consolidation. Any resulting currency translation differences are recorded in other comprehensive income and recognized under the currency translation reserve in equity if the exchange difference is not allocable to the non-controlling interests.

The exchange rates used are presented in the following table:

	Average rate			Closing rate		
	2022	2021	2020	Dec 31, 2022	Dec 31, 2021	Dec 31, 2020
USD (EUR 1)	1.05	1.13	1.14	1.07	1.13	1.23
AED (EUR 1)	3.87	4.15	4.21	3.94	4.17	4.50
INR (EUR 1)	82.69	85.18	84.57	88.17	84.23	89.66
CHF (EUR 1)	1.00	1.08	—	0.98	1.03	—
RSD (EUR 1)	117.46	117.39	—	117.33	117.27	—

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(b) Revenues from contracts with customers

The Group provides pharmaceutical solutions and diagnostic tests, enabled by its knowledge and interpretation-based platform. Revenue from contracts with customers is recognized when control of the goods or services are transferred to the customer at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services, usually on delivery of the goods.

(i) Pharmaceutical segment

The Group's contracts with customers relate to a variety of solutions provided to the Group's pharmaceutical partners in order to accelerate their development of treatments for rare diseases, including early patient recruitment and identification, epidemiological insights, biomarker discovery and patient monitoring. The collaboration agreements are structured on a fee per analysis basis, milestone basis, fixed fee basis, or a combination of these. In addition, some of the Group's contracts with its pharmaceutical partners also include sales of CentoCard filter cards for the collection of biological samples from patients.

The performance obligations in Pharmaceutical segment can either be satisfied over time or at a point in time depending on the structure of the collaborations, which are determined based on nature of the service provided, as detailed below.

- Revenue from early patient recruitment and identification, epidemiological insights, biomarker discovery and patient monitoring is based on fee per analysis, milestone fees and fixed fees. The revenues from these solutions are recognized over time using an input method based on the work rendered in order to measure progress towards complete satisfaction of the services.
- Revenue from the licensing of intellectual property for an unlimited period, usually in the structure of an upfront fee, is recognized at a point in time, when the right (or license) to use intellectual property is conveyed.
- Revenues from the licensing of intellectual property for a certain period, being a right to access such intellectual property as defined in IFRS 15, is recognized over time over the licensing period.
- Revenue from the sale of CentoCard filter cards is recognized at a point in time when the control of the CentoCard filter cards has transferred to the customer, which typically occurs on delivery.

(ii) Diagnostics segment

Revenues from the Group's Diagnostic segment are typically generated from genetic sequencing and diagnostics services that the Group provides to clients, who are typically physicians, laboratories or hospitals, either directly or through distributors. Revenues are based on a negotiated price per test or on the basis of agreements to provide certain testing volumes over defined periods. The Group has concluded that the services rendered in the Diagnostic segment comprise one performance obligation.

The performance obligation in the Diagnostics segment is recognized over time, using an input method to measure progress towards complete satisfaction of the service. In order to measure progress, the Group uses a standardized process which measures progress to completion by stages, consisting of (i) a preparation stage, (ii) a clarification stage, (iii) a sequencing stage, and (iv) an output stage. The percentages attributed to those stages are indicative of the cost incurred in performing the respective stage in relation to total cost.

Contract balances

(i) Contract assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If the Group satisfies a performance obligation by transferring goods or services to a customer before the customer pays consideration or before payment is due, a contract asset is recognized for the earned consideration that is conditional. Contract assets are subject to impairment assessment. Refer to accounting policies of impairment of financial assets in Note 5(n) "Financial instruments".

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(ii) Trade receivables

A receivable represents the Group's right to an amount of consideration that is unconditional (i.e., only the passage of time is required before payment of the consideration is due). Refer to accounting policies of impairment of financial assets in Note 5(n) "Financial instruments".

(iii) Contract liabilities

A contract liability is the obligation to transfer goods or services to a customer for which the Group has received consideration or an amount of consideration is due from the customer (whichever is earlier). If a customer pays consideration before the Group transfers goods or services to the customer, a contract liability is recognized when the payment is made or the payment is due (whichever is earlier). Contract liabilities are recognized as revenue when the Group performs under the contract.

(c) Finance income and finance costs

Interest income and expenses are recognized in the period which they relate to through profit or loss using the effective interest rate method.

(d) Current versus non-current classification

The Group presents assets and liabilities in the statement of financial position based on current/non-current classification. An asset is current when it is:

- Expected to be realized or intended to be sold or consumed in the normal operating cycle
- Held primarily for the purpose of trading
- Expected to be realized within twelve months after the reporting period; or
- Cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period

All other assets are classified as non-current.

A liability is current when:

- It is expected to be settled in the normal operating cycle
- It is held primarily for the purpose of trading
- It is due to be settled within twelve months after the reporting period; or
- There is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period

The terms of the liability that could, at the option of the counterparty, result in its settlement by the issue of equity instruments do not affect its classification.

The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities.

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(e) Intangible assets

Research and development

Expenses for research activities are recognized through profit or loss in the period in which they are incurred.

Development expenditures on an individual project are recognized as an intangible asset from the date the Group can demonstrate:

- the product or process is technically and commercially feasible so that the asset will be available for use or sale
- the Group has the ability and intention to use or sell the asset
- a future economic benefit is probable
- the Group has sufficient resources to complete the development and
- the development costs can be measured reliably.

The Group's research and development activities mainly relate to development of biomarkers where likelihood for future commercialization is probable, constant innovation for the Diagnostic and Pharmaceutical businesses with new or enhanced products, continuous improvement on the bioinformatics pipelines, AI capabilities and Medical Reporting automatization and IT driven solutions. With respect to biomarkers, the development stage is usually considered to be achieved when the target validation process is completed, and commercialization is probable. For the Diagnostics R&D the most important development is related to the launching in 2022 of multiomics referring to an integrative approach in biological research that involves the analysis of multiple omics datasets aiming to improve even further the precision of our diagnostic services. Regarding the innovation on bioinformatics, main efforts are put on enhancing the automatization of identification of disease-causing variants via variant prioritization and classification to speed up and improve diagnosis. In the realm of IT-driven solutions, there is a growing focus on automating data processing and analytics through cloud-based platforms.

Capitalized development costs are recognized at cost less accumulated amortization and any accumulated impairment losses. They are only amortized from the date the asset is ready for its intended use, which in the case of biomarkers is normally at the time the patent application for such biomarker is made. Amortization expense is recorded in cost of sales and research and development expenses.

Capitalized development costs which are still under development are tested for impairment annually and when circumstances indicate that the carrying value may be impaired.

Other intangible assets

Other intangible assets purchased by the Group with finite useful lives are recognized at cost less accumulated amortization and any accumulated impairment losses. Subsequent expenditure is only capitalized if it increases the future economic benefits of the respective asset.

Intangible assets are amortized over their estimated useful life using the straight-line method and assessed for impairment whenever there is an indication that the intangible asset may be impaired.

The estimated useful lives are as follows:

- Software, patents and trademarks: 3-7 years
- Capitalized development costs: 7 years

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The useful lives and depreciation methods are reviewed annually to ensure that the methods and periods of depreciation are consistent with the expected economic benefit from the asset.

(f) Property, plant and equipment

Property, plant and equipment are carried at cost less any accumulated depreciation and any accumulated impairment losses.

The cost of property, plant and equipment comprises its purchase price including customs duties and non-refundable acquisition taxes, and proportionate VAT not deductible from input tax as well as any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Subsequent expenditure is only capitalized if it is probable that the future economic benefits associated with the expenditure will flow to the Group.

Depreciation is calculated over the estimated useful life using the straight-line method. The Group has assessed that none of its property, plant and equipment has a residual value. The estimated useful lives of significant property, plant and equipment are as follows:

- Buildings: 12 years and
- Plant and other equipment, furniture and fixtures: 2-15 years

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of comprehensive loss when the asset is derecognized.

The depreciation methods, useful lives and residual values are reviewed, and adjusted prospectively if appropriate, as of each reporting date.

Assets under construction are reported at cost and are allocated to property, plant and equipment until they are completed and put into operational use, from which point onwards they are depreciated.

(g) Leases

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(i) Right-of-use assets

The Group recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its lease term and the estimated useful lives, as follows:

- Buildings: 33 years
- Offices: 4 – 12 years and

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- Plant and other equipment, furniture and fixtures: 2-15 years

If ownership of the leased asset transfers to the Group at the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

The right-of-use assets are also subject to impairment. Refer to accounting policies of impairment of financial assets in Note 5(n) "Financial instruments".

(ii) Lease liabilities

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for leases reasonably certain to be terminated. The variable lease payments that do not depend on an index or a rate are recognized as expenses in the period during which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

(iii) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value (i.e., below EUR 5k). Lease payments on short-term leases and leases of low-value assets are recognized as expenses on a straight-line basis over the lease term.

(iv) Sale and leaseback transactions

The Group applies IFRS 15 for determining if the transfer of an asset to the buyer (lessor) is to be accounted for as a sale of assets. After the sale of assets is concluded, the Group measures the right-of-use assets arising from the leaseback at the proportion of the previous carrying value of the asset that relates to the right of use retained by the Group. Accordingly, the Group recognizes only the amount of any gain or loss that relates to the rights transferred to the buyer (lessor).

If the fair value of the consideration for the sale of an asset does not equal the fair value of the asset, or if the payments for the leases are not at market rates, the Group makes the following adjustments to measure the sale proceeds at fair value:

- any below-market terms shall be accounted for as a prepayment of lease payments
- any above-market terms shall be accounted for as additional financing provided by the buyer-lessor to the seller-lessee.

(h) Impairment of non-financial assets

Property, plant and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Whenever the carrying amount of an asset exceeds its recoverable amount, an impairment loss is recognized in profit or loss. The recoverable amount is measured as the higher of fair value less costs to sell and value in use. Recoverable amounts are estimated either for individual assets or, if an individual asset does not generate cash flows independently of other assets, for the whole cash-generating unit.

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(i) Inventories

Inventories are measured at the lower of cost and net realizable value. Inventories are recognized at cost based on the first in first out (FIFO) method.

Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

(j) Government grants

Government grants are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. Grants that are intended to compensate the Group for expenses incurred are recognized through profit or loss in the period in which expenses are submitted and claimed.

Government grants which relate to an asset are initially recognized as deferred income at nominal amounts. They are subsequently released to profit or loss on a systematic basis over the expected useful life of the related asset.

The release of deferred income related to either type of grant is presented as other operating income (see Note 8.1).

(k) Share-based payments

Plan recipients (including senior executives and certain member of the Supervisory Board) of the Group receive remuneration in the form of share-based payments, whereby the recipients render services as consideration for equity instruments (equity-settled transactions) or settled in cash (cash-settled transactions).

Equity settled transactions

The cost of equity-settled transactions is determined by the fair value of the granted options when the grant is made, using a Black-Scholes or Monte Carlo simulation model, with further details given in Note 21.

The cost is recognized in employee benefits expense (see Note 8.4) or other relevant expenses, together with a corresponding increase in equity (capital reserves), over the period in which the service conditions are fulfilled (the vesting period). The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The expense or credit in profit or loss for a period represents the movement in cumulative expense recognized as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

No expense is recognized for awards that do not ultimately vest because non-market performance and/or service conditions have not been met. Where awards include a market or non-vesting condition, the transactions are treated as vested irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

If the terms and conditions of a cash-settled share-based payment transaction are modified with the result that it becomes an equity-settled share-based payment transaction, the transaction is accounted for as such from the date of the modification. Specifically, the equity-settled share-based payment transaction is measured by reference to the fair value of the equity instruments granted at the modification date and recognized in equity. The liability for the cash-settled share-based payment transaction as at the modification date is derecognized on that date. Any difference between the carrying amount of the liability derecognized and the amount of equity recognized on the modification date is recognized immediately in profit or loss.

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Cash-settled transactions

A liability is recognized for the fair value of cash-settled transactions. The fair value is measured initially and at each reporting date up to and including the settlement date, with changes in fair value recognized in employee benefits expense (see Note 8.4). The fair value per option is determined using the Black-Scholes model, further details of which are given in Note 21. The fair value per option is then multiplied by the Group's best estimate of the number of awards expected to vest and the portion of the expired vesting period (period in which the service conditions are fulfilled). The cumulative amount of expense recognized will be equal to the cash that is paid on settlement.

(l) Provisions, contingent assets and contingent liabilities

A provision is recognized when the Group has a present obligation (legal, contractual or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. When the Group expects some or all of a provision to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain. The expense relating to a provision is presented in the profit or loss net of any reimbursement. Provisions are reviewed at each reporting date and adjusted to reflect the current best estimate.

If the requirements for recognizing a provision are not satisfied, the corresponding obligations are recorded as contingent liabilities unless the possibility of an outflow of resources embodying economic benefits is remote.

A contingent asset is a possible asset that arises from past events and whose existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the Group. The Group does not recognize a contingent asset. Contingent assets are disclosed in the notes if the inflow of economic benefits is probable, but not virtually certain. When the inflow of economic benefits becomes virtually certain, the asset is no longer contingent and its recognition is appropriate.

(m) Income taxes

Tax expense comprises current and deferred taxes. Current taxes and deferred taxes are recognized through profit or loss apart from deferred taxes related to items recognized outside profit or loss, in which case it is recognized in correlation to the underlying transaction either directly in equity or in other comprehensive income.

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

Deferred taxes are set up for temporary differences between the carrying amounts of assets and liabilities for group financial reporting purposes at the reporting date and the amounts used for tax purposes. Deferred tax liabilities are recognized for all taxable temporary differences, except:

- temporary differences arising from the initial recognition of assets or liabilities in the course of a business transaction that is not a business combination and does not affect either the accounting profit or the taxable profit or loss
- temporary differences associated with investments in subsidiaries if the Group controls the timing of the reversal of the temporary differences, and it is probable that the differences will not reverse in the foreseeable future.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

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Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset against each other if certain conditions are met.

(n) Financial instruments

(i) Financial assets

The Group's financial assets principally consist of those accounted for as receivables, contract assets, financial assets at fair value through profit or loss and cash and cash equivalents.

Receivables and contract assets

Receivables, including contract assets, are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Contract assets and trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15. Refer to the accounting policies in note 5(b) "Revenues from contracts with customers".

After initial recognition, receivables and contract assets are subsequently carried at amortized cost using the effective interest rate method less any impairment losses. Gains and losses are recognized in the profit or loss for the period when the assets are derecognized or impaired.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognized in the statement of profit or loss.

A derivative embedded in a hybrid contract, with a financial liability or non-financial host, is separated from the host and accounted for as a separate derivative if: the economic characteristics and risks are not closely related to the host; a separate instrument with the same terms as the embedded derivative would meet the definition of a derivative; and the hybrid contract is not measured at fair value through profit or loss. Embedded derivatives are measured at fair value with changes in fair value recognized in profit or loss. Reassessment only occurs if there is either a change in the terms of the contract that significantly modifies the cash flows that would otherwise be required or a reclassification of a financial asset out of the fair value through profit or loss category.

Derecognition

A financial asset or a part of a financial asset is derecognized when the Group no longer has the contractual rights to the asset or the right to receive cash flows from the asset have expired.

Impairment

The Group recognizes an allowance for expected credit losses (ECLs). ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate.

The Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

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The Group considers a financial asset in default when contractual payments are 360 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Further disclosures relating to impairment of trade receivables, including contract assets, are in note 22.

(ii) Financial liabilities

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade and other payables, loans and borrowings including bank overdrafts and derivative financial instruments, including warrant liabilities.

Loans and borrowings

Loans and borrowings are initially recognized at fair value and subsequently measured at amortized cost using the effective interest rate method, taking into account any principal repayments and any discount or premium on acquisition and including transaction costs and fees that are an integral part of the effective interest rate.

Gains or losses are recognized through profit or loss at the time the liabilities are derecognized or disposed of.

Financial liabilities at fair value through profit or loss

Financial liabilities at fair value through profit or loss include financial liabilities designated upon initial recognition as at fair value through profit or loss. Financial liabilities are classified as held for trading if they are incurred for the purpose of repurchasing in the near term. This category also includes derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments. Gains or losses on liabilities held for trading are recognized in the statement of profit or loss. Financial liabilities designated upon initial recognition at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied.

Warrant liabilities

Warrants are classified as equity to the extent that they confer the right to purchase a fixed number of shares for a fixed exercise price. In the event that the exercise price or the numbers of shares to be issued are not deemed to be fixed, the warrants are classified as a non-current derivative financial liability. Since the exercise price of the warrants is determined in US dollars which is different from the Company's functional currency, warrants are classified as liabilities. This liability is initially recognized at its fair value on the date the contract is entered into and subsequently accounted for at fair value through profit and loss (FVTPL) at each reporting date. As the warrants are classified as financial liabilities at FVTPL, the transaction costs are expensed in the consolidated statements of comprehensive loss.

Derecognition

A financial liability is derecognized when the obligation underlying the liability is discharged, canceled or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognized through profit or loss.

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(o) Cash and cash equivalents

Cash and cash equivalents comprise cash on hand and bank balances, including short-term, highly liquid investments that can be quickly converted into cash amounts. These have original maturities of three months or less and are subject to a low risk of fluctuation in value.

6 Accounting judgments and estimates

The preparation of the consolidated financial statements requires the management board to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of revenues, expenses, assets and liabilities, and the accompanying disclosures. Actual results could differ from those estimates. Estimates and underlying assumptions are reviewed on an ongoing basis and revisions of estimates are recorded prospectively.

6.1 Judgments

Development costs

Development costs are recognized in accordance with the accounting policy for certain internally generated assets. The Group's research and development activities mainly relate to development of biomarkers, AI capabilities and Medical Reporting automatization and IT driven solutions. With respect to biomarkers, the development stage is usually considered to be achieved when the target validation process is completed and commercialization is probable. With respect to AI capabilities and Medical Reporting automatization and IT driven solutions, the development stage is considered to be achieved upon the completion of the Group's internal validation test. Before such date, any development costs are recognized in profit or loss and may not be subsequently capitalized. As of December 31, 2022, the carrying amount of capitalized development costs was EUR 6,972k (2021: EUR 7,941k). This amount includes investments in the development of biomarkers, AI capabilities and Medical Reporting automatization and IT driven solutions (the new ERP).

Provision for expected credit losses of trade receivables and contract assets

The Group uses a provision matrix to calculate ECLs for trade receivables and contract assets. The provision rates are based on days past due for groupings of various customer segments that have similar loss patterns (e.g. by segment, geography, customer type and rating).

The provision matrix is initially based on the Group's historical observed default rates. The Group will calibrate the matrix to adjust the historical credit loss experience with forward-looking information. For instance, if forecasted economic conditions (i.e., gross domestic product) are expected to deteriorate over the next year which can lead to an increased number of defaults in the manufacturing sector, the historical default rates are adjusted. At every reporting date, the historical observed default rates are updated and changes in the forward-looking estimates are analyzed.

The assessment of the correlation between historical observed default rates, forecasted economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and of forecasted economic conditions. The Group's historical credit loss experience and forecast of economic conditions may also not be representative of customer's actual default in the future. The information about the ECLs on the Group's trade receivables and contract assets is disclosed in Note 22.

Deferred tax asset on loss carryforwards

The tax losses carried forward do not expire. In the light of the Company's loss history, the recognition of deferred taxes for tax losses carried forward and deductible temporary differences is limited to the future reversal of existing taxable temporary differences.

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Fair value measurement of financial instruments

When the fair values of financial assets and liabilities recorded in the statement of financial position cannot be measured based on quoted prices in active markets, their fair values are measured using valuation techniques including the discounted cash flow model and option pricing models. The inputs to these models are taken from observable markets where possible, but where this is not feasible, a degree of judgement is required in establishing fair values. For the valuation of the loan hosting a multiple embedded option the Group used the Leveraged Loan Index spread for BBB companies and for C companies as boundary conditions. See Note 22.1 for further details.

Revenue implicit concession

The Group has a diagnostics customer in the Middle Eastern region with a history of significant payment delays. This history has resulted in the recognition of significant subsequent impairment losses by applying the expected credit loss method as the collection of the contractual consideration was historically considered probable upon recognition of revenue. In 2021, based on the developments in its collection experience, additional negotiations with the customer, and past experiences, the Group considered it necessary to reassess its judgments related to the recognition of revenue from contracts with this customer.

The Group's management concluded, based on the facts and circumstances and management's expectations regarding this customer, that this uncertainty in the amount of the contract consideration it expects to collect, and the likelihood of accepting a lower amount or changing payment terms represents an "implicit price concession" such that the contract consideration is variable.

Therefore, the Group's management estimates the amount of the contractual consideration it expects to ultimately collect and for which it is highly probable that related revenue recognized would not be subject to significant future reversals when such uncertainty is resolved. The Group's management estimates the implicit price concessions by applying an estimated rate of 2% (2021: 18% based primarily upon past collection history).

Despite the uncertainties related to the amount expected to be collected from the customer, based on experience and the facts and circumstances related to the customer, the Group considers it probable that it will collect 98% (2021: 82%) of the amount of estimated variable transaction price due to newly agreed payment plans established with the customer. Therefore, the Group records the difference between the billed amount and the amount estimated to be collectible as a reduction to revenue. At the end of each reporting period, and if necessary upon receipt of new information, the Group may revise the amount of the variable consideration included in the transaction price. The Group has applied this accounting policy and accounting estimate to arrangements with this customer prospectively with effect from the third quarter of 2021.

6.2 Assumptions and estimation uncertainties

Information concerning assumptions and estimation uncertainty that have a significant risk of causing a material adjustment to the fiscal year ended on December 31, 2022 are presented in the following disclosures. The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Share-based payments

Estimating fair value for share-based payment transactions requires a determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. For the measurement of the fair value of equity-settled transactions at the grant date (including those issued to replace the cash-settled transactions), the Group uses the Monte Carlo simulation model. The fair value at grant date of equity-settled transactions is not updated at the end of each reporting period.

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Valuation of Share Options

The Black-Scholes option pricing model requires the input of subjective assumptions, including assumptions about the expected life of share-based awards and share price volatility. The Monte Carlo simulation model utilizes multiple input variables to estimate the probability that market conditions will be achieved. As a company listed on the Nasdaq stock exchange in 2019, the Group's share price only has limited sufficient historical information to be used as a reference, and therefore subjective inputs were included when estimating the fair value of our common shares to be used in both option pricing models.

In addition, our management used different key assumptions in the models to calculate the fair value. The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in Note 21.

The Group intends to continue to consistently apply this methodology using the same comparable companies until a sufficient amount of historical information regarding the volatility of our own share price as a public company becomes available.

Going Concern

In assessing whether the going concern assumption is appropriate and whether there are material uncertainties that may cast significant doubt about our ability to continue as a going concern, management must estimate future cash flows for a period of at least twelve-months following the end of the reporting period by considering relevant available information about the future. Management has considered a wide range of factors relating to expected cash inflows which are subject to uncertainty, including the forecasted revenue from the Diagnostics and Pharmaceutical segments, as well as whether we will enter into any new significant pharmaceutical partnerships, and potential sources of convertible debt and equity financing available to us. Management has also estimated expected cash outflows such as operating and capital expenditures and debt repayment schedules, including the ability to delay uncommitted expenditures, and implementation of certain planned cost saving measures. Estimated future cash flows are derived from cash inflows from projected revenues less projected cash costs and are based on the approved budget adjusted for any earnings that have come from the year-to-date performance. Estimated future cash flows have been prepared based on assumptions such as revenue growth rates by segment, savings from planned cost measures and additional funding provided through various means of capital raising and working capital strategies.

7 Segment information and revenue from contracts with customers

7.1 Segment information

For management purposes, the Group is organized into business units based on its products and services. In line with the management approach, the operating segments were identified on the basis of the Group's internal reporting and how the chief operating decision maker ("CODM") assesses the performance of the business. On this basis, the Group has the following two operating segments, which also represent the Group's reportable segments:

- **Pharmaceutical segment:** This segment provides a variety of solutions to our pharmaceutical partners, including target and drug screening, clinical development, market access and expansion, as well as CENTOGENE Biodatabank Licenses and Insight Reports; and
- **Diagnostic segment:** This segment provides genetic sequencing and diagnostics services to our clients, who are typically physicians, laboratories or hospitals, either directly or through distributors.

In 2021, the Group decided to end its COVID-19 business activities in Q1 2022. The Group assessed that ending the activities of this operating segment would qualify as a discontinued operation. Therefore, the profit or loss related to the COVID-19 business is presented in a separate line item of the profit and loss section of the consolidated statements of comprehensive loss for the years ended December 31, 2022, 2021, and 2020 (see Note 9 – Discontinued Operations).

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The management board is the CODM and monitors the operating results of the segments separately for the purpose of making decisions about resource allocation and performance assessment. Segment performance is evaluated based on segment results and is measured with reference to the Adjusted EBITDA. Adjusted EBITDA is a financial measure which is not prescribed by IFRS, which the Group defines as income/loss before finance costs (net), taxes, and depreciation and amortization (including impairments), adjusted to exclude corporate expenses, one-off costs, as well as share-based payment expenses.

Corporate expenses, interest and similar income and expenses, as well as share-based payment expenses are not allocated to individual segments as the underlying instruments are managed on a group basis. Assets and liabilities are managed on a Group basis and are not allocated to the different segments for internal reporting purposes. Therefore, our CODM does not regularly review this information by segment and accordingly we do not report this information by segment.

	2022			
in EUR k	Pharmaceutical	Diagnostics	Corporate	Total
Total Revenues from contracts with external customers	16,115	31,358	—	47,473
Adjusted EBITDA	6,802	6,438	(41,097)	(27,857)
Capital Expenditures				
Additions to property, plant and equipment and right-of-use assets	1,244	910	1,225	3,379
Additions to intangible assets	162	14	1,551	1,727
Other segment information				
Depreciation and amortization (including impairments)	801	1,790	6,340	8,932
Research and development expenses	—	—	17,488	17,488
	2021			
in EUR k	Pharmaceutical	Diagnostics*	Corporate	Total
Total Revenues from contracts with external customers	15,641	26,593	—	42,234
Adjusted EBITDA	4,785	3,030	(45,939)	(38,124)
Capital Expenditures				
Additions to property, plant and equipment and right-of-use assets	690	261	936	1,887
Additions to intangible assets	2,401	—	386	2,787
Other segment information				
Depreciation and amortization (including impairments)	2,076	2,539	5,849	10,464
Research and development expenses	—	—	19,297	19,297
	2020			
in EUR k	Pharmaceutical	Diagnostics*	Corporate	Total
Total Revenues from contracts with external customers	16,951	21,502	—	38,453
Adjusted EBITDA	6,194	(2,912)	(42,335)	(39,053)
Capital Expenditures				
Additions to property, plant and equipment and right-of-use assets	333	602	2,682	3,617
Additions to intangible assets	3,183	—	1,802	4,985
Other segment information				
Depreciation and amortization	6,769	2,289	4,670	13,728
Research and development expenses	—	—	14,935	14,935

* Total Revenues from contracts with external customers have been restated for the years ended December 31, 2021 and 2020. Refer to Note 2.4.

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Adjustments

Adjustments to income/ loss include non-cash charges in relation to depreciation, amortization (including impairments), one-off costs, share-based payments as well as net financial costs and income taxes. Certain costs, and related income, are not allocated to the reporting segment results and represent the residual operating activities of the Group reported as 'Corporate'. These costs include general financing costs and corporate overheads related to, centralized functions such as communications, information technology, facilities, legal, finance and accounting, insurance (D&O), human resources, business development and strategic initiatives, certain professional and consulting services, procurement, research and development and other supporting activities.

Corporate expenses contain the costs incurred for the process of obtaining the equity and debt financing amounted to EUR 2,161 (2021: nil; 2020: nil) which were not directly attributable to the Oxford Loan or issuance of shares. Corporate expenses also include expenses incurred in relation to capital raising activities in 2022. For the year ended December 31, 2022, were incurred expenses for EUR 450k for the securities purchase agreement (2021: nil; 2020 July Offering: EUR 278k).

Reconciliation of segment Adjusted EBITDA to Group loss for the period

in EUR k	2022	2021*	2020*
Reportable segment Adjusted EBITDA	13,240	7,815	3,282
Corporate expenses	(41,097)	(45,939)	(42,335)
	(27,857)	(38,124)	(39,053)
Share-based payment expenses (Note 21)	16	(8,035)	(5,658)
Depreciation and amortization (including impairments)	(8,932)	(10,464)	(13,728)
Operating loss	(36,773)	(56,623)	(58,439)
Financial costs, net	(1,823)	(799)	(1,375)
Income taxes	(107)	70	(223)
Loss for the year	(38,703)	(57,352)	(60,038)

*Reportable segment Adjusted EBITDA has been restated for the years ended December 31, 2021, and 2020. Refer to Note 2.4.

Non-current asset locations

Non-current assets of the Group consist of right-of-use assets (under IFRS 16), property, plant and equipment, as well as intangible assets. All of such assets are located in Germany, which is the country of the business address of the Centogene GmbH, except for property, plant and equipment of EUR 76k (2021: EUR 147k; 2020: EUR 516k) and right-of-use assets for nil EUR as of December 31, 2022 (2021: EUR 137k; 2020: EUR 411k), which are located in the United States.

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7.2 Revenue from contracts with customers

in EUR k	2022		
	Pharmaceutical	Diagnostics	Total
Rendering of services	15,420	31,358	46,778
Sales of goods	695	—	695
Total Revenues from contracts with external customers	16,115	31,358	47,473
Recognized over time	15,420	31,358	46,778
Recognized at a point in time	695	—	695
Total Revenues from contracts with external customers	16,115	31,358	47,473
Geographical information			
Europe	361	5,927	6,288
—Germany*	—	307	307
—Netherlands**	—	7	7
Middle East	352	19,550	19,902
—Saudi Arabia#	—	12,412	12,412
North America	15,346	1,245	16,591
—United States#	15,346	1,179	16,525
Latin America	56	3,851	3,907
Asia Pacific	—	786	786
Total	16,115	31,358	47,473
in EUR k			
	2021 (Restated)		
	Pharmaceutical	Diagnostics ^(d)	Total
Rendering of services	14,879	26,593	41,472
Sales of goods	762	—	762
Total Revenues from contracts with external customers	15,641	26,593	42,234
Recognized over time	14,879	26,593	41,472
Recognized at a point in time	762	—	762
Total Revenues from contracts with external customers	15,641	26,593	42,234
Geographical information			
Europe	490	5,425	5,915
—Germany*	—	211	211
—Netherlands**	—	6	6
Middle East	117	16,315	16,432
—Saudi Arabia#	—	9,865	9,865
North America	14,940	1,643	16,583
—United States#	14,940	1,456	16,396
Latin America	94	2,499	2,593
Asia Pacific	—	711	711
Total	15,641	26,593	42,234

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in EUR k	2020 (Restated)		
	Pharmaceutical	Diagnostics ⁽¹⁾	Total
Rendering of services	15,947	21,502	37,449
Sales of goods	1,004	—	1,004
Total Revenues from contracts with external customers	16,951	21,502	38,453
Recognized over time	15,947	21,502	37,449
Recognized at a point in time	1,004	—	1,004
Total Revenues from contracts with external customers	16,951	21,502	38,453
Geographical information			
Europe	149	5,605	5,754
—Germany*	—	186	186
—Netherlands**	—	3	3
Middle East	56	12,568	12,624
—Saudi Arabia#	56	7,696	7,752
North America	16,711	970	17,681
—United States#	16,711	764	17,475
Latin America	35	1,851	1,886
Asia Pacific	—	508	508
Total	16,951	21,502	38,453

* country of the incorporation of Centogene GmbH

** country of the incorporation of Centogene N.V.

countries contributing more than 10% of the Group's total consolidated revenues for the respective year ended December 31, 2022, 2021 or 2020

⁽¹⁾ Total Revenues from contracts with external customers have been restated for the years ended December 21, 2021, and 2020. Refer to Note 2.4.

The Group collaborated with the majority of our pharmaceutical partners on a worldwide basis in 2022, 2021 and 2020. In addition, in cases where our pharmaceutical partners are developing a new rare disease treatment, it is generally anticipated that the final approved treatment will be made available globally. As a result, we allocate the revenues of our Pharmaceutical segment by geographical region by reference to the location where each pharmaceutical partner mainly operates, which is based on the region from which most of their revenues are generated. The allocation of revenues in our Diagnostic segment is based on the location of each customer.

Pharmaceutical segment

During the year ended December 31, 2022, revenues from one pharmaceutical partner represented 15.5% of the Group's total revenues (2021: 24.8%; 2020: 8.6%). As of December 31, 2022, the amount of revenues recognized that were included in the contract liability balance at the beginning of the period is EUR 1,951k (2021: EUR 3,201k; 2020: EUR 3,088k).

During the year ended December 31, 2022, we entered into collaboration agreements with certain pharmaceutical partners, of which upfront fees of approximately EUR€ 566k were received in relation to setup fees which will be recognized as revenue over the period of the partnership collaboration. During the year ended December 31, 2021, Centogene entered into several collaborations with pharmaceutical partners, of which upfront fees totaling EUR 455k were received. No such payments were received or revenues recognized for the year ended December 31, 2020.

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Diagnosics segment

During the year ended December 31, 2022, revenues from Diagnostic segment represented 66% of the Group's total revenues (2021: 63%; 2020: 56%). Revenues from the major diagnostic partner represented 17.0% of the Group's total revenues.

Contract balances

in EUR k	Dec 31, 2022	Dec 31, 2021 (Restated)	Jan 1, 2021 (Restated)
Trade receivables (note 16)	13,637	21,065	25,656
Contract assets (note 16)	2,911	2,397	3,332
Contract liabilities (note 20.2)	651	4,842	4,479

The contract assets primarily relate to the Group's rights to consider for work completed but not billed at the reporting date on the tests for the Diagnostic segment, with the satisfaction of the respective performance obligation measured by reference to stages in a standardized process. The contract assets also include work performed for pharmaceutical partners which are based on milestone fees. In 2022, EUR 10k (2021: EUR 483k; 2020: EUR 356k) was recognized as provision for expected credit losses on contract assets (see Note 22). The contract assets are transferred to receivables when the rights become unconditional. This usually occurs when the Group issues an invoice to the customer.

The contract liabilities as of December 31, 2022, amount to EUR 651k (2021: EUR 2,506k; 2020: EUR 2,516k) which relate to the advance consideration, including various contracts with performance obligations, received from pharmaceutical partners for which revenue is recognized over time, and consideration from sales of CentoCard filter cards which have not yet been delivered.

8 Other income and expenses

8.1 Other operating income

in EUR k	2022	2021 (Restated)	2020 (Restated)
Government grants	1,958	2,263	2,152
Gain on disposal of property, plant and equipment	53	18	2
VAT refund from tax authorities	970	—	—
Others	793	613	238
Total other operating income	3,774	2,894	2,392

Government grants contain performance-based grants to subsidize research, development and innovation in the state of Mecklenburg-Western Pomerania from funds granted by the European Regional Development Fund. Furthermore, government grants contain the release of deferred income from investment related grants. VAT refund from tax authorities consist of the amounts received for 2020, 2021 and 2022 financial years as a result of a change made to the VAT tax declarations of Centogene GmbH in agreement with the tax administration in Germany. Refer to Note 27 for further details.

8.2 Other operating expenses

in EUR k	2022	2021	2020
Currency losses	741	86	10
Other	—	—	172
Total other operating expenses	741	86	182

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8.3 Financial costs, net

<u>in EUR k</u>	<u>2022</u>	<u>2021</u>	<u>2020</u>
Interest expenses from loans	(2,934)	(218)	(154)
Changes in FV of warrants	2,574	—	—
Changes in FV of floor	(376)	—	—
Changes in FV of prepayment option	510	—	—
Currency losses	(963)	—	(362)
Unwinding of the discount on lease liabilities	(637)	(584)	(865)
Interest income from loans and receivables	3	3	6
Total	<u>(1,823)</u>	<u>(799)</u>	<u>(1,375)</u>

On January 31, 2022, the Company entered into the Loan Agreement with Oxford Finance LLC and the interest expenses recognized for it during 2022 were EUR 2,806k (2021: EUR nil; 2020: EUR nil). Related to the Oxford Loan, the Company also recognized EUR 963k (2021: EUR nil; 2020: EUR nil) of currency losses for the effects of the foreign exchange, EUR 510k (2021: EUR nil; 2020: EUR nil) as positive impact of the changes in the fair value of the prepayment option, and EUR 376k (2021: EUR nil; 2020: EUR nil) as negative impact of the changes in the fair value of the floor. Finally, “Changes in fair value of warrants” includes the effects of the change in the fair value of the warrants related to the securities purchase agreement and a warrant agreement signed on January 31, 2022 (see Note 22).

8.4 Employee benefits expense

<u>in EUR k</u>	<u>2022*</u>	<u>2021*</u>	<u>2020*</u>
Wages and salaries	29,690	32,655	28,008
Social security contributions	4,415	4,588	3,714
Share-based payments	(1,461)	5,471	3,486
Termination benefits	319	1,158	569
Total	<u>32,963</u>	<u>43,872</u>	<u>35,777</u>

*The comparative numbers have been re-presented as a result of discontinued operations. Refer to Note 9 – Discontinued Operations.

Social security contributions include contributions to state pension scheme of EUR 1,790k (2021: EUR 2,706k; 2020: EUR 1,851k) as defined contribution plan expenses. Additionally, the Company recognized compensation expense of EUR 1,631k (2021: EUR 3,252k; 2020: EUR 2,775k) for remuneration of supervisory board members, including share-based payments. Due to the departure of the former CEO Andrin Oswald, the former CFO René Just and former CIO Volkmar Weckesser in 2022, the share-based payment expenses include reversals of in previous periods recognized expenses based on cancelations and forfeiture of EUR 3,104k. (See “Note 21 Share-based Payments” of our consolidated financial statements as of and for the year ended December 31, 2022.)

9 Discontinued Operations

At the end of the third quarter of 2021, management updated its long-term outlook for the COVID-19 testing business, which led to management’s decision to initiate a wind down process in which lease contracts at unprofitable COVID-19 testing sites would not be renewed. Similarly, COVID-19 related inventory levels were significantly ramped down to align with the needs of the remaining test sites and laboratories.

As of March 31, 2022, operations at all COVID-19 testing sites have ceased. The Company has no intentions of renewing any of the COVID-19 testing site leases and has abandoned the COVID-19 business line. Consequently, the Company is reporting its COVID-19 segment as a discontinued operation.

All COVID-19 related property, plant and equipment have been fully depreciated as of March 31, 2022. In addition, all COVID-19 related accounts receivable and accounts payable are included in the balance sheet as of March 31, 2022 whilst all COVID-19 related inventory have been written down to zero.

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As detailed in Note 2.1, with the discontinuation of the COVID-19 business, the Group signed the Separation Agreement to terminate the collaboration agreement signed with Dr. Bauer GmbH, effective as of April 2, 2022. The Group deconsolidated Dr. Bauer GmbH from its financial statements as of this date and disclosed the impact of the deconsolidation under discontinued operations. With the Separation Agreement, Centogene ensures that any COVID-19 business related future obligations that might arise from the past activities of Dr. Bauer GmbH will be paid by Centogene in exchange for the EUR 1,640k termination fee which has been recognized under Net income from discontinued operations, net of tax for the year ended December 31, 2022. In addition, the Group recognized provision expenses under Net income from discontinued operations, net of tax in the total amount of EUR 832k to be paid to Dr. Bauer GmbH for the year ended December 31, 2022. Of this provision, EUR 200k, EUR 117k and EUR 515k have been recognized for refunds for unclaimed COVID-19 test vouchers, taxes and other provisions, respectively.

The impact of the Separation Agreement on net income for the period is EUR 1,640k, which is fully recognized under discontinued operations.

Additionally, EUR 57k and EUR 127k of unadjusted differences identified in trade receivables and revenue as of and for the years ended December 31, 2021 and 2020, respectively, are related to the COVID-19 business and corrected in discontinued operations. (Refer to Note 2.4).

Discontinued operations are presented separately from continuing operations in the consolidated statements of comprehensive loss and consolidated statements of cash flows.

	<u>2022</u>	<u>2021</u>	<u>2020</u>
in EUR k			
Results of discontinued operations			
Revenue	19,455	146,334	89,218
Cost of sales	15,120	131,713	48,151
Gross profit	4,335	14,621	41,067
General administrative expenses	503	3,259	2,495
Selling expenses	7	534	446
Other operating income	3,096	373	3
Other operating expenses			
Operating income	6,921	11,201	38,129
Financial costs, net	46	49	19
Income before taxes	6,875	11,152	38,110
Income tax expense	13	46	58
Income for the period	6,862	11,106	38,052
Total comprehensive income, attributable to equity holders of the parent	6,862	11,106	38,052
Net income per share - Basic and diluted (in EUR)	0.26	0.49	1.82

10 Income taxes

Taxes recognized through profit or loss:

in EUR k	<u>2022</u>	<u>2021*</u>	<u>2020*</u>
Current tax expenses	(152)	(72)	(16)
Current year	(144)	(56)	—
Adjustments for prior periods	(8)	(16)	(16)
Deferred tax (expense)/income	45	142	(208)
Temporary differences	45	142	(182)
Tax losses	—	—	(26)
Total income tax (expenses)/benefit	(107)	70	(224)

*The comparative numbers have been re-presented as a result of the discontinued operations. Refer to Note 9 – Discontinued Operations.

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No income taxes were recognized directly in other comprehensive income for the years ended December 31, 2022, 2021 and 2020.

A reconciliation of the effective tax rate to the Group's statutory rate of 32.1% for the year ended December 31, 2022, and 32.1% for the years ended December, 31, 2021 and December, 31, 2020, respectively are presented in the table below.

<u>in EUR k</u>	<u>2022</u>	<u>2021*</u>	<u>2020*</u>
Loss before tax	(38,596)	(57,532)	(59,552)
Taxes on the basis of the Company's domestic tax rate	12,390	14,642	6,627
Tax rate effect of foreign tax jurisdictions	78	882	65
Non-deductible expenses	(125)	(3,030)	(903)
Current year losses for which no deferred tax assets were recognized	(12,472)	(12,211)	(5,792)
Tax income related to prior years	(37)	(17)	(137)
Other effects	59	(196)	(84)
Income tax (expenses)/ benefit	(107)	70	(224)

*The comparative numbers have been re-presented as a result of the discontinued operations. Refer to Note 9 – Discontinued Operations.

The domestic tax rate of 32.1% is composed of the corporate income tax rate of 15%, the solidarity surcharge of 5.5% of this corporate income tax, as well as trade tax of 16.3%. The tax rate effects from foreign tax jurisdictions are primarily attributable to the tax-exempt profit of a foreign Group subsidiaries.

Tax losses carryforwards for which no deferred tax assets were recognized amount to EUR 133,512k in Germany (2021: EUR 85,639k; 2020: EUR 64,464k) and to EUR 2,348k in other countries (2021: EUR 1,083k; 2020: EUR 1,002k). Deductible temporary differences, for which no deferred tax asset is recognized, amount to EUR 2,310k.

Tax losses carried forward in Germany do not expire. Foreign tax losses carried forward may be restricted. In the light of the Group's loss history, the recognition of deferred taxes for tax losses carried forward and deductible temporary differences was limited to the future reversal of existing taxable temporary differences.

For temporary differences associated with investments in the amount of EUR 7,106k (2021: EUR 5,656k; 2020: EUR 4,313k), no deferred tax liability has been recognized because the Company is able to control the timing of the reversal and it is probable that the difference will not reverse in the foreseeable future.

The below table shows a breakdown of deferred taxes in the Group's statement of financial position.

<u>in EUR k</u>	<u>December 31, 2022</u>		<u>December 31, 2021</u>		<u>December 31, 2020</u>	
	<u>Deferred tax assets</u>	<u>Deferred tax liabilities</u>	<u>Deferred tax assets</u>	<u>Deferred tax liabilities</u>	<u>Deferred tax assets</u>	<u>Deferred tax liabilities</u>
Intangible assets	—	(2,184)	—	(2,439)	—	(2,934)
Property, plant and equipment	—	(21)	—	(14)	—	(133)
Right-of-use assets	—	(4,186)	—	(4,617)	—	(5,029)
Measurement of service contracts	—	(35)	—	(42)	—	(145)
Leasing liabilities	4,168	—	4,563	—	4,865	—
Government grants	1,679	—	1,693	—	1,903	—
Unused tax losses	544	—	777	—	1,266	—
Sum	6,391	(6,426)	7,033	(7,112)	8,034	(8,241)
Offset	(6,391)	6,391	(7,033)	7,033	(8,034)	8,034
Deferred Taxes	—	(35)	—	(79)	—	(207)

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11 Loss Per Share

Basic loss per share is calculated by dividing loss for the period attributable to equity holders of the Group by the weighted average number of shares outstanding during the same period. The weighted average number of outstanding shares for the year ended December 31, 2022 was 26,811,357 (2021: 22,437,301; 2020: 20,909,673).

For the periods included in these financial statements, the impact of outstanding share options and warrants are not included in the diluted loss per share calculation as the Company was loss-making in all periods. Due to the anti-dilutive nature of the outstanding share options and warrants, basic and diluted loss per share is equal. The warrants are exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares as of December 31, 2022 (2021: nil, 2020: nil)

Assets

12 Intangible assets

Reconciliation of carrying amounts

in EUR k	Internally generated /acquired biomarkers	Internally developed databases	Purchased rights, licenses, software	Total
Cost				
As of Jan 1, 2020	12,022	6,502	3,010	21,534
Additions	1,900	2,717	2,040	6,657
Deconsolidation	—	—	(151)	(151)
As of Dec 31, 2020	13,922	9,219	4,899	28,040
Additions	749	1,652	386	2,787
Reclassification	(297)	297	—	—
As of Dec 31, 2021	14,374	11,168	5,285	30,827
Additions	162	1,515	50	1,727
As of Dec 31, 2022	14,536	12,683	5,335	32,554
Accumulated amortization and impairment				
As of Jan 1, 2020	3,831	1,770	1,788	7,389
Amortization and impairment	6,917	943	508	8,368
Deconsolidation	—	—	(124)	(124)
As of Dec 31, 2020	10,748	2,713	2,172	15,633
Amortization and impairment	2,149	1,991	1,860	6,000
Reclassification	(68)	68	—	—
As of Dec 31, 2021	12,829	4,772	4,032	21,633
Amortization and impairment	801	1,845	875	3,521
As of Dec 31, 2022	13,630	6,617	4,907	25,154
Carrying amounts				
As of Dec 31, 2020	3,174	6,506	2,727	12,407
As of Dec 31, 2021	1,545	6,396	1,253	9,194
As of Dec 31, 2022	906	6,066	428	7,400

Development costs and amortization

Internally generated intangible assets include capitalized development costs for biomarkers and IT driven solutions such as the new ERP system (see notes 5 and 6 regarding measurement). The asset category “Internally developed databases” contains the Centometabolome, an Artificial Intelligence module created to accelerate biomarker developments. The carrying amount of this asset

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as of December 31, 2022, is EUR 2,181k (2021: EUR 2,540k; 2020: EUR 1,099k), and the remaining useful life as of December 31, 2022 is six years.

The amortization of patents, trademarks and development costs. is expensed and recorded under “cost of sales” to the extent the related intangible assets are used in generating revenue and recorded in research and development expenses to the extent the related intangible assets are used for R&D purposes.

As of December 31, 2022, certain identified biomarkers and internally developed databases were impaired because the probable future economic benefits related to these assets were not sufficient to cover the carrying value of each asset. The impairment

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is expensed under cost of sales and included in amortization and impairment expense in the Pharmaceutical segment. The amount of the impairment expenses recognized as of December 31, 2022, is EUR 158k (2021: EUR 1,067k; 2020: EUR 4,700k).

13 Property, plant and equipment

Please refer to the following table for the development from January 1, 2021 to December 31, 2022:

in EUR k	Buildings	Plant	Other equipment, furniture and fixtures ⁽¹⁾	Total
As of Jan 1, 2020	3,254	9,730	4,712	17,696
Additions	105	1,295	8,490	9,890
Disposal*	—	—	(612)	(612)
Transfers from right-of-use assets***	—	3,099	—	3,099
As of Dec 31, 2020	3,359	14,124	12,590	30,073
Additions	5	144	2,766	2,915
Disposal*	—	(379)	(718)	(1,097)
Transfers from right-of-use assets***	—	1,165	—	1,165
As of Dec 31, 2021	3,364	15,054	14,638	33,056
Additions	—	24	504	528
Disposal**	—	(66)	(3,021)	(3,087)
Currency translation differences	3	11	20	34
Transfers from right-of-use assets***	—	2,628	—	2,628
As of Dec 31, 2022	3,367	17,651	12,141	33,159
Accumulated depreciation and impairment				
As of Jan 1, 2020	392	6,155	2,773	9,320
Depreciation	194	993	1,913	3,100
Disposal*	—	—	(44)	(44)
Transfers from right-of-use assets***	—	1,107	—	1,107
As of Dec 31, 2020	586	8,255	4,642	13,483
Depreciation (Restated, see Note 2.4)	315	3,268	6,407	9,990
Disposal*	—	(157)	(217)	(374)
Transfers from right-of-use assets***	—	493	—	493
As of Dec 31, 2021	901	11,859	10,832	23,592
Depreciation	241	1,568	2,166	3,975
Disposal**	—	(67)	(2,918)	(2,985)
Currency translation differences	2	12	26	40
Transfers from right-of-use assets***	—	1,729	—	1,729
As of Dec 31, 2022	1,144	15,101	10,106	26,351
Carrying amounts				
As of Dec 31, 2020	2,773	5,869	7,948	16,590
As of Dec 31, 2021	2,463	3,195	3,806	9,464
As of Dec 31, 2022	2,223	2,550	2,035	6,808

* The disposal relates to the sale of a CentoTruck as part of a contract with a COVID-19 customer.

** The disposal relates to various obsolete plant and machinery equipment mainly in relation to the ramp down of the COVID-19 business segment.

*** The transfers from right-of-use assets represents assets purchased at the end of the lease.

⁽¹⁾ Property, plant and equipment has been restated as of December 31, 2021. Refer to Note 2.4.

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At the end of the third quarter of 2021, management updated its long-term outlook for the COVID-19 testing business, which led to management's decision to discontinue the COVID-19 business (see note 9). As part of the wind down, estimated useful lives of all COVID-19 related tangible assets were accelerated. As of March 31, 2022, there were no operations and no active leases on any of the testing sites. In addition, all COVID-19 related tangible assets have been fully depreciated.

14 Right-of-use assets

The Group has lease contracts for land and buildings and offices in Germany and the United States, as well as various items of plant, machinery, motor vehicles and other equipment used in its operations. Leases for land and buildings is related to the sale and leaseback transaction of the Rostock headquarters building and the office in Berlin, both with a lease term of 12 years. Leases of plant and machinery and other equipment generally have lease terms between 2 and 4 years, while motor vehicles generally have lease terms of 3 years. The Group's obligations under its leases are secured by the lessor's title to the leased assets. Generally, the Group is restricted from subleasing the leased assets. In addition, a bank guarantee of EUR 3,257k (which is secured by cash deposit of EUR 2,768k) is required to be maintained for the leases of Rostock headquarters building and Berlin offices until the expiry or termination of the leases. Leases of certain plant and machineries were also secured with rental deposits of EUR 51k.

The lease contract of Rostock headquarters building includes extension options. These options are negotiated by management to provide flexibility in managing the leased-asset portfolio and align with the Group's business needs. The lease of Rostock headquarters building allows the Group to extend the rental contract twice, each for a period of 6 years, after the expiration of agreement in September 2031 with rental payments of approximately EUR 1.5 million per annum. Such extension option was not included in the right-of-use assets and lease liabilities, as it is not reasonably certain that such extension option will be exercised.

The Group also has certain leases of motor vehicles and premises with lease terms of 12 months or less and leases of office equipment with low value. The Group applies the 'short-term lease' and 'lease of low-value assets' recognition exemptions for these leases.

Set out below are the carrying amounts of right-of-use assets and movements during the period:

In EUR k	Buildings*	Offices	Plant and equipment	Other equipment	Motor Vehicles	Total
As of Jan 1, 2020	13,126	4,407	6,989	390	20	24,932
Additions	—	426	1,265	1,112	37	2,840
Transfers to property, plant & equipment**	—	—	(1,992)	—	—	(1,992)
Depreciation expenses	(1,121)	(657)	(1,675)	(187)	(20)	(3,660)
As of December 31, 2020	12,005	4,176	4,587	1,315	37	22,120
Additions	—	133	1,121	179	19	1,452
Transfers to property, plant & equipment**	—	—	(672)	—	—	(672)
Depreciation expenses	(1,121)	(970)	(1,745)	(138)	(22)	(3,996)
As of December 31, 2021	10,884	3,339	3,291	1,356	34	18,904
Additions	—	112	95	—	21	228
Transfers to property, plant & equipment**	—	—	(772)	(127)	—	(899)
Depreciation expenses	(1,124)	(529)	(1,081)	(127)	(22)	(2,882)
As of December 31, 2022	9,760	2,922	1,533	1,102	33	15,351

* As the lease of land and buildings are made through one contract, all the related right-of-use assets are allocated to Buildings.

** Transfers of leased assets to PP&E (Note 13) represents purchased assets at the end of lease term.

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Set out below are the carrying amounts of lease liabilities and the movements during the period:

in EUR k	2022	2021*	2020
As of January 1	18,724	21,205	21,704
Additions	204	1,452	3,654
Interest expenses	637	584	865
Disposals	—	(273)	—
Payments	(4,129)	(4,244)	(5,018)
As of December 31	15,436	18,724	21,205
Current	2,311	3,330	3,528
Non-current	13,125	15,394	17,677

*Lease liabilities have been restated as of December 31, 2021. Refer to Note 2.4.

The maturity analysis of lease liabilities is disclosed in Note 22.

The following are the amounts recognized in profit or loss:

in EUR k	2022	2021	2020
Depreciation expense of right-of-use assets	2,882	3,996	3,660
Interest expenses on lease liabilities	637	584	865
Rent expenses—short-term leases	770	7,175	1,695
Rent expense—leases of low-value assets	27	48	33
Total amounts recognized in profit or loss	4,316	11,803	6,253

The Group had total cash outflows for leases of EUR 5,111k in 2022 (2021: EUR 11,467k; 2020: EUR 6,746k). The future cash outflows relating to non-cancellable short-term leases and leases of low-value assets, are disclosed in Note 25. The future cash outflow related to residual value guarantees are disclosed in Note 22.

15 Inventories

in EUR k	Dec 31, 2022	Dec 31, 2021	Jan 1, 2021
Raw materials, consumables and supplies	1,801	3,831	11,167
Finished goods and merchandise	18	38	238
Inventories	1,819	3,869	11,405

In the year ended December 31, 2022, raw materials, consumables, and changes in inventories of finished goods recorded as expenses under “cost of sales” came to EUR 19,525k (2021: EUR 9,467k; 2020: EUR 11,061k).

16 Trade and other receivables and other assets

in EUR k	Dec 31, 2022	Dec 31, 2021	Jan 1, 2021
Non-current			
Other assets—Rental deposits	2,819	2,922	1,867
Other assets—Others	92	50	100
	2,911	2,972	1,967
Current			
Trade receivables*	13,637	21,065	25,656
Contract assets*	2,911	2,397	3,332
Other assets	5,514	5,453	8,286
	22,062	28,915	37,274

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Total non-current and current trade and other receivables and other assets 24,973 31,887 39,241

* Trade receivables and contract assets have been restated as of December 31, 2021, and January 1, 2021. Refer to Note 2.4.

Other non-current assets

The non-current portion of other assets mainly include cash deposit of EUR 2,550k, used to secure a bank guarantee of EUR 3,257k, relating to the leases of Rostock headquarters building, cash deposits of EUR 218k, used to secure a bank guarantee of EUR 257k, relating to the leases of Berlin office and EUR 51k for the leases of certain plant and machineries. It also includes EUR 92k for the cash deposit for the Central Procurement & Supplies Unit of Malta.

Trade receivables

Trade receivables are non-interest bearing and are generally due in 30 to 90 days. In general, portfolio-based expected credit loss allowances are recognized on trade receivables and contract assets (see note 22.2).

Other current assets

Other current assets include VAT receivables of EUR 2,039k (2021: EUR 253k; 2020: EUR 226k), prepaid expenses of EUR 2,620k (2021: EUR 3,346k; 2020: EUR 4,431k), receivables related to exercised share-based payment grants of EUR 74k (2021: EUR 116k; 2020: 1,253k). Receivables related to COVID-19 bank or credit card transactions are EUR nil in 2022 (2021: EUR 612k; 2020: 1,076k), as well as receivables from grants of EUR nil (2021: EUR nil; 2020: 442k).

17 Cash and short-term deposits

As of December 31, 2022, the Group has pledged its short-term deposits with carrying amount of EUR 443k (2021: EUR 938k; 2020: EUR 1,500k) and EUR 2,500k (2021: EUR 2,500k) respectively, to fulfil collateral requirements in respect of existing secured bank loan and overdraft facility up to EUR 2,500k. In addition, the Group has pledged its short-term deposits of EUR 1,000k (2021: EUR 1,000k) related to two other overdraft facilities worth EUR 500k each.

The restriction applying to the collateral may be terminated at any time subject to the full amount of the relevant bank loans and the overdrafts being repaid.

Equity and liabilities

18 Equity

Issued capital and capital reserve

<u>in thousands of shares</u>	<u>Dec 31, 2022</u>	<u>Dec 31, 2021</u>	<u>Jan 1, 2021</u>
Common shares as of Jan 1, fully paid	22,568	22,118	19,862
Issued shares	4,998	—	2,000
Exercise of options	30	450	256
Common shares issued as of Dec 31, fully paid	<u>27,596</u>	<u>22,568</u>	<u>22,118</u>

<u>in thousands of shares</u>	<u>Dec 31, 2022</u>	<u>Dec 31, 2021</u>	<u>Dec 31, 2020</u>
Authorized common shares of EUR 0.12 each	79,000	79,000	79,000

Common Shares

In July 2020, the Company completed a follow-on public offering of 3,500,000 common shares of the Company, consisting of 2,000,000 common shares offered by the Company and 1,500,000 common shares offered by selling shareholders at a price to the public of USD 14.00 per common share (i.e. EUR 12.71 per share). Aggregate offering proceeds, net of underwriting discounts, commissions and transaction costs, were EUR 22 million to the Company. On January 31, 2022, pursuant to a securities purchase

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agreement signed with certain investors, the company received EUR 15.0 million as consideration for the issuance of an aggregate of 4,479,088 common shares at a price per share of USD 3.73 (EUR 3.35).

As of December 31, 2022, 27,595,835 common shares of Centogene N.V. with a nominal value of EUR 0.12 were issued and fully paid up (2021: 22,567,971; 2020: 22,117,643). As of December 31, 2022, the authorized, but unissued common share capital amounted to EUR 6,713k (2021: EUR 6,772k; 2020: EUR 6,826k).

The holders of common shares are entitled to the Company's approved dividends and other distributions as may be declared from time to time by the Company, and is entitled to vote per share on all matters to be voted at the Company's annual general meetings.

Capital reserve

As of December 31, 2022, capital reserve included a share premium of EUR 121,018k (2021: EUR 106,665k; 2020: EUR 107,498k), being amounts paid in by shareholders at the issuance of shares in excess of the par value of the shares issued, net of any transaction costs incurred for the share issuance.

On January 31, 2022, pursuant to the securities purchase agreement and a warrant agreement, each signed with certain investors, the Group received EUR 15.0 million in exchange for the issuance of an aggregate of 4,479,088 common shares at a price per share of USD 3.73 (EUR 3.35) and warrants initially exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares at an initial exercise price per common share of USD 7.72. The warrants are exercisable immediately as of the date of issuance and will expire on December 31, 2026. The fair value of warrants issued as of January 31, 2022, was USD 3.2 million (EUR 2.8 million). The amount recognized in capital reserve for the issuance of shares considering EUR 110k of transaction costs, was EUR 14.3 million. EUR 2.8 million for the issuance of warrants was also charged against capital reserve reducing the EUR 14.3 million from the issuance of shares to EUR 11.5 million.

The capital reserve consists of the share premium account and amounts recorded in respect of share-based payments. For additional information on the share-based payments, please refer to note 21.

19 Capital management

The Group's objectives when managing capital are to safeguard the Company's ability to continue as a going concern and finance all necessary sustainable developments, so that it can continue to provide returns for shareholders and benefits for other stakeholders. In particular, care is taken and an optimal capital structure is strived to reduce the cost of capital. With the IPO in November 2019, follow-on public offering of July 2020, shares and warrant issuance and aggregate debt financing in February 2022, the Group is focused on achieving a healthy capital base to increase the confidence of investors and the capital market.

The Group manages its capital structure and makes adjustments in light of changes in economic conditions and the risk characteristics of its activities. To maintain or adjust the capital structure, the Group may adjust the return to shareholders, issue new shares, or pay additional interests to reduce debt.

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20 Financial liabilities

20.1 Interest-bearing loans

in EUR k	Dec 31, 2022	Dec 31, 2021	Jan 1, 2021
Non-current liabilities			
Non-current portion of secured bank loans	40,051	—	401
Total non-current loans	40,051	—	401
Lease liabilities*	13,125	15,394	17,677
Total non-current liabilities	53,176	15,394	18,078
Current liabilities			
Current portion of secured bank loans	1,261	505	567
Other bank loans	—	—	387
Bank overdrafts	3,374	3,310	1,538
Total current loans	4,635	3,815	2,492
Current portion of lease liabilities*	2,311	3,330	3,528
Total current liabilities	6,946	7,145	6,020
Total non-current and current liabilities	60,122	22,539	24,098

* Lease liabilities as of December 31, 2021, have been restated. Refer to Note 2.4.

As of December 2022, short-term cash deposits of EUR 427k (2021: EUR 938k; 2020: EUR 1,500k) were used to secure the remaining bank loan outstanding (see Note 17).

The following table is based on the original terms and conditions:

Conditions and statement of liabilities

The outstanding interest-bearing loans as of December 31, 2022, 2021 and 2020 have the following conditions:

in EUR k	Currency	Nominal interest rate	Maturity	Dec 31, 2022		Dec 31, 2021		Jan 1, 2021	
				Nominal amount	Carrying amount	Nominal amount	Carrying amount	Nominal amount	Carrying amount
Secured bank loan	EUR	2.95%	2017-22	—	—	505	505	968	968
Secured bank loan	USD	7.93% (+0.07% for Tranche A; +4.13% for Tranche B)	2022-27	39,015	41,312	—	—	—	—
Other bank loan	USD	1%	2020-22	—	—	—	—	387	387
Bank overdrafts	EUR	4.75%	Rollover	499	499	499	499	498	498
Bank overdrafts	EUR	4.75%	Rollover	2,376	2,376	2,329	2,329	628	628
Bank overdrafts	EUR	4.31%	Rollover	499	499	482	482	412	412
Lease liabilities**	EUR	2.1%-7.20%*	2017-31	15,436	15,436	18,724	18,724	21,205	21,205
Total interest-bearing financial liabilities				57,825	60,122	22,539	22,539	24,098	24,098

* represents the incremental borrowing rate of the Group at the commencement of the leases

** Lease liabilities as of December 31, 2021 have been restated. Refer to Note 2.4.

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Secured bank loan

On January 31, 2022 the Company, Centogene GmbH, CentoSafe B.V. and Centogene US, LLC (together, the “Borrowers”), entered into a debt financing agreement in the total amount of up to USD 45.0 million (EUR 40.2 million). Under the terms of the Loan Facility, the Company drew down USD 25.0 million (EUR 22.3 million) on January 31, 2022 and a second tranche of USD 20.0 million (EUR 18.6 million) upon achievement prior to July 31, 2023, of product revenue from our diagnostics and pharmaceutical segments of at least USD 50.0 million (EUR 44.3 million) calculated on a trailing twelve month basis as of the last day of any fiscal month. The Loan Facility also includes covenants such that the Group is required to maintain product revenue, calculated as of the last day of each fiscal quarter and on a trailing twelve-month basis as of such date, of at least EUR 30.0 million for any fiscal quarter prior to obtaining the second tranche and EUR 40.0 million for any fiscal quarter on or after obtaining the second tranche. Both tranches mature on January 29, 2027, with amortized repayments commencing March 1, 2025. The loans extended under the Loan Facility bear monthly interest payments at an interest rate of 7.93% per annum plus the 1-month CME Term SOFR reference rate as published by the CME Group Benchmark Administration Limited (the first tranche, “Tranche A”, subject to a floor of 0.07% and the second tranche, “Tranche B”, subject to a floor of 4.13%). As security for the Borrowers’ obligations under the Loan Facility, the Borrowers granted the lenders thereunder a first priority security interest on all of each Borrower’s assets.

The Loan Facility is initially recognized at fair value minus transaction costs and subsequently carried at amortized cost measured using the effective interest rate method. The transaction costs deducted from the fair value of the Loan Facility at initial recognition were EUR 1,403k. The effective interest rate used for amortized cost calculation of Tranche A is 11.36% and for the Tranche B is 17.11%.

Bank overdrafts

The bank overdrafts of EUR 2,376k as of December 31, 2022 (2021: 2,329k; 2020: EUR 628k) were secured by short-term deposits with a carrying amount of EUR 2,500k (2021: EUR 2,500k; 2020: EUR 2,500k) (see note 17). The other bank overdrafts of EUR 998k (2021: EUR 981k; 2020: EUR 910k) are secured over two short-term deposits with a carrying amount of EUR 500k each as at year end December 31, 2022 (see note 17).

20.2 Trade payables and other liabilities

<u>in EUR k</u>	<u>Dec 31, 2022</u>	<u>Dec 31, 2021</u>	<u>Jan 1, 2021</u>
Trade payables	6,317	11,252	31,736
Government grants (deferred income)	7,950	9,396	10,292
Contract liabilities	651	4,842	4,479
Warrant liability	260	—	—
Derivative liabilities	376	—	—
Others*	9,601	15,592	14,123
Trade payables and other liabilities	25,155	41,082	60,630
Non-current	7,726	8,988	9,590
Current	17,429	32,094	51,040

* Other liabilities have been restated as of December 31, 2021, and January 1, 2021. Refer to Note 2.4.

Government grants mainly include investment-related government grants. These were received for the purchase of certain items of property, plant and equipment for the research and development facilities in Mecklenburg-Western Pomerania, including the Rostock facility. The grants were issued in the form of investment subsidies as part of the joint federal and state program, “Verbesserung der regionalen Wirtschaftsstruktur” (improvement of the regional economic structure) in connection with funds from the European Regional Development Fund. Additional grants received during the year ended December 31, 2022, amounted to EUR 506k (2021: EUR 168k; 2020: EUR 390k).

Contract liabilities mainly contain the deferred revenues recognized for advance payments received by the customers, in case the revenue is recognized over time. The decrease of the period is mainly due to the release amounts to EUR 1,951k (2021: EUR 3,201k; 2020: EUR 3,088k), for the revenues recognized in 2022 based on the satisfaction of the related performance obligations.

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On January 31, 2022, pursuant to a securities purchase agreement and a warrant agreement, each signed with certain investors, the Group received EUR 15.0 million in exchange for the issuance of an aggregate of 4,479,088 common shares at a price per share of USD 3.73 (EUR 3.35) and warrants initially exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares at an initial exercise price per common share of USD 7.72. The warrants are exercisable immediately as of the date of issuance and will expire on December 31, 2026. Based on the fair value per share at the issuance date, the Group recognized the warrants as liabilities in the amount of USD 3.2 million (EUR 2.8 million). The fair value of warrants decreased from EUR 2.11 per warrant as of January 31, 2022, to EUR 0.19 per warrant as of December 31, 2022. The result is a decrease in fair value of warrant liabilities of EUR 2,574k for the period ended December 31, 2022.

The fair value of the warrants was estimated at the date of issuance date using the Black-Scholes-Merton option pricing model. The key assumptions used to derive the warrants value are set out below:

	Dec 31, 2022	Jan 31, 2022
Exercise price (USD)	7.72	7.72
Share price (USD)	0.93	4.42
Volatility (%)	85.00	80.00
Risk-free interest rate (%)	4.15	1.65
Dividend yield (%)	nil	nil
Time to maturity	4.00	4.90

Other liabilities include an accrual for outstanding invoices of EUR 1,074k (2021: EUR 4,978k; 2020: EUR 1,245k), personnel-related liabilities for vacation and bonuses totaling EUR 3,717k (2021: EUR 4,812k; 2020: EUR 4,032k), a VAT payable of EUR nil (2021: EUR 905k; 2020: EUR 4,578k), an accrual for closings and audit of financial statements of EUR 1,648k (2021: EUR 932k; 2020: EUR 567k) as well as liabilities for wage and church tax of EUR 342k (2021: EUR 1,040k; 2020: EUR 1,988k).

Finally, other liabilities also contain a provision amounting to EUR 283k (2021: EUR nil; 2020: EUR nil) for expected claims regarding some US diagnostic revenues. It is expected that these costs will be incurred in the next financial year. Assumptions used to calculate the provision for these probable claims were based on current information available regarding the invoicing process for that kind of revenues.

21 Share-based payments

As of December 31, 2022 and 2021, the Group had the following share-based payment arrangements.

(i) 2019 Equity Incentive Plan (2019 Plan)

The Company established a long-term incentive plan (the “2019 Plan”) in 2019. The 2019 Plan governs issuances of equity and equity-based incentive awards from and after the consummation of the IPO. Awards under the 2019 Plan may be granted to the employees, the members of management board and supervisory board, consultants or other advisors. As of January 1, 2023 the maximum number of common shares underlying awards that may be granted pursuant to the 2019 Plan (other than replacement awards) will not exceed 25% of the Company’s issued share capital. Such maximum number will be increased on January 1 of each calendar year, by an additional number of common shares equal to 3% of the Company’s issued share capital on such date (or a lower number of common shares as determined by the management board or supervisory board, where appropriate on the basis of a recommendation of the compensation committee (as the case may be, as prescribed by the 2019 Plan and, collectively, the “Committee”).

In the event of a change in control of the Company (as defined in the 2019 Plan), outstanding awards that will be substituted or exchanged for equivalent replacement awards, in connection with the change in control will be cancelled. Outstanding rewards that are not substituted or exchanged for equivalent replacement awards, in connection with the change in control will immediately vest and settle in full, unless otherwise decided by the Committee.

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In November 2022, the Company amended the 2019 plan to include stock grants (SGAs) and PSUs and to modify the settlement of the awards. Accordingly, the awards will be delivered as promptly as reasonably practicable following the exercise or settlement of the relevant award, but in no event later than 30 days following such exercise of settlement.

The grants disclosed in the following paragraphs were granted under the 2019 Plan.

(ii) ESOP/ VSOP 2017

During 2019, 805,308 new share options were granted pursuant to the Centogene N.V. 2019 Plan, replacing previously established virtual share option program in 2017 (“ESOP 2017”), with each option representing the right to acquire one common share of Centogene N.V., with an exercise price equal to the nominal value of a share of Centogene N.V., which is EUR 0.12. The options were considered vested upon the completion of the IPO, but were not exercisable in the first 180 days after the IPO (lock-up period).

	2022		2021	
	Number	WAEP	Number	WAEP
Outstanding as of January 1	357,440	0.12	549,005	0.12
Granted during the year	—	0.12	—	0.12
Cancelled during the year	—	0.12	—	0.12
Exercised during the year	(29,509)	0.12	(191,565)	0.12
Outstanding as of December 31	327,931	0.12	357,440	0.12
Vested as of December 31	327,931	0.12	357,440	0.12
Exercisable as of December 31	327,931	0.12	357,440	0.12

During 2021, 191,565 options were exercised. The weighted average share price at the date of exercise was USD 9.76. During 2022, 29,509 options were exercised. The weighted average share price at the date of exercise was USD 1.25.

The contractual term of the share options as of December 31, 2022 is seven years.

The share options issued under ESOP 2017 are equity-settled and the fair value of the options were recognized in equity under capital reserve on the date of grant.

(iii) Equity share option 2019 (ESOP 2019) to Flemming Ornskov

On December 18, 2020, in an extraordinary general meeting of shareholders of Centogene N.V., the shareholders approved the grant of 300,000 restricted stock units (“RSUs”) to Flemming Ornskov under the 2019 Plan, which replaced the originally granted share options under ESOP 2019 (awards initially granted in 2019) and pursuant to which Flemming Ornskov will forfeit the options awarded to him thereunder in exchange for the RSUs granted to him. The RSUs will expire after ten years, will not be subject to any other performance criteria, will have no exercise price and will be settled in shares. With respect to the RSUs granted:

1. 33% will vest immediately;
2. the remaining 67% will vest in two equal annual instalments on each relevant anniversary of October 1 following the date of grant; and

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3. will vest in full upon the occurrence of a change in control (as defined in the 2019 Plan), provided that the holder of the awards is an eligible participant (as defined in the 2019 Plan) on the date of such change in control.

	2022		2021	
	Number	WAEP	Number	WAEP
Outstanding as of January 1	300,000	—	300,000	—
Cancelled during the year	—	—	—	—
Replacement awards granted during the year	—	—	—	—
Granted during the year	—	—	—	—
Exercised during the year	(300,000)	1.0	—	—
Outstanding as of December 31	—	—	300,000	—
Vested as of December 31	—	—	200,000	—
Exercisable as of December 31	—	—	200,000	—

(iv) 2021 grants to management board and employees

During the year ended December 31, 2021, 167,326 RSUs and 15,000 Options were granted under 2019 Plan.

RSUs do not have any market or performance based vesting criteria and vest in three or four equal annual tranches starting from their grant dates. Each RSU represents a right to receive a payment in cash or shares equal to the value of the RSU on the settlement date. The Company has a choice to settle either in cash, in shares or a combination thereof. In line with this policy, both types of awards are to be settled in shares.

Options vest in three equal tranches over a three-year period starting on January 1, 2022, and are subject to market or performance based vesting conditions. These options will vest only if the 20-trading day volume-weighted average stock price of the Company's shares preceding the vesting date of each tranche exceeds the exercise price of USD 12.52. Therefore, expenses would not be reversed, if the tranches do not ultimately vest. All grants expire on the 10th anniversary of grant date.

(v) 2022 grants to management board and employees

During the year ended December 31, 2022 the following awards were granted under 2019 Plan:

Award Type (2019 Plan)	Market/ Performance Based Vesting Conditions	Number of Awards	Vesting Conditions	Expiration Date
RSUs	No	284,788	Four equal annual tranches over a four-year period starting on the grant date	10th anniversary of Grant Date
RSUs	Yes	174,394	Four equal tranches over a four-year period, starting February 1, 2023 on each anniversary of the grant date once the market/performance condition is met.	10th anniversary of Grant Date
RSUs	Yes	424,799	Will vest in full once the market/performance condition is met	10th anniversary of Grant Date
SGAs	No	425,093	Four equal tranches over a four-year period, starting within 1 year after grant date and on each anniversary thereafter	10th anniversary of Grant Date

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The grant date fair value of these grants will be recognized in profit or loss over the service period by using the graded approach. 174,394 RSUs referred above vest only if the three months volume-weighted average stock price of the Company's shares preceding the vesting date of each tranche exceeds the exercise price of USD 12 and USD 15, respectively. This performance option will expire January 2, 2024. The 58,132 of 424,799 RSUs referred to above will vest only if the three months volume-weighted average stock price of the Company's shares preceding the vesting date of each tranche exceeds the exercise price of USD 12 and USD 15. The related performance option will expire on February 1, 2024. The remaining 366,667 RSUs with performance based vesting conditions will vest only if the three months volume-weighted average stock price of the Company's shares preceding the vesting date of each tranche exceeds the exercise price of USD 15 upon a change of control of the Company. All the hurdles explained above are considered a market condition. Therefore, expenses would not be reversed, if the tranches do not ultimately vest.

All the remaining RSUs referred to above have same characteristics as the RSUs granted in 2021 (Note 21 (iv)).

On May 2, 2022, Volkmar Weckesser resigned from his duties as the Chief Information Officer effective as of May 3, 2022. Pursuant to his separation agreement, his service agreement terminated on June 29, 2022. Upon the termination of his service agreement, the vesting of 10,000 options that had been granted in 2020 were fully cancelled. 20,000 RSUs that had been granted in 2020 and 10,000 options that had been granted in 2021 remained unvested and they were fully forfeited as of the date of termination of this service agreement. A total amount of EUR 149k that had been recognized in the financial statements in the previous periods for these RSUs and options was reversed during the year ended December 31, 2022.

An additional amount of EUR 139k of expense that had been recognized in the financial statements in the previous periods for certain awards granted to other officers was reversed during the year ended December 31, 2022 upon the forfeiture of such awards.

(vi) 2020 grants to Dr. Andrin Oswald

In 2020, the Company and Mr. Oswald entered into an award agreement under the 2019 Plan pursuant to which Mr. Oswald would receive certain awards in the form of RSUs. According to the award agreement, a total of 324,000 RSUs were granted on December 1, 2020, subject to the purchase of ordinary shares of the Company on the open market in the amount of CHF 1,000k after the grant date, which would vest pro rata to the number of shares actually purchased up to the full investment amount of CHF 1,000k on each quarterly installment.

The RSUs referred to above had no performance-based vesting criteria. RSUs represented a right to receive a payment equal to the value of the RSU at the exercise date. All the RSUs would vest in four equal annual installments following the grant date, subject to Mr. Oswald's continued service with the Company as of the vesting date and will be charged to profit or loss over the period by using the graded approach. Additionally, a total of 500,000 performance-based vesting RSUs were granted to Mr. Oswald on December 1, 2020 which were subject to certain market conditions.

On February 1, 2022, Mr. Oswald stepped down from his position and signed a separation agreement. Pursuant to his separation agreement, all unvested RSUs held by Mr. Oswald under the Company's long term incentive plan continued to vest in accordance with their terms through the date of his termination on April 30, 2022. However, the number of RSUs he would receive would not exceed 62,284 RSUs. As a result, 69,428 RSUs were vested and the remaining unvested RSUs granted to him were forfeited on the termination date as of April 30, 2022. Since Mr. Oswald had a right to only 62,284 RSUs, the remaining 7,144 RSUs from the total vested RSUs were cancelled. Expenses related to total unvested RSUs in the amount of EUR 2,775k that had been recognized in the financial statements in the previous periods were reversed during the year ended December 31, 2022. This amount excluded the 69,428 RSUs vested, of which 62,284 RSUs vested pursuant to his separation agreement and 7,144 RSUs were cancelled.

(vii) 2022 grants to Kim Stratton

On February 1, 2022, Kim Stratton (the "CEO") was awarded 174,394 initial performance RSUs subject to time-vesting and performance-vesting ("Performance-vested RSUs"), 166,667 initial time-vested RSUs subject to only time-vesting ("Time-vested RSUs"), and a number of RSUs equal to CHF 200,000 divided by the VWAP calculated as of the date of grant and 44,444 annual RSUs (together, "Annual RSUs"). All RSUs have a maturity of 10 years, are settled with ordinary shares and have no exercise price. In case of a termination of the service agreement by the CEO, all unvested RSUs will be forfeited to the extent they have remained unvested following the expiration of a 12-month period after termination.

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Performance-vested RSUs also have a market condition that 50% of the Performance-vested RSUs vest only if the VWAP exceeds USD 12 and the remaining 50% of the Performance-vested RSUs vest if the VWAP exceeds USD 15. The Time-vested RSUs are not subject to any performance conditions, so their fair value equals the share price at grant date (after deduction of expected dividends during the respective vesting period, if any). The fair value for the Performance-vested RSUs is calculated by using an appropriate option pricing model (as described below) as these RSUs are subject to a market performance condition. Both Performance-vested RSUs and Time-vested RSUs vest over four years in four equal installments after the grant date and are recognized using the graded vesting method.

The fair value of the Performance-vested RSUs as of the grant date was determined using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables to estimate the probability that market conditions will be achieved. The key assumptions used to derive the Performance-vested RSUs' value are set out below:

	February 1, 2022	
	Tranche 1	Tranche 2
Share price at grant date (USD)	4.42	4.42
Vesting hurdle	12	15
Date to reach vesting hurdle	January 1, 2024	January 1, 2024
Expected volatility	80%	80%
Risk-free rate	1.1%	1.1%
Time to vesting hurdle year	1.91	1.91
Dividend yield	nil	nil

Regarding the Annual RSUs, the CEO will receive an annual number of RSUs, starting from 2023, that will vest in four equal annual installments. The allocation of RSUs will be done in the future, so to receive the RSUs the CEO must stay with Centogene during the period until the allocation of an annual grant of RSUs. Since these RSUs include a service condition, expenses regarding the services received are recognized starting from February 1, 2022. The CEO's service agreement does not specify any end date for granting such annual RSUs, therefore the Company estimates the duration of her service period as four years, which is the duration of the CEO's appointment by the Supervisory Board. The fair value of each grant of Annual RSUs is measured at each reporting date until the respective grant date is reached and the expenses are adjusted to this new fair value.

In the event of a change of control of the Group, all granted RSUs will vest immediately including a maximum of 275,000 additional RSUs (the "M&A RSUs") with a grant date February 1, 2022. The fair value of the M&A RSUs were determined to be EUR 156k. However, since the M&A RSUs will vest only if there is an occurrence of a change of control, which is not deemed probable by management in the foreseeable future, the Group did not account for these RSUs.

(viii) 2022 grants to Miguel Coego Ríos

On May 27, 2022, Miguel Coego Ríos, (the "CFO") was awarded 58,132 initial Performance-vested RSUs and 55,556 initial Time-vested RSUs. All RSUs have a maturity of 10 years, are settled with ordinary shares and have no exercise price.

The Time-vested RSUs awarded to the CFO have the same vesting conditions as those awarded to the CEO, and their fair values are determined using the same methodology as that used for the CEO's awards.

The Performance-vested RSUs awarded to the CFO also have the same vesting conditions (including performance conditions on the Performance-vested RSUs) as those awarded to the CEO, except for the absence of a time vesting condition, and their fair values are determined using the same methodology as that used for the CEO's awards. In the case of the CFO's Performance-vested RSUs, since there is no time vesting condition, the expense for these RSUs are recognized fully on the service start date.

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Similar to the Performance-vested RSUs awarded to the CEO, the fair value of the Performance-vested RSUs awarded to the CFO as of the grant date was determined using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables to estimate the probability that market conditions will be achieved. The key assumptions used to derive the Performance-vested RSUs value are set out below:

	May 27, 2022	
	Tranche 1	Tranche 2
Share price at grant date (USD)	2.70	2.70
Vesting hurdle	12	15
Date to reach vesting hurdle	February 1, 2024	February 1, 2024
Expected volatility	80%	80%
Risk-free rate	2.2%	2.2%
Time to vesting hurdle year	1.68	1.68
Dividend yield	nil	nil

Fair value amounts of Tranche 1 and Tranche 2 on the grant date were USD 0.50 and USD 0.35, respectively.

In case of a change of control of the Group, all granted Performance-Vested RSUs and Time-Vested RSUs will vest immediately, if the service agreement is not terminated based on a predetermined market condition. Additionally, if a change of control occurs within the 9 months following termination of the CFO's service agreement, a maximum of 50,000 unvested RSUs will time-vest and performance-vest. However, since the M&A RSUs will vest only if there is an occurrence of a change of control, which is not deemed probable by management in the foreseeable future, the Group did not account for these RSUs.

(ix) 2022 and 2021 supervisory board grants

In connection to the IPO 10,000 Share Options have been granted as an extraordinary incentive to Mr. Berndt Modig as approved at the annual general meeting of shareholders on June 24, 2021. The Options have a strike price of USD 14 and vest in four equal installments following the grant date.

In the extraordinary general meeting of shareholders on December 18, 2020, shareholders approved a new incentive compensation scheme for supervisory board members, under which certain members of the supervisory board will annually receive an award of options and RSUs for ordinary shares of the Company under the 2019 Plan with a target value of EUR 80,000 multiplied by the LTI factor. For each award, RSUs will constitute 75% of the value of the award while options will constitute the remaining 25% of the value of the award. The LTI factor will be 100% or less based on the volume-weighted average stock price of the shares over a 60 trading day period preceding December 31 of the relevant financial year. Furthermore, the chairman and vice-chairman of the supervisory board, the chairman of the audit committee and the chairman of the compensation committee would receive an additional award which would also be multiplied by the LTI factor.

In the Company's annual general meeting of shareholders on June 22, 2022, shareholders modified the initial incentive compensation scheme approved at the December 18, 2020 extraordinary general meeting. Pursuant to this modified compensation scheme, certain members of the supervisory board will annually receive an award of options and RSUs for ordinary shares of the Company with a target value of EUR 140,000 multiplied by the LTI factor. Furthermore, the chairman and vice-chairman of the supervisory board will each annually receive an additional award with a value of EUR 105,000 and EUR 70,000, respectively, multiplied by the LTI factor; the chairman of the audit committee and the chairman of the compensation committee will each annually receive an additional award with a value of EUR 70,000 and EUR 14,000, respectively, multiplied by the LTI factor. Also, if a supervisory board member was in office during all or part of a financial year but would cease to be a supervisory board member before the LTIs are granted for such financial year, such former supervisory board member will retain his or her entitlement to such LTIs based on a pro rata tempore basis.

The grant date criteria for these awards will be met at each future annual grant date, upon the approval of the audited annual accounts, at such time when the terms and value of the awards to be granted become fixed.

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The LTI Factor determines the final number of RSUs and options after the end of the financial year for which the annual LTI is granted. Therefore, the LTI Factor is a market performance condition and the expected achievement of the performance condition is part of the fair value measurement. The awards will be charged to profit or loss over the service period using the graded approach, pursuant to the equal annual vesting instalments. As the modification on June 22, 2022 increased the number of equity awards granted, the Group included the fair value of the additional RSUs and options, measured at the date of the modification in the measurement of the amount recognized for services received.

The awards will vest in four equal annual instalments on each relevant anniversary of the grant date and will vest in full upon a change in control of the Company (provided that the holder remains an eligible participant on the date of the change in control). The awards will expire on the ten-year anniversary of the grant date and will be settled in shares.

Equity share option 2019

Equity share option 2017 and Equity share option 2019

The fair values of ESOP 2019 were estimated at the date of grant using the Black-Scholes option pricing model, taking into account the terms and conditions under which the share options were granted. The model takes into account historical and expected dividends, and the share price volatility of other public companies in the relevant industries to predict the share performance. There are no cash settlement alternatives for either the option holders or the Company.

The key assumptions used to derive the option value are set out below:

	2019	
	ESOP 2017	ESOP 2019
Exercise price (EUR)	0.12	12.58
Share price at grant date (EUR)	12.58	12.58
Volatility (%)	70	70
Risk-free interest rate (%)	(0.7)	(0.7)
Dividend yield (%)	nil	nil
Option term (years)	10	10

Valuation of 2022 and 2021 grants

The fair value of the options granted to Mr. Modig and Mr. Sheldon was estimated at the date of grant using the Black-Scholes option pricing model, taking into account the terms and conditions on which the options were granted. In addition to that the fair value of the options granted to the Mr. Kim was estimated at the date of modification also using the Black-Scholes option pricing model. The awards granted to participants under the 2019 Plan in 2021 were estimated at the grant date. The fair value of the standard RSUs (i.e., those without performance-based vesting criteria) is based on the observed value of the underlying shares. As no dividend payments are expected over the vesting period, no further adjustment is required. The weighted average fair value of standard RSUs granted under the 2019 Plan during the year ended December 31, 2022 and 2021 were USD 1.93 and USD 10.96, respectively. The key assumptions used to derive the option and performance-based RSUs value and the weighted average fair value are set out below:

	2021 Fair Value assumptions				2022 Fair Value assumptions			
	Options Mr. Modig and Mr.Sheldon	Add. Options Mr. Modig	Options Mr. Kim	Options 2019 Plan	Performance Based RSUs Mrs. Stratton	Change of Control Based RSUs Mrs. Stratton	Performance Based RSUs Mr. Coego Ríos	Change of Control Based RSUs Mr. Coego Ríos
Exercise price (USD)	9.92	14.00	11.60	12.52	12.00/15.00	=>5 to <=15	12.00/15.00	=>5 to <=15
Share price at grant date (USD)	10.01	10.01	10.80	12.54	4.42	4.42	2.70	2.70
Volatility (%)	75	75	75	75	80	85	80	80
Risk-free interest rate (%)	1.7	1.7	1.7	1.9	1.1	1.1	2.2	2.2
Dividend yield (%)	nil	nil	nil	nil	nil	nil	nil	nil
Expected contractual life (years)	10.0	10	9	10	10	10	10	10
Weighted average fair value (USD)	7.86	7.45	8.21	7.36	2.10/1.60	1.45/1.71	0.50/0.35	0.84/0.65

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The expense recognized for the above share-based payment transactions during the year is shown in the following table:

in EUR k	2022	2021	2020
Expenses arising from equity-settled share-based payment transactions			
- ESOP 2019, including replacement by RSUs	2,376	7,000	2,105
- Grants to management board and employees	852	985	3,486
- Supervisory board grant	—	50	67
- Reversals	(3,244)	—	—
Total expenses arising from share-based payment transactions	(16)	8,035	5,658

Financial instruments

22 Financial instruments-fair values and risk management

22.1 Classifications and fair values

The fair values of the Company's cash and cash equivalents, trade receivables and contract assets and trade and other payables approximate their carrying values because of the short-term nature of these instruments.

Except for the warrant liability, the prepayment option and interest rate floor derivatives, the Group does not carry any financial instruments at fair value through profit and loss but at amortized cost. The fair value of the loan is EUR (40,787)k as of December 31, 2022. (December 31, 2021: EUR nil).

IFRS 13 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value as follows:

- Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2 - inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices); and
- Level 3 - inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The following table shows the fair values of financial instruments as of December 31, 2022, including their level in the fair value hierarchy. It does not include fair value information for financial assets and financial liabilities not measured at fair value if the carrying amount is a reasonable approximation of fair value:

in EUR k	Level 1	Level 2	Level 3	Carrying value	Category measurement
Non-current loans	—	(40,787)	—	(41,312)	Amortized Cost
Warrants liability	—	—	(260)	(260)	FVTPL
Prepayment option derivative asset	—	—	510	510	FVTPL
Interest rate floor derivative liability	—	—	(376)	(376)	FVTPL

As of December 31, 2021, carrying amount of all financial assets or financial liabilities approximated their fair value.

Net gain recognized in the consolidated statements of comprehensive loss, within changes in fair value of warrants, from the warrant liability fair value measurement differences was EUR 2,574k for year ended December 31, 2022. The net gain or loss recognized in the consolidated statements of comprehensive loss related to the fair value of the prepayment option and interest rate floor derivatives was, respectively, EUR 510k (gain) and EUR (376)k (loss) for year ended December 31, 2022 (December 31, 2021: EUR nil for both derivatives) (see Note 8.3).

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The valuation techniques used in measuring level 2 and 3 fair value for financial instruments in the consolidated statements of financial position, as well as the significant unobservable inputs used, were as follows:

- The fair value of the warrant liabilities, recognized as non-current financial liability at FVTPL, was calculated by applying a Black-Scholes-Merton option pricing model. This model uses the Centogene’s share price and the share price volatility as material input factors. The volatility is considered as material unobservable input factor (Level 3).
- The initial measurement of the fair value of the loan is calculated as being the amount funded less the Fair Value of bifurcated embedded derivatives at entry. The subsequent measurement is determined using a calibrated Income Approach. Cashflows at entry are forecast based on the contractual terms and Interest Rate forward curves sourced from Bloomberg. The internal rate of return (“IRR”) is calculated such that the Present Value of the forecast cashflows is equal to the initial measurement amount. This is categorized as Level 2.
- The bifurcated embedded option is measured initially and subsequently using a binomial option pricing model, selected to account for the variable strike and American style exercise features. The company operates 2 implementations of this model in tandem to be able to cross-reference inputs and results: (i) the first is based on direct projection of the bond price, against which the payoff function is applied. This method is adapted to exclude extreme paths from where amortization begins, noting strike increases rapidly making exercise uneconomic. Volatility is set based on the movement of the associated loan value driven by historical leveraged loan index moves applied to the associated loan yield; (ii) The second approach is based on projection of the associated loans’ yields (subject to boundary conditions based on leveraged loan index spreads), which are used to imply bond prices at each node to incorporate in the payoff calculations. Boundary conditions for the yield are set as the Leveraged Loan Index spread for BBB companies and for C companies added to the risk-free rate. For both approaches, option strike for each node is based on the contractual terms, adjusted for historic transaction costs and the value of the associated floor. Discounting is at the benchmark risk free rate. This is categorized as Level 3 due to the following unobservable inputs: (i) tree termination point; (ii) the credit spread element of the loan yield rate; (iii) volatility.
- The fair value of the floor was calculated initially and subsequently using the Black-76 model. Inputs are the credit spread implied for the associated loans, interest rate swap and forward curves from Bloomberg, and volatility calibrated to Bloomberg’s volatility cube for the reference interest rate. This is categorized as Level 3 due to the following unobservable inputs: (i) the credit spread element of the discounting rate; (ii) anticipated term.

The table below summarizes the profit or loss impact on the fair values of Level 3 instruments by changing the significant unobservable input factors.

in EUR k	Shift	2022	
		increase	decrease
Tranche A Option (yield) - Volatility	+/- 5%	219	(150)
Tranche A Option (yield) - Discount rate	+/- 10%	2	(0)
Tranche B Option (yield) - Volatility	+/- 5%	136	(105)
Tranche B Option (yield) - Discount rate	+/- 10%	3	(1)
Tranche B Floor - Credit spread	+/- 10%	9	(9)
Warrant - Volatility	+/- 5%	45	(44)

22.2 Financial risk management

The Group is exposed to the following risks from the use of financial instruments:

- *Credit risk*
- *Liquidity risk*
- *Currency risk*
- *Interest rate risk*

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Credit risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Group is exposed to credit risk from its operating activities (primarily trade receivables) and from its financing activities, including deposits with banks and financial institutions and foreign exchange transactions.

The carrying amount of the financial assets corresponds to the maximum default risk.

Trade receivables and contract assets

The Group utilizes a receivables management system that closely manages open items of major customers. The Group's customers in the Pharmaceutical segment are mainly pharmaceutical companies which are usually listed companies, or strongly financed by private equity funds. The Group's customers in the Diagnostic segment are mainly hospitals, labs and physicians, of which a large part are generating revenues. To avoid default, the Company may request prepayment for new business.

In addition to the macroeconomic situation generally, the development of international healthcare markets is a key economic factor in assessing the default risk related to trade receivables and contract assets. These markets are closely monitored by the Group.

An impairment analysis is performed at each reporting date using a provision matrix to measure expected credit losses. The provision rates are based on days past due for groupings of various customer segments with similar loss patterns (i.e. by customers from different segment; customers from different geographical region and customer type). The calculation reflects the probability weighted outcome, the time value of money and reasonable and supportable information that is available at the reporting date about past events, current conditions and forecasts of future economic conditions. The maximum exposure to credit risk at the reporting date is the carrying value of each class of financial assets disclosed in Note 16. The Group does not hold collateral as security and does not request letters of credit or other forms of credit insurance. The Group evaluates the concentration of risk with respect to trade receivables and contract assets and recorded credit losses reflecting the expected lifetime loss, based on different types of customers.

Considering the major exposure to the credit risk arising from the Diagnostic segment, the Group focused its impairment analysis on the trade receivables due from customers in the Diagnostic segment, in particular the MENA and Europe regions as they represent the majority of that segment's revenue. In addition to applying the provision matrix, the Group performed an individual customer analysis on major debtors, with reference to the past history (such as sales and collection in the previous periods) and the assessment of their current financial condition and other relevant factors and evaluated if additional specific impairment losses would be necessary.

Set out below is the information regarding the credit risk exposure of the Group's trade receivables and contract assets using a provision matrix.

As of December 31, 2022					
in EUR k	Total Gross amount	Not past due	Past due 1 - 30 days	Past due 31- 90 days	Past due by more than 90 days
Middle East	15,291	8,021	1,081	1,533	4,656
Europe	1,987	1,494	124	64	305
Latin America	825	742	62	12	9
North America	2,443	2,275	21	48	99
Asia Pacific	143	142	1	—	—
Contract assets	251	251	—	—	—
Total	20,940	12,925	1,289	1,657	5,069
Expected credit loss rate	21.0 %	1.0 %	3.9 %	7.4 %	80.8 %
Expected credit loss	4,392	124	50	122	4,096

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**As of December 31, 2021
(Restated)**

in EUR k	Total Gross amount	Not past due	Past due 1 - 30 days	Past due 31- 90 days	Past due by more than 90 days
Middle East	13,967	3,999	1,013	2,056	6,899
Europe	11,486	10,771	351	259	105
Latin America	683	531	23	72	57
North America (Restated)	2,513	2,513	—	—	—
Asia Pacific	130	115	9	6	—
Total	28,779	17,929	1,396	2,393	7,061
Expected credit loss rate	19.0 %	2.0 %	7.7 %	11.7 %	64.1 %
Expected credit loss	5,317	403	107	280	4,526

**As of December 31, 2020
(Restated)**

in EUR k	Total Gross amount	Not past due	Past due 1 - 30 days	Past due 31- 90 days	Past due by more than 90 days
Middle East	10,515	3,338	486	385	6,306
Europe	20,017	19,193	706	113	5
Latin America	387	313	24	13	37
North America (Restated)	2,584	1,205	994	262	123
Asia Pacific	178	136	18	24	—
Total	33,681	24,185	2,228	797	6,471
Expected credit loss rate	14.0%	1.6%	3.1%	7.7%	65.0%
Expected credit loss	4,693	387	69	61	4,176

Overdue trade receivables from the Middle East region mainly relate to major customers from the Diagnostic segment. The trade receivables due from the top 10 diagnostics customers in the MENA region as of December 31, 2022 represent over 83% of total overdue balances for this region. These customers are mainly government hospitals administered by the Ministry of Health in the respective countries as well as distributors and, based on our past experience, these customers normally require a longer period to settle outstanding trade receivables. The average turnover period from these customers are 201 days. Therefore, a higher country specific loss rate has been used for the MENA region. To manage the credit risk and improve the cash collection, the Group increased the sales commission percentage to be paid to local agents for the receivables overdue since 2020 and 2021 from MENA region.

Set out below is the movement in the allowance for expected credit losses of trade receivables and contract assets:

in EUR k	2022	2021*	Jan 1, 2021*
As of January 1	5,317	4,693	2,355
Provision/(reversal) for expected credit losses	(829)	827	3,636
Derecognition of trade receivables	(96)	(203)	(1,298)
As of December 31	4,392	5,317	4,693

* Trade receivables and contract assets have been restated as of December 31, 2021, and January 1, 2021. Refer to Note 2.4.

The reversal for expected credit losses as of December 31, 2022 amounts to EUR 829k, and it is mainly related to the decreased amount of receivable past due by more than 90 days (2022: EUR 5,069k; 2021: EUR 7,061k). This amount was included in the impairment of financial assets in the profit and loss account. In 2022, trade receivables of EUR 96k (2021: EUR 7k; 2020: EUR 1,466k) were outstanding for more than 365 days and were derecognized.

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Cash and cash equivalents

As of December 31, 2022, the Group held cash and cash equivalents of EUR 35,951k (2021: EUR 17,818k; 2020: EUR 48,156k). Therefore, this total also represents the maximum default risk with regard to these assets. The cash and cash equivalents are deposited principally with financial institutions with investment grade credit ratings.

Liquidity risk

The liquidity risk is the risk of the Group possibly not being in a position to meet its financial liabilities as contractually agreed by providing cash or other financial assets.

The Group's objective is to maintain a balance between continuity of funding and flexibility through the use of bank overdrafts and lease contracts.

Managing liquidity within the Group is intended to ensure that - as far as possible - sufficient cash and cash equivalents are always available to meet payment obligations when these fall due, in both normal and challenging conditions, without incurring unacceptable losses or damaging the Group's reputation.

The Group strives to maintain cash and cash equivalents at a level above that of the expected cash outflows for financial liabilities (apart from trade payables) during the next 60 days. As of December 31, 2022, 11.6% of the Group's interest-bearing liabilities mature in less than one year (2021: 31.7%; 2020: 25.0%) based on the carrying value of borrowings reflected in the financial statements. As of December 31, 2022, the expected cash inflows from trade and other receivables within two months amounts to EUR 7,251k (2021: EUR 6,418k; 2020: EUR 14,857k), which would be EUR 1,243k lower than the amount of trade payables due as of then.

The Company completed the IPO in November 2019. In July 2020, the Company completed a follow-on public offering of 3,500,000 common shares of the Company, consisting of 2,000,000 common shares offered by the Company and 1,500,000 common shares offered by selling shareholders at a price to the public of USD 14.00 per common share (i.e. EUR 12.71 per share). Aggregate offering proceeds, net of underwriting discounts, commissions, and transaction costs, were EUR 22 million to the Company. On January 31, 2022, pursuant to a securities purchase agreement signed with certain investors, we received EUR 15.0 million as consideration for the issuance by us of an aggregate of 4,479,088 common shares at a price per share of USD 3.73. As of December 31, 2022, the Group had cash and cash equivalent of EUR 35,951k (2021: 17,818k; 2020: EUR 48,156k). The cash and cash equivalents are deposited principally with financial institutions with investment grade credit ratings.

In addition to the cash and cash equivalents available as of December 31, 2022, the Group also has access to other sources of funding. As of December 31, 2022, the Group has secured credit lines totaling EUR 3,500k. These bear interest of 4.31% - 4.75% (2021: 3,500k; 3.75% - 4.75%; 2020: EUR 3,500k; 3.75% - 4.75%). EUR 3,374k were utilized as of December 31, 2022 (2021: EUR 3,310k; 2020: EUR 1,538k).

The table below presents the remaining contractual terms of the financial liabilities on the reporting date, including estimated interest payments. The figures are undiscounted gross amounts, including estimated interest payments and interest on undrawn loan funds, but without showing the impact of offsetting.

Dec 31, 2022 in EUR k	Carrying amount	Contractually agreed cash flows				
		Total	Less than 2 months	2 to 12 months	1 to 5 years	More than 5 years
Bank overdrafts	3,374	3,374	3,374	—	—	—
Secured bank loans	41,312	59,473	678	3,516	55,279	—
Lease liabilities	15,436	17,713	552	2,265	7,967	6,929
Trade payables	6,317	6,317	6,317	—	—	—
	66,439	86,877	10,921	5,781	63,246	6,929

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Dec 31, 2021 (Restated) in EUR k	Carrying amount	Contractually agreed cash flows				
		Total	Less than 2 months	2 to 12 months	1 to 5 years	More than 5 years
Bank overdrafts	3,310	3,310	3,310	—	—	—
Secured bank loans	505	505	105	400	—	—
Lease liabilities	18,724	21,777	703	3,337	8,844	8,893
Trade payables	11,252	11,252	11,252	—	—	—
	33,791	36,844	15,370	3,737	8,844	8,893

Dec 31, 2020 in EUR k	Carrying amount	Contractually agreed cash flows				
		Total	Less than 2 months	2 to 12 months	1 to 5 years	More than 5 years
Bank overdrafts	1,538	1,538	1,538	—	—	—
Secured bank loans	968	997	5	584	408	—
Other bank loans	387	394	—	394	—	—
Lease liabilities	21,205	24,897	716	3,580	9,861	10,740
Trade payables	31,736	31,525	31,011	514	—	—
	55,834	59,351	33,270	5,072	10,269	10,740

Reconciliation of liabilities arising from financing activities

in EUR k	Jan 1, 2022	Cash flows	Non-cash changes		Dec 31, 2022
			Additions	Changes in maturity and FX	
Non-current financial liabilities	15,394	36,631	65	1,086	53,176
Non-current portion of secured bank loans	—	38,965	—	1,086	40,051
Non-current lease liabilities	15,394	(2,334)	65	—	13,125
Current financial liabilities	7,145	(1,518)	1,319	—	6,946
Current portion of secured bank loans	505	(505)	1,261	—	1,261
Bank loans	—	—	—	—	—
Bank overdrafts	3,310	64	—	—	3,374
Current lease liabilities	3,330	(1,077)	58	—	2,311
Total	22,539	35,113	1,384	1,086	60,122

in EUR k	Jan 1, 2021	Cash flows	Non-cash changes		Dec 31, 2021
			Additions	Changes in maturity and FX	
Non-current financial liabilities	18,078	(594)	865	(2,955)	15,394
Non-current portion of secured bank loans	401	(401)	—	—	—
Non-current lease liabilities	17,677	(193)	865	(2,955)	15,394
Current financial liabilities	6,020	(2,881)	1,438	2,568	7,145
Current portion of secured bank loans	567	(62)	—	—	505
Bank loans	387	—	—	(387)	—
Bank overdrafts	1,538	1,505	267	—	3,310
Current lease liabilities	3,528	(4,324)	1,171	2,955	3,330
Total	24,098	(3,475)	2,303	(387)	22,539

Currency risk

The Group is exposed to currency risk in cases where contracts are concluded in foreign currencies. The vast majority of goods delivered and services the Company provided, including those for international customers, are invoiced in euro.

**Notes to the consolidated financial statements as of December 31, 2022 and 2021 and
for the three years ended December 31, 2022, 2021 and 2020**

The main functional currencies of group companies are the Euro, USD, the Indian rupee and the Arab Emirates Dirham. The following table presents the net foreign currency exposure of the Group as of December 31, 2022, 2021 and 2020.

in EUR k	Dec 31, 2022		
	USD	INR	AED
Trade receivables	3,720	8	—
Trade payables and other liabilities	(2,701)	—	—
Net exposure	1,019	8	—

in EUR k	Dec 31, 2021 Restated		
	USD	INR	AED
Trade receivables	2,604	8	—
Trade payables and other liabilities	(2,394)	(4)	—
Net exposure	210	4	—

in EUR k	Dec 31, 2020 Restated		
	USD	INR	AED
Trade receivables	1,224	18	—
Trade payables and other liabilities	(3,631)	(55)	(17)
Net exposure	(2,407)	(37)	(17)

Sensitivity analysis relating to changes in exchange rates

The following tables demonstrate the sensitivity at the end of the reporting period to a reasonably possible change in the USD exchange rates, with all other variables held constant, of the Group's earnings before tax and equity movement. The Group's exposure to foreign currency risk for all other currencies is not material.

in EUR k	Earnings before tax		Equity	
	5% increase	5% decrease	5% increase	5% decrease
December 31, 2022	(94)	104	(94)	104
December 31, 2021	(101)	112	(101)	112

Interest rate risk

Interest bearing liabilities with floating interest rates exist for non-current loans as of December 31, 2022.

The following sensitivity analyses has been determined based on the exposure to interest rates at the reporting date. For the floating rate liabilities, the analysis is prepared assuming the amount of liability outstanding at the reporting date was outstanding for the whole period. In accordance with the relevant loan agreement, the interest rate cannot be lower than the determined interest rate and therefore the analysis has only been performed for the scenario where interest rate increases.

If interest rates had been 5.0 percentage point higher and all other variables were held constant, the Group's earning before tax would decrease by EUR 1,160k for the twelve months ended December 31, 2022 (December 31, 2021: EUR nil).

**Notes to the consolidated financial statements as of December 31, 2022 and 2021 and
for the three years ended December 31, 2022, 2021 and 2020**

23 List of subsidiaries

The major subsidiaries of the Group are listed below.

Name	Country in which primary activities are pursued	Equity interests (%)	
		Dec 31, 2022	Dec 31, 2021
Centogene GmbH*	Germany	100	100
Centogene FZ-LLC	United Arab Emirates	100	100
Centogene US, LLC	USA	100	100
Centogene GmbH	Austria	100	90
Centogene India Pvt. Ltd**	India	100	100
Centogene Switzerland AG	Switzerland	100	100
Centosafe B.V.	Netherlands	100	100
Centogene d.o.o Belgrade	Serbia	100	100
Dr. Bauer Laboratoriums GmbH***	Germany	—	—

(*) Centogene IP GmbH and Centogene Shared Service GmbH were merged with Centogene GmbH on January 1, 2021.

(**) The Group acquired the remaining 10% of Centogene GmbH, Austria in 2022.

(***) See note 4.

24 Non-controlling interests

As of December 31, 2022, the Group has no non-controlling interests, since in 2022 the Group acquired the remaining 10% of Centogene GmbH (Austria). In addition, with the decision to cease COVID-19 operations as of March 31, 2022, Centogene terminated its cooperation agreement with Dr. Bauer GmbH and the control over Dr. Bauer GmbH ceased; Centogene no longer meets the criteria of the control model under IFRS 10 as it no longer has exposure to variable returns and the ability to use power to affect returns through COVID-19 operations (see note 4).

Dec 31, 2021 in EUR k	Centogene GmbH, Vienna	Dr. Bauer Laboratoriums GmbH
Net assets/(liabilities)	(528)	245
Carrying amount of non-controlling interests	(53)	—
Revenue	—	109,015
Profit/(loss)	(6)	98
Profit/(loss) allocated to non-controlling interests	(1)	98

Dec 31, 2020 in EUR k	Centogene GmbH, Vienna	Dr. Bauer Laboratoriums GmbH
Net assets/(liabilities)	(522)	148
Carrying amount of non-controlling interests	(52)	—
Revenue	—	55,596
Profit/(loss)	(1)	122
Profit/(loss) allocated to non-controlling interests	—	122

**Notes to the consolidated financial statements as of December 31, 2022 and 2021 and
for the three years ended December 31, 2022, 2021 and 2020**

25 Commitments

Future payments for non-cancellable leases

The Group has various lease contracts in relation to the expansion of the Rostock headquarters. The future lease payments and utilities for these non-cancellable lease contracts are EUR nil within one year, EUR 1,272k within five years and EUR 318k thereafter (2021: EUR 107k and 2020: EUR 283k within one year; 2021: EUR 2,370k and 2020: EUR 1,686k within five years; 2021: EUR 4,219k and 2020: EUR 4,855k thereafter).

The Group has various non-cancellable lease contracts of office equipment and storage spaces which had a lease term of less than 12 months or were related to leases of low-value assets, and therefore the short-term lease recognition exemption was applied to these contracts. The future lease payments for these non-cancellable lease contracts are EUR 59k within one year (2021: EUR 44k; 2020: EUR 33k) and EUR 25k within five years (2021: EUR 49k; 2020: EUR 9k).

Future payment obligations

During 2022, the Group concluded agreements with suppliers, for goods and services to be provided in 2022 with a total payment obligation of EUR 6,670k (2021: EUR 6,620k; 2020: EUR 4,669k).

26 Related parties

Transaction with shareholders

In July 2020, we completed a follow-on public offering of 3,500,000 common shares of the Company (the "Follow-on Equity Offering"), consisting of 2,000,000 common shares offered by the Company and 1,500,000 common shares offered by selling shareholders at a price to the public of \$14.00 per common share (i.e., EUR 12.71 per share). Aggregate offering proceeds, net of underwriting discounts, commissions and transaction costs, to the Company were EUR 22 million.

On January 31, 2022, pursuant to a securities purchase agreement and a warrant agreement, each signed with certain investors, the Group received EUR 15.0 million in exchange for the issuance of an aggregate of 4,479,088 common shares at a price per share of USD 3.73 (EUR 3.35) and warrants initially exercisable for the purchase of up to an aggregate of 1,343,727 additional common shares at an initial exercise price per common share of USD 7.72. The warrants are exercisable immediately as of the date of issuance and will expire on December 31, 2026. Based on the fair value per share at the issuance date, the Group recognized the warrants as liabilities in the amount of USD 3.2 million (EUR 2.8 million). The fair value of warrants decreased from EUR 2.11 per warrant as of January 31, 2022, to EUR 0.19 per warrant as of December 31, 2022. The result is a decrease in fair value of warrant liabilities of EUR 2,574k for the period ended December 31, 2022. We are not aware of any ordinary shares which were issued by the Company and sold in this transaction to related parties.

Based on a shareholder agreement from January 2016 the payment to the option holders of the VSOP 2016 will be reimbursed by the original shareholders to the Company at the same time when the obligation to pay the options holders arises. The payables by the Group to the holders of vested options were recorded as a liability with a carrying value of EUR 2,769k as of December 31, 2019 and a corresponding receivable against shareholders was recorded (see note 15). The shareholders agreement had a term until December 31, 2023. Upon completion of the July 2020 Offering, the relevant payables to the holders of vested options were settled mainly by the proceeds received from such original shareholders from the sale of their shares.

During 2020, the Company entered into a service contract with the former CEO Prof. Arndt Rolfs, a major shareholder, to serve as an advisor during the transition period after his departure from the Company until December 31, 2020. For the year ended December 31, 2020, fees totaling EUR 11k were charged to profit or loss related to these services and the Group had payables of EUR 12k outstanding as of December 31, 2020. In 2021 and 2022, no further service agreement has been entered into.

**Notes to the consolidated financial statements as of December 31, 2022 and 2021 and
for the three years ended December 31, 2022, 2021 and 2020**

Remuneration of management in key positions

Key management have been defined as the members of the management board and the Company's other key executive officers.

in EUR k	2022	2021	2020
Short-term employee benefits	4,138	4,098	4,273
Post-employment pension and medical benefits	—	23	23
Termination benefits	679	235	565
Share-based payment transactions	(1,929)	822	1,822
Total compensation to key management	2,888	5,178	6,683

Due to the departure of the former CEO Arndt Rolfs in 2020, share-based payments include additional share-based expenses of EUR 776k for the accelerated vesting of outstanding equity awards and termination benefits include the severance payout of EUR 565k. As of December 31, 2020, the Group had amounts of EUR 1,231k (2019: EUR 769k) accrued for key management compensation. Due to the departure of the former CEO Andrin Oswald, the former CFO René Just and former CIO Volkmar Weckesser in 2022, the share-based payment expenses include reversals of expenses recognized in previous periods and forfeiture of about EUR 3,104k. (See "Note 21 Share-based Payments" and "Note 28 – Subsequent Events" of our consolidated financial statements as of and for the year ended December 31, 2022.)

There are no pension commitments for members of the management board.

During 2022 908,953 RSUs were granted under the 2019 Plan to key management personnel which are recognized as share-based payment expenses in profit and loss (see Note 21(vi)).

As of December 31, 2022, the Group has receivables of EUR nil (2021: EUR nil) recognized related to the exercise of options by key management personnel.

Remuneration of members of the Supervisory Board

The supervisory board received remuneration for its activities of EUR 216k in the reporting year (2021: EUR 688k; 2020: EUR 603k). In addition, as disclosed in note 21, certain members of the supervisory board received share-based awards under the 2019 Plan. For the year ended December 31, 2022, share-based payment expenses of EUR 1,446k (2021: EUR 2,564k, 2020: EUR 2,172k) related to these awards were charged to profit and loss.

Transactions with members of management in key positions and other related parties

The Company purchased supplies used for genetic sequencing from an entity related to a member of the supervisory board that joined the board in 2020. Expenses totaling EUR 699k were charged to profit and loss related to the period of service of the board member.

The Company deconsolidated Dr. Bauer GmbH from April 2, 2022 (see Note 2.1 – Basis of consolidation) and assessed Dr. Bauer GmbH under IAS 24 as of the Deconsolidation Date. Accordingly, Dr. Bauer GmbH is a related party through Dr. Peter Bauer who is a key management personnel of Centogene.

Transactions with Dr Bauer GmbH for the year ended December 31, 2022 was EUR 1,815k.

As of December 31, 2022, the Group had receivables balances with Dr. Bauer GmbH of EUR 321k with a related provision for doubtful accounts of EUR 58k (December 31, 2021: nil).

As of December 31, 2022, the Group had provisions in the total amount of EUR 100k to be paid to Dr. Bauer GmbH

**Notes to the consolidated financial statements as of December 31, 2022 and 2021 and
for the three years ended December 31, 2022, 2021 and 2020**

27 Contingent assets and liabilities

Contingent Assets

Contingent assets comprise of possible VAT refunds for the financial years between 2016 and 2019. Prior to 2022, Centogene GmbH used a VAT exemption for certain diagnostic test services. During the fourth quarter of 2022, the Company changed the VAT settlement for the financial years between 2020 and 2022 and sent a VAT declaration correction to the tax administration in November 2022. Consequently, the Company received VAT refund in the amount of EUR 970k and recognized this amount as other operating income (refer to Note 8.1) for the year ended December 31, 2022. For the financial years between 2016 and 2019, management assessed that a reimbursement amount of approximately EUR 2,012k is favorable for the Group as the VAT settlement for the financial years between 2020 and 2022 has been approved by the same authorities. However, the amount has not been recognized in the financial statements since the reimbursement is subject to approval of the tax administration which is not within the control of the Group.

Contingent Liabilities

In May 2016, the Company was informed in writing by the Universitair Medisch Centrum Utrecht ("UMCU") that a claim had been initiated against UMCU regarding a prenatal diagnostic test that the Company conducted at their request which failed to identify a specific mutation present in a patient. On October 1, 2018, the UMCU and Neon Underwriting Limited formally filed a legal claim in the local court in Rostock, Germany against the Company alleging that the Company's negligence in performing the test resulted in the misdiagnosis of the patient. UMCU is seeking recovery for compensatory damages as a result of the alleged misdiagnosis. By court order of November 8, 2018, the Regional Court of Rostock set the amount in dispute at EUR 880k.

On November 12, 2018, the Company submitted a notice to the Regional Court of Rostock of the intention to defend against the claim. On January 3, 2019, the Company filed a motion to dismiss in which the Company denied the merits of the claim. UMCU and Neon Underwriting Limited responded to this motion on March 15, 2019 with a statement of reply, and the parties made several court filings setting out their arguments since. By order dated June 3, 2019, the Regional Court of Rostock provided a first set of questions to be answered by an expert witness.

As of December 31, 2020, the amount in dispute was EUR 1.3 million. The matter was assigned to a new judge, due to the illness of the prior judge, and the decision to appoint the recommended expert witness is still pending. Since then, several potential experts were approached by the court but eventually declined to prepare an expert witness report due to the possibility of bias.

The Company intends to continue to rigorously defend its position and considers that it is not probable the legal claim towards the Company will be successful and as a result has not recognized a provision for this claim as of December 31, 2022. In addition, in case a settlement would be required, the Company believes that the corresponding liability will be fully covered by the respective existing insurance policies.

28 Subsequent Events

On January 19, 2023, the Company announced the resignation of Dr. Florian Vogel as CPO effective February 28, 2023. According to the separation agreement signed on September 29, 2022, all vested RSUs held by the Dr. Vogel as of February 28, 2023 that have not yet been exercised and settled must be exercised and settled in accordance with their terms within six months following this date and, if such RSUs are not exercised and settled within such period, they will be cancelled automatically upon the expiry of such six-month period without compensation for the loss of such RSUs. All unvested and granted RSUs as of February 28, 2023, will vest in full.

On January 24, 2023, Prof. Peter Bauer, M.D., the Company's Chief Medical and Genomic Officer, has been appointed to the Management Board of Centogene N.V., to be confirmed at the Company's next General Meeting of Shareholders. Prof Bauer has also been appointed as Managing Director of the subsidiary Centogene GmbH.

**Notes to the consolidated financial statements as of December 31, 2022 and 2021 and
for the three years ended December 31, 2022, 2021 and 2020**

On March 15, 2023, Ian Rentsch was appointed as Chief Commercial Officer and General Manager (“CCO”) of the Group. With his employment agreement, the CCO was granted a sign-on bonus equivalent to the amount of EUR 60k which will be paid fully in company shares upon completion of his probation period of six months. The number of shares will be calculated using the 60-day VWAP preceding the contract signature date.

On April 24, 2023, the Company and Mr. Patrice Denefle, the Chief Scientific Officer, entered into a separation agreement, which terminated the employment agreement of Mr. Denefle, effective on June 20, 2023 (“Termination Date”). According to the separation agreement, all vested RSUs held by Mr. Denefle as of the Termination Date which have not yet been exercised and settled must be exercised and settled within six-months following this date. If such RSUs are not exercised and settled within such period, they will be cancelled automatically upon the expiry of such six-month period without compensation for the loss of such RSUs. All unvested and granted RSUs will be cancelled as of the last day of his employment.

The Loan and Security Agreement with Oxford Finance was amended on April 30, 2023 which introduced new requirements that the Group will prepay any outstanding loans under the Loan and Security Agreement in an amount of USD 5.0 million (plus fees, interest and expenses, in each case, pursuant to the terms of the Loan and Security Agreement) upon the first new business development or financing transaction the Group will enter and maintain at least EUR 9.1 million in unrestricted cash on deposit in collateral accounts subject to the Lender’s perfected security interest granted under the Loan and Security Agreement.

These consolidated financial statements were approved by management on May 16, 2023.

Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K on the basis that the registrant customarily and actually treats that information as private or confidential and the omitted information is not material. Information that has been omitted has been noted in this document with a placeholder identified by the mark “***”.

Dated 2023

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

- and -

CENTOGENE GmbH

**GLOBAL MASTER SUPPLY AND
SERVICES AGREEMENT**

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This **GLOBAL MASTER SUPPLY AND SERVICES AGREEMENT** (this “**Agreement**”) is by and between:

- (1) **TAKEDA PHARMACEUTICALS INTERNATIONAL AG**, a Swiss stock corporation incorporated under the laws of the Swiss Confederation under identification number CHE-113.444.401, having its registered office at Thurgauerstrasse 130, 8152 Glattpark (Opfikon), Switzerland (“**Takeda**”); and
- (2) **CENTOGENE GmbH** (formerly CENTOGENE AG), a German limited liability company registered with the commercial register of the local court ('Amtsgericht') of Rostock under the number HRB 14967 and having a business address at, Am Strande 7, 18055 Rostock, Germany, (“**Centogene**”),

each a “**Party**” and together the “**Parties**”.

PREAMBLE

- (A) Takeda is a global biopharmaceutical company focusing on, amongst other therapeutic areas, the development of treatments for lysosomal storage diseases (e.g., Fabry disease, Hunter syndrome and Gaucher disease) and other rare diseases.
- (B) Centogene is a global company focusing on, amongst other therapeutic areas, genetic and biochemical testing of rare diseases including lysosomal storage diseases.
- (C) Takeda, its Affiliates, and Centogene recognize each other as global leaders in the field of treating and diagnosing rare genetic diseases and acknowledge their resulting responsibility for patients suffering from rare diseases. Worldwide access to appropriate diagnostic testing and disease monitoring is a significant unmet need for these patients. A central aim of the long-standing cooperation between Takeda and Centogene has been enhancing diagnosis of patients suffering from one of these diseases. Although past joint efforts of the Parties have partially addressed this unmet patient need, a significant number of patients still remain undiagnosed. Takeda and Centogene have therefore agreed to pursue the common mission of diagnosing any remaining patients.
- (D) The Parties or their Affiliates entered into a Global Master Services Agreement dated 1 January 2015 and a Supply Agreement dated 1 January 2016, both of which were amended and supplemented on multiple occasions throughout their respective terms (together the “**Expired Agreements**”). The Expired Agreements will expire on 31 March 2023, and so Takeda and Centogene now aim to extend the cooperation with respect to the supply of products and services under this Agreement.

NOW, THEREFORE, Takeda and Centogene, intending to be legally bound, hereby agree as follows:

1. DEFINITIONS

- 1.1 In this Agreement, the following terms shall have the following meanings:

“**Affiliate**” shall mean and include in relation to each Party, any person, firm, corporation or other entity directly or indirectly Controlling, Controlled by or under common Control with a party. “**Control**” in this context means (a) ownership, directly or indirectly, as to 50% or more of the voting securities or other ownership interest of

another entity, or (b) the possession, directly or indirectly, of the power to direct or cause the direction of its management and policies of another entity, whether by reason of ownership of voting securities, by contract relating to voting rights, resolution, regulation or otherwise.

“**Anti-Bribery Laws**” shall have the meaning set forth in Section 19.3.1.

“**Applicable Laws**” shall mean all applicable provisions of any and all laws, statutes, constitutions, treaties, rules, regulations, ordinances, directives judicial, executive, legislative or administrative orders, decrees, injunctions, judgments, permits, codes of conduct, guidance documents and guidelines of or from any supra-national, national, state, provincial or local governmental or non-governmental authority, agency, undertaking or body (whether present or future and in any territory) which has any jurisdiction in respect of or relevance to the applicable Party (or its Affiliates) and its business and/or (i) the manufacture of Customized DBS Test Kits and their provision to Physicians in the Territory; (ii) the submission of Samples to Centogene; (iii) the conducting of Development Services and Tests; (iv) the provision of Test Results to Physicians; (v) the Processing of Personal Data of any kind, including any applicable laws in relation to data protection, privacy, interception and monitoring of communications or any kind (“**Applicable Data Protection Laws**”); and (vi) other activities in the course of performing this Agreement.

“**Arising Intellectual Property**” means Intellectual Property generated by or on behalf of Centogene during the course of the Testing Services.

“**Business Continuity Plan**” shall have the meaning set forth in Section 15.3.1.

“**Business Day**” shall mean any day (other than Saturday or Sunday) on which banks are open for business in Zurich, Switzerland, or Rostock, Germany, as the case may be.

“**Centogene Background Intellectual Property**” shall mean any and all Intellectual Property that is owned or controlled by Centogene prior to the Effective Date.

“**Centogene DBS Cards**” shall mean any DBS Cards that were manufactured by or on behalf of Centogene.

“**Change of Control**” means with respect to Centogene:

- (i) the sale to a third party of all or substantially all of Centogene’s assets or business relating to this Agreement;
 - (ii) a merger, reorganization or consolidation involving Centogene after which the voting securities of Centogene (or its parent entity) outstanding immediately prior thereto cease to represent at least fifty per cent (50%) of the combined voting power of the surviving entity as a consequence of such merger, reorganization or consolidation; or
 - (iii) a transaction or series of related transactions in which a third party or group of persons or entities acting in concert becomes the direct or indirect beneficial owner of at least fifty per cent (50%) of the combined voting equity securities or otherwise controls Centogene.
-

“**CLIA**” shall mean the Clinical Laboratory Improvement Amendments, which regulate laboratory testing and require clinical laboratories to be certificated by their state as well as the Center for Medicare and Medicaid Services (“**CMS**”) before they can accept human samples for testing, and implementing CMS regulations and guidance, and all applicable state clinical laboratory licensing laws and regulations.

“**Complaint**” shall mean any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a Customized DBS Test Kit after it is released for distribution.

“**Confidential Information**” shall mean and include all know-how, data, documents, materials and information, whether in written, electronic, oral or other form, not in the public domain, relating to the Services, business affairs, finance plans, employee and business partner information, Intellectual Property, company policies and procedures, contractual relationships of the Parties (including any of the foregoing which has been disclosed prior to the Effective Date).

“**Covered Personal Data**” means Personal Data Processed by Centogene or any Centogene Affiliates or subcontractor in connection with this Agreement.

“**Customized DBS Test Kits**” shall mean the country specific DBS test kits listed in Exhibit 1 or as may be developed by Centogene pursuant to Section 6 from time to time, in each case to be supplied to Takeda in accordance with the Specifications, the relevant Purchase Order and the terms of this Agreement for distribution in the Territory. The Customized DBS Test Kits will not bear any logo of or reference to Takeda or any Takeda Affiliate.

“**Data Controller**” means the entity which, alone or jointly with others, determines the purposes and means of the processing of Personal Data.

“**Data Subject Request**” means any communication addressed to one or both Parties under this Agreement made by a Data Subject exercising one or several of his/her data protection rights under Applicable Data Protection Laws.

“**DBS**” shall mean dried blood spot.

“**DBS Cards**” shall mean dried blood spot filter cards.

“**Development Order**” shall mean any written development order which Centogene and Takeda or its Affiliates may execute from time to time, and which governs Development Services. A template Development Order is attached hereto as Exhibit 2.

“**Development Plan**” shall have the meaning set forth in Section 6.1

“**Development Services**” shall mean the development of certain Customized DBS Test Kit in accordance with Section 6 and the relevant Development Order for use in one or more countries. Development Services include (i) obtaining Regulatory Approval; (ii) meeting all regulatory requirements to import, distribute, supply and use the respective Customized DBS Test Kits in the relevant country in accordance with Applicable Laws; and (iii) development of the design and matrix for the DBS cards, instructions and informed consents. Development Services may include Customized DBS Test Kit

artwork content changes and translation into additional languages as further defined in the Development Order.

“**Effective Date**” shall mean 1 April 2023.

“**Expired Agreements**” shall have the meaning set forth in the Preamble, and subject to Section 4.

“**Force Majeure**” means, in relation to a Party (the “**Affected Party**”), any circumstances beyond the control of the Affected Party or its Affiliate which directly prevent or have a material adverse effect on the Affected Party’s performance of its obligations under this Agreement and includes (a) acts of God, flood, drought, earthquake or other natural disaster, war, threat of or preparation for war, armed conflict; (b) terrorist attack, civil war, civil commotion or riots; (c) epidemic or pandemic; and (d) any law or government order, rule, regulation or direction, or any action taken by a Governmental Entity, including but not limited to imposing an embargo, export or import restriction, quota or other restriction or prohibition, or failing to grant a necessary licence or consent. Force Majeure does not include any event or thing that, in relation to a Party (i) is attributable to the wilful act, neglect or failure to take reasonable precautions against such event by that Party; (ii) merely increases the cost of that Party’s performance of its obligations; or (iii) results from a failure or delay by any third party in the performance of its obligations under a contract with that Party (unless that third party is itself prevented from or delayed in complying with its obligations as a result of Force Majeure);

“**Forecast**” shall have the meaning set forth in Section 7.1.1.

“**General Records**” shall have the meaning set forth in Section 10.2.

“**Incident**” shall mean in accordance with Applicable Laws any malfunction or deterioration in the characteristics and/or performance of Customized DBS Test Kits, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to (i) the death of a Patient, or user or of other persons or to a serious deterioration in their state of health; (ii) incorrect testing results and/or an incorrect diagnosis.

“**Intellectual Property**” shall mean and include any intellectual property of whatever nature relating to raw data and interpretations thereof, patents, patentable inventions, trade secrets, design rights, copyright, trademarks, service marks, codings, social media and domain names, know how, whether registered, registrable or otherwise and including all applications (or rights to apply), renewals and extensions for such rights.

“**Joint Steering Committee**” or “**JSC**” shall have the meaning set forth in Section 16.3.1.

“**Legal Manufacturer**” shall mean the manufacturer of a medical device under Applicable Laws, i.e., the natural or legal person who is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a Third Party.

“Manufacturing Facility” shall mean the facility of Centogene or of Centogene’s Third Party subcontractor where the Customized DBS Test Kits are manufactured.

“Non-CG DBS Cards” shall mean any DBS Cards used by Takeda or its Affiliates that are based on and essentially similar to used Centogene DBS Cards but not manufactured by Centogene or its subcontractor under this Agreement.

“Non-CG DBS Test Kits” shall mean any test kits in use by Takeda or its Affiliates which contain Non-CG DBS Cards.

“Patients” shall mean individual persons whose Samples are tested by Centogene by using the Tests for rare diseases identified on the Testing Request Form as part of the Services.

“Personal Data” means any information relating to an identified or identifiable natural person (**“Data Subject”**); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

“Physicians” shall mean physicians in the Territory which have received Customized DBS Test Kits or Non-CG DBS Test Kits, and which submit Samples to Centogene for Services.

“Process” or **“Processing”** means any operation or set of operations which are performed on Personal Data or on sets of Personal Data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

“Purchase Order” shall mean any purchase order which Takeda may place, and which governs the manufacture and supply of Customized DBS Test Kits.

“Regulatory Approvals” shall mean any certifications, licenses, permits, approvals and authorizations for devices that are necessary in order to permit the manufacture, storage, marketing, promotion, distribution and provision of Customized DBS Test Kits or the provision of the Services in the Territory under Applicable Laws.

“Regulatory Authority” shall mean any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council, notified body or other governmental entity in each country in the Territory having competence over any activities in relation to this Agreement, including the provision of Customized DBS Test Kits to Physicians in the Territory, the submission of Samples to Centogene, the conducting of Tests, the provision of Test Results to Physicians and other activities in the course of rendering Services under this Agreement.

“Reports” shall have the meaning set forth in Section 10.1.

“Samples” shall mean blood samples of Patients in the Territory on DBS Cards or on

buccal swabs (only Oragene OCR-100 buccal swab collection sets are accepted), whole blood samples or plasma samples submitted to Centogene by Physicians for the purposes of carrying out Tests.

“**Scientific Research**” shall mean a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice.

“**Security Incident**” means any actual or reasonably suspected accidental, unlawful or unauthorised loss, destruction, alteration, access, use, disclosure of, damage or corruption to Covered Personal Data Processed under this Agreement. For the avoidance of doubt, this includes Personal Data Breach, as this term is defined in the Applicable Data Protection Laws.

“**Services**” shall mean the Development Services and the Testing Services to be performed by Centogene in accordance with this Agreement.

“**Specifications**” shall mean the design specifications for Customized DBS Test Kits identified and agreed in the relevant Development Order and Purchase Order, the latter with regards to existing Customized DBS Kits.

“**Standards**” shall mean any applicable and generally accepted international standards relating to the design, development, manufacture, quality control, quality assurance, distribution, risk management and vigilance of the Customized DBS Test Kits and Testing Services, including, as applicable, DIN EN ISO 13485, EN ISO 15189, ISO/IEC 27001:2017, CLIA, CAP and GCLP standards in their current and applicable versions.

“**Supply Failure**” shall mean Centogene’s inability to provide for any period of at least (i) three (3) consecutive months an average of [*****] per cent ([*****]%), or (ii) two (2) consecutive months an average of [*****] per cent ([*****]%), or (iii) one (1) month an average of [*****] per cent ([*****]%) of the binding amounts of the Forecast, in each case in accordance with the Turnaround Time.

“**Suspension Event**” shall have the meaning set forth in Section 8.8.

“**Takeda Product(s)**” shall mean any medicinal products under development or commercialized by or on behalf of Takeda or any Affiliate for the treatment rare genetic diseases for which such products are authorized.

“**Technical Quality Agreement**” shall mean the quality agreement for contract manufacturing and analytical testing services between the Parties dated 9 March 2021, as amended and updated from time to time.

“**Term**” shall have the meaning set forth in Section 21.1.

“**Territory**” shall mean worldwide.

“**Test Results**” shall mean the results of the Tests performed by Centogene.

“**Testing Facility**” shall mean the facility of Centogene, Am Strande 7, 18055 Rostock Germany where the Testing Services are to be performed.

“Testing Failure” shall mean with respect to Testing Services, Centogene’s inability to provide for any period of at least (i) three (3) consecutive months an average of [*****]per cent ([*****]%) of the Testing Services within the Turnaround Time, or (ii) two (2) consecutive months an average of [*****] per cent ([*****]%) of the Testing Services within the Turnaround Time, or (iii) one (1) month an average of [*****]per cent ([*****]%) of the Testing Services, in each case in accordance within the Turnaround Time.

“Testing Forecast” shall have the meaning set forth in Section 8.2.

“Testing Methodology” shall mean the agreed algorithm and methodology, further set out in Exhibit 8, pursuant to which Centogene will perform the Testing Services.

“Testing Request Form” shall mean the DBS test request forms included in the Customized DBS Test Kits and submitted by Physicians directly to Centogene.

“Testing Services” shall mean the performance of Tests on Samples by Centogene for the purpose of identifying Patients suffering from rare genetic diseases as the Parties may agree, and the services and activities set out in Exhibit 9 in accordance with Applicable Laws.

“Testing Services Fee” shall have the meaning set forth in Section 9.3.

“Test(s)” shall mean a test/the tests used by Centogene in the testing of Samples for the purpose of identifying Patients suffering from rare genetic diseases and/or monitoring their condition, as identified on the Testing Request Form. A Test shall be counted as the testing of one disease or one disease follow-up testing in accordance with the Testing Methodology. If a Testing Request Form for a Sample specifies the request for testing of more than one disease, then the number of Tests is defined as the sum of all Tests performed per Sample based on the diseases requested to be tested.

“Third Party” shall mean any legal entity or natural person other than the Parties or their Affiliates.

“Turnaround Time” or **“TAT”** shall mean:

- (i) in respect of Development Services, (i) Centogene providing Takeda with the first artwork file (technical file) within [*****] ([*****]) calendar days after the effective date of a Development Order; (ii) Centogene incorporating Takeda’s input into the artwork and providing the artwork file to Takeda within [*****] ([*****]) calendar days (or in exceptional cases within [*****] ([*****]) calendar days) after receipt of Takeda’s comments; and (iii) Centogene submitting the revised file for Regulatory Approval within [*****] ([*****]) month of the date of artwork approval by Takeda in accordance with Section 6.2;
 - (ii) in respect of the manufacture and supply of Customized DBS Test Kits, (a) an average period of [*****] ([*****]) Business Days between Centogene’s receipt of a Purchase Order and the Delivery of the ordered Customized DBS Test Kit in accordance with Section 7.8; or (b) any other timelines mutually agreed between the Parties in writing; and
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- (iii) in respect of Testing Services, an average period of [*****] ([*****]) Business Days between receipt of a complete order (including the Sample, the completed request form and the informed consent form) and reporting of Test Results to the Physician provided that the Sample has passed Centogene's sample entry quality control. Where the Test Results are sent by postal mail pursuant to Section 8.4.2, the Turnaround Time shall be [*****] ([*****]) Business Days, however, only as long as there is no delay during shipment which is not under the control by Centogene.

1.2 In this Agreement, unless the context otherwise requires:

- 1.2.1 "including" or "includes" or "in particular" (or any similar phrase) shall not be deemed to be terms of limitation, but rather shall be interpreted as though immediately followed by the words "without limitation";
- 1.2.2 a reference to any law, regulation, statute, order, rule, guideline or equivalent is a reference to the most up-to-date version in force from time to time;
- 1.2.3 a reference to a Party or any other person includes its successors, heirs and permitted assigns, and words denoting persons include individuals, bodies corporate, partnerships, unincorporated associations and other bodies (whether or not having separate personality);
- 1.2.4 singular includes plural and vice versa, and words denoting any gender shall include all genders; and
- 1.2.5 descriptive headings are for convenience only and shall not control or affect the meaning or construction of any provision of this Agreement.

2. SCOPE OF THE AGREEMENT

2.1 This Agreement defines the terms and conditions under which Centogene shall diligently, within the agreed timeframes and at a standard to be expected from a reputable, specialised and professional manufacturer and supplier of medical devices, development services and testing services:

- 2.1.1 perform the Services; and
- 2.1.2 manufacture and supply Takeda with Customized DBS Test Kits.

3. GEOGRAPHICAL COVERAGE

- 3.1 The Parties agree that, subject to Takeda's performance of its importation obligations under this Agreement, as of the Effective Date the Customized DBS Test Kits are available for use in the countries listed as Existing Customized DBS Test Kit Countries in Exhibit 1.
 - 3.2 Upon Takeda's request and in accordance with Section 6, Centogene will develop Customized DBS Test Kits for use in a country other than one listed as Existing Customized DBS Test Kit Countries in Exhibit 1.
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4. EXPIRED AGREEMENTS

Any activities currently on-going under the Expired Agreements or pursuant to statements of work governed by the Expired Agreements as at the Effective Date shall be governed by and rendered by Centogene in accordance with the terms of this Agreement.

5. STRUCTURE OF AGREEMENT

- 5.1 **Framework Agreement for Development Services.** This Agreement shall serve as a framework agreement under which Takeda or any Takeda Affiliate may request that Centogene performs Development Services from time to time on the basis of an individual Development Order. Each Development Order shall constitute a separate and distinct agreement and the terms and conditions of this Agreement shall be deemed incorporated by reference into each Development Order. The Parties agree that Takeda or any Takeda Affiliate may execute Development Orders under this Agreement, and in such (i) all references to “Takeda” in this Agreement as it relates to Development Services shall mean the Takeda Affiliate which executes the Development Order; and (ii) in all events, the sole contracting parties for all purposes related to such Development Order shall be Centogene and the Takeda Affiliate that executes the Development Order. For the avoidance of doubt, this Agreement shall not establish any obligation of Takeda or any Takeda Affiliate to enter into any Development Order or any obligation for Centogene to accept a Development Order. In the event of any ambiguity, doubt or conflict between this Agreement and any terms and conditions appearing or referred to in any Development Order, the terms and conditions of this Agreement shall take precedence over any terms and conditions of such Development Order unless such Development Order expressly provides that the Parties intend to overrule the corresponding provision in this Agreement with respect to such Development Order only.
- 5.2 **Supply of Customized DBS Test Kits.** Where Takeda or its Affiliates wish to purchase Customized DBS Test Kits from Centogene and Centogene agrees to supply Customized DBS Test Kits, Takeda or its Affiliate shall place a Purchase Order in accordance with Section 7.2. Takeda shall remain fully responsible for the performance of its obligations under this Agreement by its Affiliate regarding the supply of Customized DBS Test Kits and Centogene shall have no recourse against such Affiliate but shall address any claims or demands exclusively to Takeda.
- 5.3 **Performance of Testing Services.** This Agreement defines the terms and conditions under which Centogene shall provide Testing Services to Takeda and its Affiliates.

6. DEVELOPMENT SERVICES

- 6.1 **Development Services.** Takeda or its Affiliates may from time to time request from Centogene a quotation (“RFQ”) to perform Development Services. On the condition that Centogene is willing to perform the requested Development Services, Centogene shall submit to Takeda a project plan setting forth detailed steps and timelines for each of the countries requested by Takeda, including regulatory actions, development of, translations of and/or changes to the design and matrix for the DBS cards, instructions
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and informed consents (a “**Development Plan**”). Following receipt of a Development Plan, Takeda may request that the proposed Development Plan is amended or supplemented, and Centogene shall not unreasonably withhold its consent to any such request. Once the Development Plan is agreed, Takeda or its Affiliates may submit a Development Order in respect of that and upon signature of the Development Order by Centogene and Takeda (or its Affiliate), the Development Services specified in the Development Plan will be carried out by Centogene in accordance with the Turnaround Time and the terms of the relevant Development Order, generally accepted professional standards and Applicable Laws and Standards.

- 6.2 **Artwork Approval.** Any artwork prepared by Centogene in the course of the Development Services shall be submitted to Takeda in draft form for review and written approval (in its sole discretion).
- 6.3 **Variation.** Each Party may request, and the other Party shall not unreasonably withhold its consent, to amend and/or supplement a Development Order. The Party receiving the request shall consider it in good faith and shall inform the other Party of its decision within [*****] ([*****]) Business Days of receipt of such request. If the Parties are unable to reach agreement on any change request, the dispute shall be referred to the JSC. Once agreed between the Parties, Centogene shall implement the revised Development Order in accordance with its terms and the terms of this Agreement. In the event that the implementation of an agreed change to a Development Order results in any unforeseen costs and/or delays in agreed timelines, Centogene shall notify Takeda of such consequences in writing within [*****] ([*****]) Business Days of implementation and the Parties shall discuss any such consequences in good faith.
- 6.4 **Translations.** Centogene shall procure that the local translations of the Customized DBS Test Kits, and in particular the informed consent forms, will be made by certified translators and will meet the applicable industry standards, including as to accuracy and quality. Should the translation be below applicable industry standards and result in all or part of the informed consent being not understandable to the layman (e.g. Takeda receiving reasoned complaints from Physicians or Patients and providing evidence of such complaints to Centogene) so that the validity of the consent would be impacted, Centogene will, as the Legal Manufacturer and after reflecting on the severity of the issue in each case, remediate the language of the translation and replace the respective informed consent forms with amended versions in the Customized DBS Test Kits at [*****] as soon as possible, but in any event before the next shipment into the relevant country.
- 6.5 **Project Manager.** Each Party shall appoint an individual as project manager in respect of each Development Order. Centogene’s project manager shall be the responsible person for the overall conduct of the relevant Development Services and both project managers shall be the principal point of contact for the Parties for all matters relating to such Development Services. Neither Party shall change the project manager without the other Party’s prior written consent.

7. MANUFACTURE AND SUPPLY OF CUSTOMIZED DBS TEST KITS

7.1 Rolling Forecast.

- 7.1.1 Takeda will provide Centogene with a rolling forecast of its requirements
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for Customized DBS Test Kits for the shorter of the remaining period of the Term and twelve (12) months (“**Forecast**”). Takeda will update the Forecast on a monthly basis. The Forecast will be binding as follows:

7.1.1.1 [*****] per cent ([*****]%) of the forecasted amounts of Customized DBS Test Kits specified in the Forecast for month [*****] ([*****]) will be binding for both Parties, i.e., Takeda commits to order the forecasted amounts and Centogene agrees to supply Takeda with the forecasted amounts in the agreed Turnaround Times; and

7.1.1.2 the amounts forecasted for months [*****] to [*****] ([*****] – [*****]) will be non-binding for both Parties

7.1.2 Takeda may order, and Centogene agrees to supply, up to [*****] per cent ([*****]%) of the forecasted amounts for month [*****] ([*****]) of the Forecast in the agreed Turnaround Times. Orders above [*****] per cent ([*****]%) of the forecasted amounts shall be supplied on timelines to be agreed by the Parties.

7.2 **Purchase Orders.**

7.2.1 Takeda and/or its Affiliates will issue Purchase Orders on a [*****] basis which set forth (i) the respective Customized DBS Test Kit(s), (ii) the respective countries, languages and Specifications; (iii) the quantities of Customized DBS Test Kits; (iv) requested Delivery dates; (v) requested Delivery location and recipient; and (vi) Takeda’s Purchase Order number.

7.2.2 Purchase Orders shall become binding if Centogene has not rejected the Purchase Order in writing within [*****] ([*****]) Business Days from receipt of the Purchase Order. For clarity, any addition by Centogene in an order acceptance or similar document that is different from the terms of the Purchase Order will be deemed a rejection of the Purchase Order. Any terms that are in addition to or different from the terms of the Purchase Order that are contained in any order acceptance or similar document issued by Centogene will have no force or effect unless expressly accepted by Takeda in writing (e-mail shall suffice).

7.3 **Manufacture and Supply.** Centogene shall manufacture and supply the Customized DBS Test Kits in accordance with the relevant Purchase Order, the Specifications, the Turnaround Time, generally accepted professional standards and Applicable Laws and Standards.

7.4 **Manufacturing Facility.** Centogene shall, [*****], ensure that at all times during the Term, the Manufacturing Facility and all equipment required for the manufacture of Customized DBS Test Kits is in a qualified and validated state as required by the terms of this Agreement, Applicable Laws and Standards. Centogene shall be responsible for all aspects of the manufacturing of Customized DBS Test Kits (including, if applicable conducting design, installation, operational and performance qualification).

7.5 **Notification of Contaminants.** In the event Centogene identifies potential cross-

contamination in the Manufacturing Facility that may affect compliance with related regulatory requirements (including any Regulatory Approval), Centogene shall, as part of its Incident reporting procedures, immediately inform Takeda and any relevant Affiliate in writing and shall, upon request, submit to Takeda the remediation plan to resolve the problem.

- 7.6 **Minimum Stock.** Centogene shall store, or cause its Third Party subcontractor to store, under appropriate conditions, a minimum stock of all raw materials and components necessary to manufacture Customized DBS Test Kits of at least [*****] ([*****]) months of Forecast volumes or such amount as is otherwise mutually agreed between the Parties.
- 7.7 **Minimum Order Quantities.** Takeda agrees to place Purchase Orders in multiples of [*****] ([*****]) Customized DBS Test Kits and in accordance with a minimum order quantity of [*****] ([*****]) Customized DBS Test Kits per artwork for Belgium or Switzerland, and otherwise a minimum order quantity of [*****] ([*****]) Customized DBS Test Kits per artwork.
- 7.8 **Delivery.**
- 7.8.1 Unless otherwise agreed, Centogene shall deliver the Customized DBS Test Kits [*****] ([*****]) as defined by Incoterms 2010) to the destination specified in the relevant Purchase Order (“**Delivery**”).
- 7.8.2 Risk in the Contract Customized DBS Test Kits shall pass from Centogene to Takeda on Delivery. Title to the Customized DBS Test Kits shall pass upon written acceptance and approval of the Customized DBS Test Kits by Takeda at Takeda’s named place of destination.
- 7.8.3 Shipment shall be accompanied by complete documentation, including shipping documents and bills of lading, certificate of conformity per production batch and Takeda’s Purchase Order number.
- 7.8.4 Centogene shall perform all quality reviews, controls and process checks in accordance with the Technical Quality Agreement and Applicable Laws and Standards.
- 7.8.5 The Customized DBS Test Kits shall have a shelf life of no less than [*****] ([*****]) years and [*****] ([*****]) months remaining as at the date of Delivery unless otherwise agreed by the Parties on a case by case basis (such agreement not to be unreasonably withheld).
- 7.8.6 Subject to this Section 7.8, Centogene shall bear [*****] and risks involved in Delivery. Except as otherwise set out in Exhibit 1, Centogene shall clear the Customized DBS Test Kits for export and import and carry out any customs formalities for export, transportation and import, provided, however, that Takeda shall reasonably assist Centogene, upon Centogene’s request, with customs clearance, in particular that Takeda shall provide any documentation and execute any documents required to assist customs clearance and to meet the import customs formalities of any country of the Territory. To the extent Takeda requests a translated copy of any such
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document prior to execution, Centogene shall procure a translated copy of such document [*****] and Takeda shall be under no obligation to execute such document until it has been provided with such translated copy.

- 7.9 **Revisions to Delivery schedule.** Centogene shall ensure prompt Delivery to Takeda or Takeda's nominee as indicated by Takeda in the Purchase Order in accordance with the Turnaround Times. In the event Centogene becomes aware that it shall not be able to deliver Customized DBS Test Kits in accordance with the Turnaround Times to Takeda or Takeda's nominee, Centogene shall promptly notify Takeda in writing. The Parties shall promptly discuss the reasons for such occurrence. Centogene shall propose solutions and an alternate Delivery date. Centogene shall promptly (i) adhere to all instructions provided by Takeda to resolve the issue and (ii) implement all actions required to meet the new Delivery date. Centogene acknowledges that any revised Delivery shipment date agreed under this Section 7.9 shall not prevent or otherwise restrict Takeda from determining whether there has been a Supply Failure due to the failure of Centogene to meet the Turnaround Time.
- 7.10 **Non-Conforming Customized DBS Test Kit.** If Takeda notifies Centogene and specifies in reasonable detail that a certain Delivery of Customized DBS Test Kits does not contain the quantity of ordered Customized DBS Test Kits, does not meet the Specifications or Applicable Laws or Standards or was not manufactured according to the relevant Purchase Order, Takeda shall be entitled to reject such part of a delivered batch of Customized DBS Test Kits. In any case Centogene shall answer Takeda's question(s) as soon as possible and in any event within [*****] ([*****]) Business Days after receipt of Takeda's question(s) and provide Takeda with all information requested or necessary to evaluate the batch in question. If such non-conformance is not due (in whole) to acts or omissions of Takeda or any Third Party after Delivery, Centogene shall, subject to Section 7.11 and at Takeda's sole discretion, either (i) refund that part of the payment that relates to the production of such non-conforming Customized DBS Test Kits, or (ii) replace such non-conforming Customized DBS Test Kits [*****] and [*****] by Takeda in the return of Customized DBS Test Kits to Centogene or their destruction. In the event Centogene is required to replace such non-conforming Customized DBS Test Kits, Centogene shall replace such Customized DBS Test Kits within [*****] ([*****]) Business Days to enable continuity of supply of Customized DBS Test Kits.
- 7.11 **Independent Expert.** In case of any disagreement between the Parties as to whether a certain Delivery of Customized DBS Test Kits conforms to the applicable Specifications, the project managers will discuss in good faith to attempt to resolve any such disagreement. If the foregoing discussions do not resolve the disagreement within [*****] ([*****]) days, a representative sample of such Customized DBS Test Kits will be submitted to an independent testing laboratory mutually agreed upon by the Parties for tests and final determination of whether such Customized DBS Test Kits conform with such Specifications. The laboratory must be of recognized standing in the industry, and consent to the appointment of such laboratory will not be unreasonably withheld or delayed by either Party. Such laboratory will use the test methods contained in the applicable Specifications. Absent manifest error, determination of conformance by such laboratory with respect to all or part of such batch of Customized DBS Test Kits will be final and binding on the Parties. The Party against whom the determination is made will pay the fees and expenses of the laboratory incurred in making such determination.
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7.12 **Additional Information.** Upon Takeda's reasonable request, Centogene shall without undue delay provide all reasonable support and training materials to Takeda in order for Takeda to provide information on Customized DBS Test Kits and their relevant Specifications to healthcare professionals.

7.13 **Regulatory Information.** Upon Takeda's reasonable request, Centogene shall without undue delay provide all reasonable support and materials to Takeda in order for Takeda to provide information on Customized DBS Test Kits and their relevant Specifications to Regulatory Authorities. Any sharing of Customized DBS Test Kits information and materials with Regulatory Authorities by Takeda requires approval by Centogene.

7.14 **Changes to Customized DBS Test Kits.**

Unless otherwise agreed between the Parties, Centogene shall only make changes to the Specifications of the Customized DBS Test Kits if required by Applicable Law. In such case, Centogene will inform Takeda of the requirements under Applicable Law, the impact on the relevant Specifications of the Customized DBS Test Kit and the timelines for implementing the change. Centogene will provide Takeda with a sample of the new Customized DBS Test Kit at least [*****] ([*****]) calendar days prior to the first Delivery (as defined above) of said Customized DBS Test Kit. Centogene [*****] related to any changes to Specifications of the Customized DBS Test Kits required by Applicable Law.

8. TESTING SERVICES

8.1 Performance of Testing Services.

8.1.1 Centogene will perform Testing Services in accordance with generally accepted professional standards, the agreed Testing Methodology and Applicable Laws and Standards. In particular, Centogene will use the Tests to test Samples that are submitted to Centogene and will provide the Test Results to the Physicians. Centogene shall not change the agreed Testing Methodology without obtaining Takeda's prior written approval.

8.1.2 Centogene shall only perform Tests for diseases/indications explicitly requested by the Physician, subject to this Agreement, on the relevant Testing Request Form.

8.1.3 As part of the Testing Services, and at the regular rate of Customized DBS Test Kits and [*****], Centogene shall also process Non-CG DBS Test Kits and whole blood Samples, however, Centogene shall only process Non-CG DBS Test Kits when such processing is approved by Centogene's quality department prior to the use of the Non-CG DBS Test Kits.

8.2 **Testing Forecast.** Takeda will provide Centogene with a non-binding testing forecast of its requirements for Testing Services (forecast of Tests volume) for the Term for each country in the Territory ("**Testing Forecast**") no later than upon the Effective Date of this Agreement.

8.3 **Timeframes for Performance of Tests.** Centogene shall process submitted Samples in accordance with the Turnaround Time, provided the Customized DBS Test Kits

and/or Testing Request Forms submitted to Centogene contain sufficient testing material and all information required (e.g., Patient consent, sender information, disease, clinically relevant information as regards to Customized DBS Test Kits, etc.). If Centogene receives a Sample that is inadequate, incomplete or insufficient to perform the Testing Services, Centogene shall make reasonable efforts to obtain the missing information or, if necessary, a new Sample, and to process the relevant Sample as quickly as possible thereafter.

8.4 **Result Reporting and Use of CentoPortal®**

8.4.1 The Parties agree that during the Term, Centogene shall enable Physicians and Takeda and its Affiliates to access its web-based entry portal CentoPortal® free of charge as further set out in this Section 8.4. Test Results will be made available through electronic means exclusively via the CentoPortal®, subject to Section 8.4.2.

8.4.2 Where individual Physicians indicate that they cannot use CentoPortal® for technical or IT-infrastructure reasons or because of local legal concerns, Centogene shall provide access to the Test Results via postal mail without additional charge and in accordance with the Turnaround Time for Testing Services (provided that the necessary contact details have been duly and in full given by the Physician). Centogene may charge EUR [*****] per Test Result provided to a Physician via postal mail unless such provision of Test Result is required by any local law or regulation or requested by no more than [*****] ([*****]) Physicians per country. Upon notification of Physicians, Centogene shall inform Physicians about the existence of this exception, and shall not challenge any request made by Physicians to rely on it.

8.4.3 **CentoPortal® functionalities:**

- (i) **General.** Centogene shall provide Physicians who have received Customized DBS Test Kits and submitted Samples to Centogene with access to CentoPortal® within [*****] ([*****]) days of Sample receipt in order to directly enter Patient data needed for the testing of a Customized DBS Test Kit, to track and monitor the status of a kit sent to Centogene and to download Test Results. The use of CentoPortal® is subject to the terms as set out on <https://www.centoport.com/terms-of-use> and <https://www.centoport.com/api/static-resources/terms-conditions/en>.
 - (ii) **Language.** At a minimum, Centogene will offer CentoPortal® in the following languages: English and Spanish. By 1 July 2023, Centogene shall implement CentoPortal® in Italian language.
 - (iii) **Minimum operational availability.** CentoPortal® shall be available [*****] ([*****]) hours per day and [*****] ([*****]) days per week. Where maintenance is needed and the CentoPortal® will be offline, Centogene shall:
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- provide to Takeda at least [*****] ([*****]) days advance written notice in an email; and
- provide a notification in CentoPortal [*****] ([*****]) days in advance, specifying the date and time when CentoPortal® is planned to go through a maintenance procedure; such notification shall include a support phone number for Physicians.

CentoPortal® shall not be offline for more than [*****] ([*****]) hours.

- (iv) **Bug resolution.** Centogene will diagnose and solve errors in the CentoPortal® as soon as possible and use best efforts to provide a solution to sustain the basic functional features of the CentoPortal® (including the ability for Physicians to log-in, check the status of sent Samples and view Test Results) within [*****] ([*****]) Business Days after acknowledgement of the error or bug.

- 8.4.4 **Centogene Email Hotline.** Centogene shall establish and provide a dedicated email hotline service for healthcare personnel. Centogene shall procure that (i) any query made via such email hotline by healthcare personnel is responded to, and in complex queries replied with the first response, within [*****] ([*****]) hours of such query being made, (ii) the response time will be recorded; and (iii) any query may be made in English or German and that the relevant response shall be made in the same language.
- 8.5 **Testing Methodology and Training Materials.** Upon Takeda's request Centogene will provide training materials in English language, via e-mail only, clearly explaining the Testing Methodology in order for Takeda to train and/or answer questions of healthcare professionals.
- 8.6 **Testing Facility.** Centogene shall, [*****], ensure that at all times during the Term the Testing Facility is in a qualified and validated state appropriate for provision of Testing Services as required by the terms of this Agreement, Applicable Laws and Standards and by Regulatory Authorities. Centogene shall be responsible for validating and qualifying the instruments and equipment used for the Tests (including conducting installation, operational and performance qualification) and maintaining all such instruments and equipment in a compliant state.
- 8.7 **Notifications to Takeda.** In the event Centogene identifies potential cross-contamination in the Testing Facility or an issue that may affect compliance with related regulatory requirements (including to any Regulatory Approval), Centogene shall, as part of its Incident reporting procedures, immediately inform Takeda and any relevant Affiliate in writing and shall, on request, submit to Takeda the remediation plan to address the problem.
- 8.8 **Suspension.** Takeda may suspend the provision of Testing Services, in whole or in part, immediately by providing written notice if:
- 8.8.1 the provision of Customized DBS Test Kits to Physicians and the performance of Tests with Samples in any country of the Territory is (i)
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found by any Regulatory Authority, court, industry association or other entity with competence over any Takeda Affiliate to be impermissible, or (ii) in the reasonable written opinion of Takeda's compliance function likely to be impermissible; or

8.8.2 Centogene loses any Regulatory Approvals required to provide the Testing Services in accordance with Applicable Laws,

(any of the foregoing being a "**Suspension Event**") provided that Takeda may only suspend the provision of Testing Services with respect to the country(ies) directly affected by such Suspension Event(s).

8.9 **Resumption of services.** Takeda may, at its reasonable discretion, end the partial or complete suspension of the testing services pursuant to Section 8.8, in whole or in part, at any time by providing written notice to Centogene. Upon either (i) receipt of Takeda's written notice, or (ii) final resolution of the Suspension Event, as agreed between the Parties in good faith, whichever of (i) or (ii) comes first, Centogene shall re-establish the suspended Testing Services as soon as reasonably practicable.

9. PRICE AND TERMS OF PAYMENT

9.1 **Development Services.** The prices for Development Services are set out in Exhibit 7 and Centogene shall invoice Takeda (and not any Affiliate of Takeda, whether or not an Affiliate is the contracting party under a Development Order) for the Development Services specified in each Development Order immediately upon completion of all Development Services specified in such Development Order.

9.2 **Supply of Customized DBS Test Kits.** The prices for the manufacture and supply of Customized DBS Test Kits are set forth in Exhibit 7. Centogene shall invoice Takeda upon Delivery of Customized DBS Test Kits.

9.3 Testing Services.

9.3.1 In consideration for the performance of the Testing Services, Takeda will pay a fee for each Test in respect of which Testing Services are performed in accordance with the terms of this Agreement to Centogene (the "**Testing Services Fee**") as set out in Exhibit 7.

9.3.2 Centogene shall invoice Takeda in respect of the Testing Services Fee on a calendar monthly basis in arrears.

9.3.3 The Testing Services Fee represents all of Centogene's costs and fees relating to each Test in respect of which Testing Services are performed, and is fixed for the Term. Centogene shall [*****] in respect of Testing Services or any ancillary services or activities absent the Parties' agreement in writing following a material change in scope of the Testing Services envisaged under this Agreement.

9.4 Payment Terms. Unless otherwise stated:

9.4.1 all payments under this Agreement will be due within [*****] ([*****]) days of receipt of invoice; and

9.4.2 all prices and fees are net prices, meaning exclusive of VAT and are in Euros.

10. REPORTING & RECORD KEEPING

- 10.1 **Reports.** Centogene shall provide Takeda, within [*****] ([*****]) calendar days after the end of a calendar month, with written reports on the Development Services, manufacture and supply of Customized DBS Test Kits and Testing Services in that month, which shall include the details set forth in Exhibits 3 and 4 (“**Reports**”). Centogene will only send the Reports to the Takeda email address: Global.Support.DBS@takeda.com.
- 10.2 **Maintenance of Records.** Centogene shall maintain accurate and complete records of all Testing Request Forms, Samples received, correspondence, invoices, and/or other information in Centogene’s possession relating to the activities performed under this Agreement (collectively, “**General Records**”). The General Records shall be maintained in accordance with recognized commercial accounting practices and retained during the Term and thereafter for a period of five (5) years or such longer period required by Applicable Laws.
- 10.3 **Audit of General Records.** Not more than [*****] per calendar year during the Term and not more than [*****] within three (3) years after the end of the Term, upon reasonable prior written notification and during normal business hours and with the purpose of confirming Centogene’s compliance with the terms of this Agreement, Centogene agrees to permit independent auditors bound to professional secrecy selected by Takeda and reasonably acceptable to Centogene to examine and audit the General Records, [*****]. The independent auditors shall be bound by the confidentiality and non-use obligations set forth in this Agreement. For clarity, any such audit (or failure to inspect) shall not relieve Centogene of its obligation to comply with Applicable Laws and the provisions of this Agreement and does not constitute a waiver of any right otherwise available to Takeda or its Affiliates. Takeda shall [*****] independent auditors. Centogene shall use reasonable efforts to ensure that all corrective or preventive actions identified in audits carried out pursuant to this Section 10.3 are carried out promptly and [*****] in accordance with a mutually agreed timetable defined at the audit close, and provide evidence to Takeda that such actions have been carried out as soon as reasonably practicable following the carrying out of such actions. Any re-audits shall be carried out at the frequency specified in the last audit report.

11. DATA PROTECTION AND INFORMED CONSENT FORMS

11.1 Data Protection and Data Use.

- 11.1.1 Centogene agrees to comply with the Data Protection Requirements as set out in Exhibit 6 in performing its obligations and other activities under this Agreement.
- 11.1.2 Centogene shall Process Covered Personal Data for the purposes of performing its obligations under this Agreement.
- 11.1.3 Centogene shall not use Covered Personal Data for the promotion of any medicinal product.
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- 11.1.4 Subject always to Sections 11.1.5 and 11.1.6, Centogene and any Centogene Affiliate or subcontractor may share Covered Personal Data with Third Parties, or otherwise use such data, only for Scientific Research and the diagnosing of patients. When Centogene or any Centogene Affiliate or subcontractor (either alone or jointly with one or more others, directly or indirectly) wishes to use or share Covered Personal Data, whether or not de-identified, for the purpose of offering or providing a service or benefit to any Third Party for Scientific Research in the disease areas [*****], then Centogene will inform Takeda about the nature of the Scientific Research and how the Covered Personal Data shall be used, and both Parties will discuss whether there is any mutual interest for collaboration. Such informing shall take place in the regular weekly alliance management meetings, the JSC meetings and the bi-annual cross-functional workshops planned to be implemented by the Parties, and shall be documented in writing either per email or in the minutes of the meetings.
- 11.1.5 Covered Personal Data in respect of patients shall not be shared with any Third Party unless in de-identified form.
- 11.1.6 To the extent any Covered Personal Data in respect of healthcare professionals is shared with a Third Party, Centogene shall ensure that it does not disclose whether or not such healthcare professionals have diagnosed a patient with [*****].
- 11.1.7 Centogene shall not share, or otherwise use, any Covered Personal Data for Scientific Research pursuant to Section 11.1.4 to the extent that the sharing or use of such Covered Personal Data may in any respect adversely affect the reputation of Takeda or any of its Affiliates.
- 11.2 **Informed consent forms.** The Parties are aware of the importance of the Customized DBS Test Kits' conformity with Applicable Laws, in particular the informed consent forms' conformity with Applicable Data Protection Laws and gene diagnostic laws in each agreed country of the Territory as well as in the country where the Diagnostic Testing Services are performed. Centogene shall:
- 11.2.1 ensure conformity of the Customized DBS Test Kits, in particular the informed consent forms, with Applicable Laws and Standards at the point of time of delivery of a batch of Customized DBS Test Kits with respect to such respective batch.
- 11.2.2 as part of the Testing Services, diligently monitor Applicable Laws and Standards in accordance with Centogene's internal quality system and Applicable Laws to ensure compliance of the Customized DBS Test Kits, in particular the informed consent forms, with Applicable Laws and Standards, so that compliance is ensured at the point of time of the delivery of a batch of Customized DBS Test Kits with respect to such respective batch. Centogene shall inform Takeda of any changes immediately after it becomes aware of any changes to Applicable Laws or Standards that would affect the supply and provision of any Customized DBS Test Kits in any country of the Territory;
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- 11.2.3 provide Takeda with any updates to the informed consent form or privacy notice (in pdf) at least [*****] ([*****]) days prior to the first implementation and agrees to remedy any potential data privacy compliance deficiencies identified by Takeda. Centogene represents and warrants that the local translations of the DBS Test Kits, and in particular the informed consent forms, will be made by certified translators and will meet the applicable industry standards in terms of accuracy and quality. Should the quality and accuracy of the translation be below applicable industry standards and result in the fact that (parts of) the informed consent is absolutely, even by logical interpretation, not understandable to the layman (e.g. Takeda receiving reasoned complaints from Physicians or Patients and provides proof to Centogene) so that the validity of the consent would be impacted, Centogene will — as the responsible manufacturer and after reflecting on the severity of the issue in each case — remediate the language of the translation and replace the respective informed consent forms with amended versions in the Customized DBS Test Kits [*****], either immediately or as soon as reasonably possible, but in any event before implementation in such country.

12. REGULATORY

- 12.1 **Regulatory Responsibility.** Centogene, as the Legal Manufacturer of the Customized DBS Test Kits, shall, subject to the provisions of this Agreement, (i) bear all related legal and regulatory responsibility for manufacture and Delivery of the Customized DBS Test Kits under its own name, and (ii) unless otherwise required under Applicable Laws, be solely responsible for all regulatory activities, regulatory reporting and maintenance requirements and medical information services, in each case relating to an individual Customized DBS Test Kit and its respective destination country. Centogene, in particular, shall [*****]:

- 12.1.1 diligently monitor Applicable Laws and Standards of the Territory in accordance with Centogene's internal quality system and Applicable Laws to ensure compliance and will immediately inform Takeda of any changes that would affect the manufacture, supply and provisions of any Customized DBS Test Kits or the provision of Services
- 12.1.2 obtain and maintain in its own name all Regulatory Approvals required to provide the Services;
- 12.1.3 obtain and maintain all Regulatory Approvals and meet all regulatory requirements for the manufacture of Customized DBS Test Kits and for the Customized DBS Test Kits to be supplied to Takeda for use in the relevant country in accordance with Applicable Laws, provided that if a change in Applicable Laws and Standards in a country in the Territory will lead to material cost increases for Centogene during the Term then the Parties shall discuss in good faith how to mitigate such increase;
- 12.1.4 except otherwise necessary or agreed between the Parties in writing on a case by case basis, act as the sole interface with and handle all correspondence, meetings and interactions with the relevant Regulatory
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Authorities;

- 12.1.5 ensure conformity of the Customized DBS Test Kits, in particular the informed consent forms, with all Applicable Laws (including Applicable Data Protection Laws and gene diagnostic laws), the Specifications and Standards of the Territory at the point of time of delivery of a batch of Customized DBS Test Kits with respect to such respective batch; and
 - 12.1.6 keep Takeda informed of its material regulatory activities related to Customized DBS Test Kits and Testing Services and outcomes of meetings with and decisions made by Regulatory Authorities.
- 12.2 Where Takeda or a Third Party contracted by Takeda is acting as importer and/or distributor of Customized DBS Test Kits in any country under this Agreement as required by Applicable Laws, Takeda shall be responsible for compliance with the relevant Applicable Laws regarding the import and distribution of Customized DBS Test Kits, in each case only to the extent set out in Exhibit 1 and [*****] of managing importation licenses.
- 12.3 **Transparency.** Upon request, Centogene shall provide reasonable assistance to Takeda or its Affiliates in relation to any obligations to report the value of any of the activities performed by Centogene under this Agreement as a transfer of value as defined under the EFPIA HCP/HCO Disclosure Code. Centogene undertakes to provide the necessary information and assistance to Takeda or its Affiliates, as the case may be, on a calendar quarterly basis within [*****] ([*****]) days after the end of a calendar quarter. A pro forma quarterly transparency report is attached in Exhibit 4.

13. QUALITY

- 13.1 **Technical Quality Agreement.** The Technical Quality Agreement between the Parties shall be binding upon the Parties to this Agreement. The Parties intend in good faith to update the Technical Quality Agreement until 1 April 2023 to correctly reflect the relationship between the Parties which is not based on contract manufacturing.
- 13.2 **Precedence.** In the event of any discrepancy or inconsistency between the tasks listed in such Technical Quality Agreement and the terms of this Agreement, the terms of the Technical Quality Agreement will govern with respect to quality matters, and the terms of this Agreement shall govern with respect to all other matters.
- 13.3 **Quality Systems.** Centogene shall maintain and diligently document a quality assurance system and a risk management system for the manufacture and supply of Customized DBS Test Kits in accordance with the Technical Quality Agreement, Applicable Laws, Standards and Regulatory Approvals as evidenced by certificates from Regulatory Authorities, such certificates to be based on Applicable Laws and Standards governing the manufacture and distribution of the product, as classified on the Effective Date. In the EU, the Customized DBS Test Kit is, as of the Effective Date, classified as a Class I IVD device. Centogene's quality systems shall include written policies and procedures that address, at a minimum design control, training, supplier and purchasing controls, Sample management and change control, supplier audits, vendor change notifications, facilities and equipment, exception / deviation notification, Complaint reporting and CAPA, facilities and equipment systems, laboratory control
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systems, data integrity standards, data protection, paper and electronic archiving and protection of IT networks.

- 13.4 **Audit of Manufacturing Facility and Testing Facility.** Not more than [*****] per calendar year during the Term and not more than [*****] within three (3) years after the end of the Term, Takeda and its Affiliates or Third Party appointed by Takeda may, upon written request, conduct a coordinated quality audit at the Manufacturing Facility and the Testing Facility, each audit including any alternate facilities and those of Centogene's approved subcontractors, during normal business hours of the manufacturing controls, quality control testing, Centogene's oversight of assembly/manufacturing/testing operations and storage, including appropriate quality records. Takeda may also conduct 'for cause' audits at shorter notice to address serious or on-going supply or quality issues, as well as follow up audits in respect of any observations noted during any audit carried out pursuant to this Section 13.4. Centogene shall use reasonable efforts to ensure that all corrective or preventative actions identified in audits carried out pursuant to this Section 13.4 are carried out promptly and [*****] in accordance with a mutually agreed timetable defined at the audit close, and provide evidence to Takeda that such actions have been carried out as soon as reasonably practicable following the carrying out of such actions. Any re-audits shall be carried out at the frequency specified in the last audit report.
- 13.5 **Inspections.** Centogene shall notify Takeda immediately of critical or major inspection report observations issued by a Regulatory Authority related to the Customized DBS Test Kits, the Services, the Specifications, the Manufacturing Facility or the Testing Facility, and shall promptly send Takeda a copy of any such critical or major inspection report observations (or other findings) as well as the relevant sections of responses to any inspection reports prepared in accordance with this Section 13.5.
- 13.6 **Validation Studies.** Centogene shall perform all validation studies and stability studies required under Applicable Laws and provide Takeda with copies of the results of such studies on request and during the audit pursuant to Section 13.4.

14. VIGILANCE

- 14.1 **Vigilance System.** Centogene shall maintain and document a vigilance system for Customized DBS Test Kits which is in accordance with Regulatory Approvals, Applicable Laws and Standards. To the extent required by Applicable Laws, Centogene shall be responsible for literature review, maintaining a global safety database, Incident reporting, Incident follow-up reports, preparation and submission of all safety reports towards Regulatory Authorities, as well as deciding upon field safety notices and conducting any field safety corrective notices/ actions, subject to the terms of this Agreement.
- 14.2 **Takeda Assistance.** Takeda will report Complaints and Incidents to Centogene and assist in the conduct of field safety corrective actions, e.g., recalls, under responsibility of Centogene. Takeda shall notify Centogene of any Complaint or Incident immediately, but not later than [*****] ([*****]) calendar day after awareness of Takeda. Such notice shall be forwarded to Centogene by email and include the name, address, and telephone number of the person making the Complaint or report of an Incident, the Customized DBS Test Kit(s) involved and the nature of the Incident.
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- 14.3 **Complaint and Incident Investigation.** Centogene shall be responsible for the evaluation of Complaints and reported Incidents. Centogene shall investigate any Complaint or report of an Incident. Takeda shall cooperate with, and provide reasonable and necessary information and assistance to, Centogene in connection with such investigation. Centogene shall immediately notify Takeda of the results of any investigation related to Customized DBS Test Kits in the Territory.
- 14.4 **Incident Documentation.** Centogene shall provide, in a timely fashion and as requested during an audit, implemented Incident reporting and consultation procedures for Incidents as well as problem solutions.
- 14.5 **Field Safety Corrective Actions; Cost.** To the extent required by Applicable Laws, Centogene shall be responsible for any field safety notices and field safety corrective actions regarding the Customized DBS Test Kits in the Territory. Centogene [*****] of any field safety notices and field safety corrective actions resulting from the manufacture and quality assurance of the Customized DBS Test Kits to the extent that the Customized DBS Test Kits were manufactured and quality assured by or on behalf of Centogene.

15. GENERAL OBLIGATIONS

- 15.1 **Personnel.** Centogene shall exercise, and ensure that its personnel exercise, all reasonable skill, care, and diligence in manufacture and supply of Customized DBS Test Kits and in the performance of the Services. Centogene shall ensure that all its personnel who are involved in the manufacture and supply of Customized DBS Test Kits and in the performance of the Services are technically competent and suitably qualified to carry out their duties.
- 15.2 **Continuous Improvement.** Centogene shall use reasonable efforts to develop and implement continuous cost and quality improvement programs.
- 15.3 **Business Continuity.**
- 15.3.1 Centogene acknowledges the importance to Takeda of an uninterrupted manufacture and supply of Customized DBS Test Kits, and uninterrupted provision of the Services. Centogene shall take, throughout the Term, all necessary steps to identify and mitigate potential threats to its ability to perform its obligations under this Agreement and any Development Orders. The current version of Centogene's written business continuity and risk mitigation plan to maintain continuity of the provision of Customized DBS Test Kits and Services under adverse conditions ("**Business Continuity Plan**") has been provided to Takeda as at the Effective Date. Centogene shall implement and maintain the Business Continuity Plan, as amended from time to time, during the Term.
- 15.3.2 Centogene shall evaluate and update the Business Continuity Plan in accordance with industry standards. Upon the reasonable request of Takeda, Centogene will provide details to Takeda of the implementation of and any updates to such Business Continuity Plan. Centogene shall consider in good faith any reasonable comments that Takeda may have with respect to the Business Continuity Plan and shall incorporate Takeda's
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comments in the Business Continuity Plan as agreed by the Parties without undue delay.

15.4 Service or Supply Failures.

- 15.4.1 During the Term Centogene shall promptly, and in any event within [*****] ([*****]) Business Days, notify Takeda in writing of any potential or actual disruption to the manufacture and supply of Customized DBS Test Kits or the provision of Services, and present to Takeda a corrective action plan addressing when the (potential) disruption of manufacture and supply of Customized DBS Test Kits or the provision of Services will be resolved and any proposed alternative supply arrangements in the interim in order to minimise the disruption to Takeda (the “**Takeda Corrective Plan**”). Takeda shall have the right to approve or reject a Takeda Corrective Plan on reasonable grounds, such grounds to be provided to Centogene in writing within [*****] ([*****]) Business Days of receipt of the relevant Takeda Corrective Plan from Centogene. If Takeda reasonably rejects the Takeda Corrective Plan, Centogene shall within [*****] ([*****]) Business Days following such rejection make the necessary changes to the Takeda Corrective Plan and submit the updated Takeda Corrective Plan to Takeda for approval or rejection. If Takeda rejects the updated Corrective Plan on reasonable grounds, detailed to Centogene in writing within [*****] ([*****]) Business Days, both Parties shall convene and negotiate in good faith the Takeda Corrective Plan. Centogene shall implement any agreed Takeda Corrective Plan within the timetable set out in the Takeda Corrective Plan. The Parties acknowledge that the process for agreeing a Takeda Corrective Plan, and any subsequent implementation of an agreed Takeda Corrective Plan, shall be without prejudice to Takeda’s other rights and remedies under this Agreement.
- 15.4.2 Without limiting any other rights or remedies of Takeda, if Centogene fails, or the Parties mutually determine that it is likely that Centogene will fail, to meet the Turnaround Time for any Development Services, then Takeda shall be entitled, as liquidated damages, to a discount of [*****] per cent ([*****]%) of the price of the affected Development Services and a [*****] per cent ([*****]%) discount for each additional month’s delay in meeting the relevant deadlines.
- 15.4.3 Without limiting any other rights or remedies of Takeda, if any, if there is, or the Parties mutually determine there is likely to be, a Supply Failure, then Centogene shall reimburse Takeda for any difference between the price of (A) the relevant Customized DBS Test Kits, and (B) alternative or replacement test kits that the Parties agree may be obtained from a Third Party, together with Takeda’s reasonable and documented, direct out-of-pocket costs and expenses incurred in engaging the Third Party. In addition to the aforementioned, in the event if a Supply Failure, Takeda shall be entitled, as liquidated damages, to a discount of [*****] per cent ([*****]%) off the price of the affected Customized DBS Test Kits for each month that delivery is delayed. The Parties confirm that this sum represents a genuine pre-estimate of Takeda’s loss. The adjusted price for the Customized DBS Test Kits shall be reflected by Centogene in its
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invoice.

15.4.4 Without limiting any other rights or remedies of Takeda, if there is, or the Parties mutually determine there is likely to be, a Testing Failure, then Takeda shall have the right to request that Centogene and Centogene shall be obliged to immediately take all necessary measure to start providing Testing Services from an alternate facility as soon as possible and in any event no later than within [*****] ([*****]) calendar days upon occurrence of a Testing Failure.

15.5 **Subcontracting.** Centogene shall not subcontract any activities or obligations under this Agreement to a Third Party without Takeda's prior written consent or as agreed in any Development Order or the Technical Quality Agreement. Centogene may propose to subcontract certain defined activities under this Agreement to a Third Party and Takeda shall consider in good faith such proposal and inform Centogene of its decision within [*****] ([*****]) days of receipt of the consent request. Any consent given by Takeda shall require that the agreements between Centogene and such Third Parties are made in writing and fully correspond to the agreements between Takeda (and any of its Affiliates) and Centogene. Centogene shall ensure that Centogene's obligations under this Agreement shall be fulfilled including, without limitation, with regards to Intellectual Property, publications, confidentiality and data protection. In particular, Centogene shall ensure that such Third Parties have executed appropriate agreements with Centogene containing substantially similar terms regarding confidentiality, Intellectual Property and publications as those set out in this Agreement. In the event that Centogene fulfils its obligations through a permitted subcontractor, Centogene shall remain fully liable for the fulfilment of its obligations under this Agreement. Centogene shall be responsible for the qualification and validation of any subcontractor.

15.6 **No Conflict.** Centogene shall not, during the Term, enter into any agreements that limit its capacities and resources which are required to meet the binding portion of the Forecast. Centogene will provide all staff, facilities, equipment and any other means necessary to meet such obligation in accordance with the terms of this Agreement.

15.7 **No Exclusivity.** Nothing in this Agreement shall prevent Takeda or any of its Affiliates from (i) appointing a Third Party to conduct services that are the same as, or similar to, the Services, or (ii) obtaining its demand for DBS test kits, which are not processed by Centogene under this Agreement, from any Third Party. Nothing in this Agreement shall prevent Centogene from providing services to any Third Party that are the same as, or similar to, the Services.

16. ALLIANCE MANAGERS; JOINT STEERING COMMITTEE

16.1 **Alliance Managers.** Promptly following the Effective Date, each Party shall designate [*****] ([*****]) individuals ("Alliance Managers") and form a project team ("Alliance Team") to exchange information, facilitate communication and coordinate the Parties' operational day-to-day activities under this Agreement. The Alliance Team shall meet as often as necessary to accomplish its objectives, but at least [*****] ([*****]) every [*****] during a teleconference or videoconference. Unless agreed otherwise between the Alliance Managers, the Alliance Team will meet face-to-face at least [*****] ([*****]) per [*****]. The Alliance Team shall attend all meetings between the Parties including Joint Steering Committee meetings. Each Party may

change its designated Alliance Manager from time to time upon written notice to the other Party.

- 16.2 In the event either Party raises an operational issue, both Parties will seek to resolve this during the weekly calls and within the timelines agreed by the Parties. If no timely resolution or agreement can be found, the Parties commit to find a solution during the quarterly face-to-face meeting. If an issue is still not resolved or is deemed sufficiently serious by either Party, the matter can be escalated to the Joint Steering Committee.

16.3 **Joint Steering Committee (JSC).**

16.3.1 Promptly after the Effective Date the Parties shall establish and during the Term the Parties shall operate a joint steering committee, which shall have the primary role in ensuring the overall success of the cooperation (“**Joint Steering Committee**” or “**JSC**”). The Joint Steering Committee will act as a forum between the Parties for discussion of business reviews, strategic decision-making, and resolution of issues escalated by the Alliance Managers to the JSC or disputes between the Parties pursuant to Section 23.1. The JSC shall be comprised of an equal number of [*****] ([*****]) managing directors or board members of each Party.

16.3.2 The initial JSC members shall be:

16.3.2.1 For Takeda: [*****] and [*****].

16.3.2.2 For Centogene: [*****] and [*****].

16.3.3 Takeda shall designate the chairman of the JSC who shall be responsible to call for ad hoc meetings upon either Party’s request. The meeting place shall alternate between the offices of Takeda and Centogene, or as otherwise decided by the JSC. JSC meetings may be conducted in person, by telephone or videoconference.

16.3.4 Each Party shall provide the other Party with written notice of its new representatives for the JSC immediately upon replacement. Each Party may invite guests to the meetings, in order to discuss special technical or commercial topics.

16.3.5 Takeda shall keep accurate and complete minutes of the JSC meetings and shall circulate such minutes in English to Centogene within [*****] ([*****]) Business Days after each meeting, and the Parties shall agree on the minutes of such meeting promptly. Each Party shall be responsible for the expenses incurred by its employees and its members of the JSC.

16.3.6 All decisions of the JSC are to be made in good faith and in the best interest of the Agreement, and the Parties shall use their reasonable efforts to take decisions unanimously. In the event of any failure to agree, if the Joint Steering Committee (or the Parties) determines that the matter should be referred to an expert (but not any matter which may be determined at the

sole discretion of Takeda or Centogene or their respective Affiliates), then the dispute will be referred for resolution to an expert. The expert will only be authorized to address those matters specifically referred to the expert. If the expert's opinion is not accepted in whole or in part by either or both Parties, any remaining dispute will be resolved under the dispute resolution provisions set forth in Section 23.1.

- 16.3.7 The JSC shall not have any power to amend, modify or waive compliance with this Agreement. Each Party shall retain its rights, powers and discretion and no such rights, powers or discretion shall be delegated or vested in the JSC unless the Parties expressly so agree in writing.

17. CONFIDENTIALITY

- 17.1 **Confidentiality.** All Confidential Information disclosed, revealed or otherwise made available by one Party ("**Disclosing Party**") to the other Party ("**Receiving Party**") under, or as a result of, this Agreement is furnished to the Receiving Party solely to permit the Receiving Party to exercise its rights, and perform its obligations, under this Agreement. The Receiving Party shall not use any of the Disclosing Party's Confidential Information for any other purpose, and shall not disclose, reveal or otherwise make any of the Disclosing Party's Confidential Information available to any Third Party, without the prior written authorization of the Disclosing Party.
- 17.2 **Safeguards.** In furtherance of the Receiving Party's obligations under Section 17.1 hereof, the Receiving Party shall take all appropriate steps, and shall implement all appropriate safeguards, to prevent the unauthorized use or disclosure of any of the Disclosing Party's Confidential Information. Without limiting the generality of this Section 17.2, the Receiving Party shall disclose any of the Disclosing Party's Confidential Information only to those of its officers, employees, commercial agents, distributors, consultants, licensees, potential licensees and financial investors that have a need to know the Disclosing Party's Confidential Information, in order for the Receiving Party to exercise its rights and perform its obligations under this Agreement, and only if such officers, employees, agents, consultants, licensees, potential licensees and financial investors have executed appropriate non-disclosure agreements containing substantially similar terms regarding confidentiality as those set out in this Agreement or are otherwise bound by obligations of confidentiality effectively prohibiting the unauthorized use or disclosure of the Disclosing Party's Confidential Information. The Receiving Party shall furnish the Disclosing Party with immediate written notice of any unauthorized use or disclosure of any of the Disclosing Party's Confidential Information and shall take all actions that the Disclosing Party reasonably requests in order to prevent any further unauthorized use or disclosure of the Disclosing Party's Confidential Information.
- 17.3 **Exceptions.** The Receiving Party's obligations under Section 17.1 and 17.2 hereof shall not apply to the extent that the Receiving Party can prove by written evidence that the respective Confidential Information:
- 17.3.1 passes into the public domain, or becomes generally available to the public through no fault of the Receiving Party;
 - 17.3.2 was known to the Receiving Party prior to disclosure hereunder by the
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Disclosing Party;

17.3.3 is disclosed, revealed or otherwise made available to the Receiving Party by a Third Party that is under no obligation of non-disclosure and/or non-use to the Disclosing Party;

17.3.4 is required to be disclosed under Applicable Law or by court order; provided, however, that the Receiving Party shall furnish the Disclosing Party's with as much prior written notice of such disclosure requirement as reasonably practicable, so as to permit the Disclosing Party, in its sole discretion, to take appropriate action in order to prevent the Disclosing Party's Confidential Information from passing into the public domain or becoming generally available to the public; or

17.3.5 is independently developed by the Receiving Party without breach of this Agreement as evidenced by contemporaneous written records.

17.4 **Return of Information.** Upon request, after expiration or termination of this Agreement for any reason whatsoever, the Receiving Party shall return to the Disclosing Party, or destroy, as the Disclosing Party shall specify in writing, all copies of all documents and other materials that contain or embody any of the Disclosing Party's Confidential Information, except to the extent that the Receiving Party is required by Applicable Law or permitted under this Agreement to retain such documents and materials (in which case it shall retain them for no longer than the minimum period required by Applicable Law or permitted under this Agreement). Within thirty (30) calendar days after the date of expiration or termination of this Agreement, the Receiving Party shall furnish the Disclosing Party with a written certificate, confirming that the Receiving Party has complied with its obligations under this Section 17.4.

17.5 **Survival.** All of the Receiving Party's obligations under Section 17.1 and 17.2 hereof, with respect to the protection of the Disclosing Party's Confidential Information, shall survive for a period of ten (10) years following the expiration or termination of this Agreement for any reason whatsoever.

18. INTELLECTUAL PROPERTY

18.1 **Ownership of Intellectual Property.** Nothing in this Agreement shall affect Centogene's ownership of the Centogene Background Intellectual Property. Centogene shall own all right, title and interest in the Arising Intellectual Property. Centogene will have the exclusive right (but not the obligation) to prosecute and maintain, through counsel of its choice, its Intellectual Property.

18.2 **Centogene's License to Takeda.** Centogene hereby grants to Takeda and its Affiliates for the Term a non-exclusive, worldwide, fully paid-up, irrevocable and transferable license, with the right to grant sublicenses, to the Centogene Background Intellectual Property and the Arising Intellectual Property to test, distribute and train users on the Customized DBS Test Kits. To the extent Takeda holds stocks of Customized DBS Test Kits as at the date of termination or expiry of the Agreement, the license granted under this Section 18.2 shall be extended for [*****] ([*****]) months as required for Takeda to distribute such remaining stocks or as agreed between the Parties in a close-out agreement as set out in Section 21.8.

18.3 **Rights in Reports.** Without prejudice to Section 18.1, the Parties agree that Takeda shall own all right, title and interest in and to the Reports provided in the form of Exhibit 3 or 4.

18.4 **Third Party IP.**

18.4.1 In the event either Party becomes aware of any Third Party Intellectual Property which might interfere with:

18.4.1.1 the use and exploitation of the Reports;

18.4.1.2 the provision of the Services; and/or

18.4.1.3 the manufacture, supply or placing on the market of Customized DBS Test Kits,

it shall immediately inform the other Party hereof. If, in the opinion of Takeda, the activities set out in Sections 18.4.1.1, 18.4.1.2 and/or 18.4.1.3 infringe or are reasonably expected to infringe or misappropriate any Intellectual Property right of a Third Party, then Centogene, if Centogene (acting reasonably and in good faith) agrees with Takeda's opinion, shall, upon consultation with Takeda through the JSC, use reasonable efforts to negotiate and obtain a license or other rights from such Third Party to such rights as necessary or desirable in order for Takeda to perform such activities. Any such licence shall be [*****] to the extent it relates to the activities set out in Sections 18.4.1.2 and/or 18.4.1.3; to the extent it relates to the activities set out in Section 18.4.1.1 then Takeda [*****].

18.4.2 Each Party may consult with the other Party on the material aspects of the defence of any infringement actions brought by such a Third Party claim which would impair any of Sections 18.4.1.1, 18.4.1.2 and/or 18.4.1.3 above.

18.5 **Enforcement.**

18.5.1 Each Party shall furnish the other Party with written notice of any and all infringements and other unauthorized uses by any Third Party of any Intellectual Property relating to the Reports, Customized DBS Test Kits and/or the Testing Services promptly after it receives notice thereof, or any challenge to the validity or enforceability of any Centogene Background Intellectual Property or Arising Intellectual Property.

18.5.2 Centogene will have the sole right, but not the obligation, to enforce the Centogene Background Intellectual Property and the Arising Intellectual Property. In the event Centogene chooses not to enforce the Arising Intellectual Property, then Takeda will have the right, but not the obligation, to enforce it.

18.5.3 The enforcing Party shall consider in good faith the interests of the non-enforcing Party in any enforcement against any such infringement, and the

non-enforcing Party shall not, and shall procure that its Affiliates shall not, make any admissions relating to such claims.

- 18.5.4 At the request of the enforcing Party, the non-enforcing Party will provide reasonable assistance in connection with the enforcement action, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required (at the enforcing Party's expense). Any recovery realized as a result of such enforcement action (whether by way of settlement or otherwise) will be retained by such Party.

19. REPRESENTATIONS AND WARRANTIES

19.1 Centogene Warranties. Centogene warrants and represents that:

- 19.1.1 as of the Effective Date it has all necessary certifications in place required for the manufacturing of CE-marked Customized DBS Test Kits under EU IVDR and, except for the pending review of regulatory requirements for the countries as specified in Exhibit 1, all Regulatory Approvals necessary for it to manufacture and supply Customized DBS Test Kits and perform the Services in accordance with the terms of this Agreement, the relevant Development Order and/or Purchase Order, Applicable Laws and Standards;
- 19.1.2 it is not party to any agreement that would prevent it from fulfilling its obligations under this Agreement;
- 19.1.3 it has and will maintain during the Term the experience, the scientific know-how, the human resources and the capacities required to manufacture and supply the Customized DBS Test Kits and to perform the Services in accordance with Applicable Laws, Standards, and the terms of this Agreement;
- 19.1.4 it will perform the Tests and submit the Test Results in accordance with the terms of this Agreement;
- 19.1.5 to its present knowledge, as of the Effective Date, the Centogene Background Intellectual Property rights do not infringe any Third Party Intellectual Property;
- 19.1.6 as of the Effective Date, Centogene has not received any communication from any Third Party that the Services or the Customized DBS Test Kits, including the informed consent form provided with the Customized DBS Test Kits, are not in compliance with any Applicable Laws in the Territory;
- 19.1.7 as of the Effective Date, no material litigation, arbitration or administrative proceeding is pending or threatened in relation to the manufacturing and supply of Customized DBS Test Kits or performance of the Services;
- 19.1.8 it does not conduct and will not conduct any activity that involves or relates to or is alleged to involve or relate to fraud, the proceeds of crime, corruption or any other similar matter; and
-

- 19.1.9 in the course of providing Services, it will not make any statement on any Takeda Product to any Physician or any Third Party and will not provide any treatment recommendation.
- 19.2 **Warranties upon Delivery.** Centogene warrants and represents that upon Delivery and with regard to the specific Customized DBS Test Kit delivered:
- 19.2.1 such Customized DBS Test Kits will comply to the Specifications and Applicable Laws and Standards; and
- 19.2.2 the delivered Customized DBS Test Kits, and in particular the informed consent form, will comply with Applicable Laws and Standards in the respective intended destination country; and
- 19.2.3 unencumbered title to such Customized DBS Test Kits will be transferred to Takeda or its respective Affiliate.
- 19.3 **Anti-Bribery.**
- 19.3.1 The Parties represent, warrant and covenant that neither the Parties nor any Affiliate nor any officer, employee or agent of the Parties (or any of its Affiliates) has, nor shall it, offer, promise, give or receive, any financial or other advantage in violation of the Bribery Act 2010 (UK) or Foreign Corrupt Practices Act 1977 (USA), as amended from time to time, respectively, or any comparable laws in the Territory (collectively, “**Anti-Bribery Laws**”) and the Parties and its Affiliates shall each maintain procedures designed to prevent bribery falling within the Anti-Bribery Laws.
- 19.3.2 Centogene further represents, warrants and covenants that no person employed by Centogene and no person acting as agent of Centogene in connection with Centogene’s obligations under this Agreement (other than those persons who have been notified from time to time by Centogene to Takeda and in respect of whom Takeda has provided its prior written approval), is an official of the government of any country (or of any agency of such government), and that no part of any monies or consideration paid to Centogene under this Agreement shall accrue for the benefit of any such official.
- 19.3.3 For the purposes of enabling Takeda to monitor its their compliance with Anti-Bribery Laws, Centogene shall make available for audit by Takeda or its designee, upon Takeda’s reasonable request at any time during the Term, books, records and other documentation relevant to Centogene’s business activities conducted pursuant to this Agreement.
- 19.3.4 Takeda shall be entitled to terminate this Agreement immediately on written notice to Centogene if Centogene fails to perform its obligations in accordance with this Section 19.
- 19.4 **Insurance.** Centogene shall maintain liability and other appropriate forms of insurance at levels sufficient to support its indemnification obligations assumed herein but in no
-

case shall this insurance be less than the minimum limits shown below:

- 19.4.1 workers compensation and/or employers' liability to limits required by Applicable Law;
 - 19.4.2 general liability insurance in amounts of [*****] euros (€[*****]) per occurrence and [*****] euros (€[*****]) in the annual aggregate;
 - 19.4.3 product liability insurance in amounts of [*****] euros (€[*****]) per occurrence; and [*****] euros (€[*****]) in the annual aggregate;
 - 19.4.4 errors and omissions liability insurance in amounts of [*****] euros (€[*****]) per occurrence and in the annual aggregate;
 - 19.4.5 technology errors and omissions liability (including coverage for electronic media activities, network operations security liability, privacy liability and miscellaneous professional liability) in amounts of [*****] euros (€[*****]) per claim and in the annual aggregate; and
 - 19.4.6 crime coverage (employee dishonesty and computer fraud), including an endorsement and/or coverage amendment for Third Party coverage (client coverage) in the amounts of [*****] euros (€[*****]) per each and every event.
- 19.5 The insurance policies referenced in Section 19.4 shall be maintained by Centogene during the Term and for a period of [*****] ([*****]) years following the expiration or termination of this Agreement. All such insurances will be provided by a reputable company or companies licensed to do business in Germany. Centogene shall provide certificates of insurance evidencing such coverage as requested by Takeda. The minimum limits of insurance required shall not be construed to create a limit of Centogene's liability or indemnification obligations under this Agreement

20. INDEMNIFICATION

- 20.1 **No Liability.** Takeda does not accept any liability or damage claims related to the manufacture, quality control, release and placing on the market of any Customized DBS Test Kits and the provision of the Services in the Territory. The Parties agree that Centogene will not be held liable for legal/regulatory issues related to the export and sending of whole blood (EDTA) samples from Ireland to Centogene in Germany. Takeda will indemnify and hold harmless Centogene for any damages, fines, fees and loss resulting and/or claimed by third parties and/or authorities relating to such export/sending and Centogene's successive acceptance and processing of the respective samples received hereunder, to the extent that such damage, fine, fee and/or loss has not been caused by the gross negligence or wilful misconduct of Centogene.
- 20.2 **Indemnification by Centogene.** Centogene shall, at its sole expense, indemnify, defend and hold harmless Takeda, its Affiliates and their respective officers, directors, agents and employees (the "**Takeda Indemnitees**") from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and court costs) (collectively, "**Losses**") arising out of Third Party claims due to:
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- 20.2.1 a failure to manufacture, quality control, release, supply and placing on the market of Customized DBS Test Kits in the Territory or provide the Services in each case in accordance with Regulatory Approvals, Applicable Laws and Standards,
- 20.2.2 a failure to maintain CLIA certification;
- 20.2.3 incorrect Test Results;
- 20.2.4 any negligent or wilful act or omission of Centogene; or
- 20.2.5 any breach of a representation or warranty set forth under this Agreement,

provided, however, that Centogene will not be liable to indemnify the Takeda Indemnitees for any Losses to the extent that such Losses were caused by the negligence or wilful misconduct of the Takeda Indemnitees.

- 20.3 **Procedure.** Takeda shall notify Centogene promptly in writing upon learning of any Third Party action in respect of which indemnification may be sought under Section 20.2. Centogene shall (i) actively defend against every claim using counsel approved by Takeda, such approval not to be unreasonably withheld or delayed; (ii) shall promptly inform Takeda and its attorneys of all developments concerning Takeda; and (iii) shall generally consult with Takeda regarding the strategy of the defence of any claim. The Takeda Indemnitees shall reasonably cooperate with Centogene in defending or settling any such claim. No settlement of any claim for which indemnification is sought, shall be made without the prior written approval of Centogene. Centogene will have sole control over the defence and/or settlement, subject to the Takeda Indemnitees' right to select and use their own counsel at their sole cost and expense.

21. TERM, TERMINATION

- 21.1 **Term.** This Agreement shall come into force on the Effective Date and shall remain in full force for a term of one (1) year (the "**Term**"), subject to Section 21.2 below.
- 21.2 **Additional Term.** The Agreement, with amendments if any, may be extended by mutual agreement of the Parties three (3) months before expiration of the Agreement. In addition, Takeda shall have the right to extend the Agreement for a period of one (1) additional year by providing at least three (3) month's prior written notice before the expiry of the Term, subject to the Parties agreeing revised pricing and volume for the supply of the Development Services, Customized DBS Test Kits and Testing Services during such one (1) additional year period.
- 21.3 **Termination by Takeda.** Takeda shall have the right to terminate the Agreement and/or any Purchase Order or Development Order with immediate effect by providing written notice to Centogene in case:
- 21.3.1 Centogene experiences a Change of Control in which a company or group of companies is the acquirer (by asset purchase, merger, consolidation, reorganization or otherwise) who is a direct competitor of Takeda or any Takeda Affiliate with regards to Takeda Products.
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- 21.3.2 the provision of Customized DBS Test Kits to Physicians and the performance of Testing Services is found or alleged by any Regulatory Authority, court, industry association or other entity with competence over any Takeda Affiliate to be impermissible; or
- 21.3.3 Centogene ceases to provide laboratory testing services.
- 21.4 **Insolvency.** In the event that either Party becomes or is declared insolvent or bankrupt, admits in writing of its inability to pay its debts generally as they become due, is the subject of any proceedings relating to its liquidation or insolvency or for the appointment of a receiver or administrator for it, makes an assignment for the benefit of all or substantially all of its creditors, or enters into an agreement for the composition, extension, or readjustment of all or substantially all of its obligations the non-insolvent Party may terminate this Agreement and/or any Purchase Order, as the case may be.
- 21.5 **Material Breach.** In the event that either Party commits a material breach or default of any of its obligations hereunder, the other Party shall give the breaching Party written notice of such material breach or default, and shall request that such material breach or default be cured as soon as reasonably practicable. In the event the breaching Party fails to cure such breach or default within [*****] ([*****]) calendar days after the date of the non-breaching Party's notice thereof, the non-breaching Party may terminate this Agreement and/or any Purchase Order or Development Order, as the case may be. In case the breach is incapable of cure, the non-breaching Party is entitled to terminate this Agreement and/or any Development Order with immediate effect without the need to grant a cure period. Termination of this Agreement in accordance with this Section 21.5 shall not affect or impair the non-breaching Party's right to pursue any legal remedy, including the right to recover damages, for any harm suffered or incurred by the non-breaching Party as a result of such breach or default. Without limiting the foregoing:
- 21.5.1 Takeda shall be deemed to have committed a material breach of its payment obligations hereunder if it fails to meet its payment obligations after one written reminder by Centogene by more than [*****] ([*****]) days in [*****] ([*****]) consecutive calendar months,
- 21.5.2 Centogene shall be deemed to have committed a material breach if it (i) is unable or unwilling to manufacture or supply Customized DBS Test Kits or provide any Services for a period longer than two (2) months, (ii) persistently fails to process submitted Samples in accordance with this Agreement, (iii) fails to maintain the Manufacturing Facility or Testing Facility in accordance with Sections 7.4 and 8.6, (iv) significantly deviates from quality standards defined in the Technical Quality Agreement, including material findings in an audit, or (v) breaches a representation and warranty under Section 19.
- 21.6 **Consequences of Termination.** Termination of this Agreement or any Purchase Order or Development Order for any reason shall not affect the accrued rights or obligations of the Parties as at the date of termination.
- 21.7 **Survival.**
- 21.7.1 On termination (or expiry) of this Agreement, howsoever arising, each
-

Development Order then in force at the date of such termination shall continue in full force and effect for the remainder of the term of such Development Order, unless terminated earlier in accordance with the terms of such Development Order.

- 21.7.2 The termination of any Development Order shall not affect any other Development Order or this Agreement.

Sections 1 (Definitions), 10 (Reporting & Record Keeping), 15.5 (Subcontracting) 17 (Confidentiality), 18 (Intellectual Property), 19.4 and 19.5 (Insurance), 20 (Indemnification), 21.6 through 21.7 and 23 (Miscellaneous) of this Agreement shall survive the termination and remain in full force and effect.

- 21.8 The Parties agree that before the termination of this Agreement the Parties need to enter into a close-out agreement to ensure an orderly wind-down of the Sponsored Testing Program, including information obligations to physicians, remaining stock and wind-down of testing.

22. FORCE MAJEURE

- 22.1 Neither Party shall be liable to the other Party by reason of any delay in performance, or the non-performance of any of its obligations under this Agreement, to the extent that the delay or non-performance is due to any Force Majeure, provided the Affected Party (a) notifies the other Party within [*****] ([*****]) days of becoming aware of such Force Majeure event giving full particulars thereof including the date of first occurrence, the circumstances giving rise to it and an indication of the duration of such circumstances; and (b) uses reasonable efforts to mitigate its effect.
- 22.2 If the Affected Party is prevented or delayed from performance of its obligations under this Agreement by Force Majeure for [*****] days or more, consecutively or cumulatively, in any [*****] period, the other Party shall in its discretion have the right to terminate this Agreement with immediate effect by giving written notice to the Affected Party.

23. MISCELLANEOUS

- 23.1 **Governing Laws; Dispute Resolution.** This Agreement shall be governed and construed in accordance with the laws of Germany, without reference to conflict of laws principles. If there is a dispute between the Parties relating to this Agreement, the Parties shall in the first instance attempt to solve the dispute amicably. If they cannot do so, the dispute shall be referred to the JSC which shall meet to try to resolve the matter. If the JSC is unable to resolve the dispute within [*****] ([*****]) calendar days of the referral of the dispute to them, the dispute shall be finally settled in accordance with the Arbitration Rules of the German Institution of Arbitration (DIS) without recourse to the ordinary courts of law. The place of arbitration shall be Berlin. The number of arbitrators shall be three (3). The language of the arbitral proceedings shall be English. Nothing in this Section 23.1 shall prevent or delay a Party from seeking interim relief in any court of competent jurisdiction.
- 23.2 **Assignment.** This Agreement may not be assigned by either Party in whole or in part
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without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, provided, however, that the prior written consent of either Party shall not be required for the other Party to assign this Agreement to an Affiliate.

- 23.3 **Severability.** The invalidity of any provision or provisions of this Agreement shall not affect the other provisions contained therein. Any invalid provision shall be deemed to have been replaced by a provision which achieves as closely as legally permissible what the invalid provision was intended to achieve for commercial purposes.
- 23.4 **No Authority.** Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party or its Affiliates, without the prior written consent of the other Party.
- 23.5 **Counterparts, Electronic Signatures and Delivery.** This Agreement may be executed in one (1) or more duplicate originals, all of which together shall be deemed one and the same instrument. Each Party agrees that any digital (and encrypted) electronic signature of one of the Parties, included in or apposed to this Agreement is intended to execute and authenticate this Agreement and to have the same force and effect as a manuscript signature. Delivery of a copy of this Agreement bearing an original manuscript or electronic signature by facsimile transmission, electronic mail, or any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing an original manuscript or electronic signature.
- 23.6 **Amendments.** Any amendment to this Agreement shall be effective only if made in writing and signed by the Parties. This also applies to a waiver of the written form requirement.
- 23.7 **Entire Agreement.** This Agreement, including its Exhibits, sets out the entire agreement between the Parties relating to its subject matter.
- 23.8 **Costs.** Each Party shall bear the costs of its own accountants, attorneys, consultants and other professional advisors in connection with the negotiation and execution of this Agreement.
- 23.9 **Effective Date.** This Agreement comes into force and takes effect as of the Effective Date.

[signature page follows]

Place: _____

Place: _____

Date: _____

Date: _____

**for and on behalf of
Takeda Pharmaceuticals
International AG**

**for and on behalf of
Centogene GmbH**

Name:

Name:

Title:

Title:

Name:

Name:

Title:

Title:

Exhibit 1
Existing Customized DBS Test Kit Countries

*****	*****	*****
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Exhibit 2
Template Development Order

This Development Order number [#] dated [*date*] is between:

- (1) [full legal name and address of Takeda Affiliate] (“**Takeda Affiliate**”)
- (2) **CENTOGENE GmbH**, a German limited liability company registered with the [xxx] under the number [xxxx] and having a business address at, Am Strande 7, 18055 Rostock, Germany, (“**Centogene**”).

Preamble

- (A) This Development Order is made subject to the provisions of the Global Master Supply and Services Agreement entered into by Takeda Pharmaceuticals International AG and Centogene as of [insert date of the Agreement] (“**Agreement**”), which are incorporated into this Development Order.
- (B) Pursuant to the Agreement, Takeda Affiliate requests certain development services to be provided by Centogene, and Centogene agrees to provide such services to the Takeda Affiliate, in accordance with this Development Order.

The Parties agree as follows:

1. Definitions

Capitalized terms shall have the meaning set forth in the Agreement, unless specifically defined otherwise in this Development Order.

2. Country

Centogene shall
[Option 1 – kit modification] modify the Customized DBS Test Kits for distribution in [country] in accordance with Applicable Laws.

[Option 2 – kit development] develop Customized DBS Test Kits for distribution in [country] in accordance with Applicable Laws.

3. Development Plan

[add the project plan submitted by Centogene and agreed with Takeda pursuant to Section 6.1 of the Agreement, setting forth detailed steps and timelines for, i.a., regulatory actions and development of, translations of and/or changes to the design and matrix for the DBS cards, instructions and informed consents]

4. Project Managers

[specify project managers]

5. **Specifications**

[describe the specifications]

6. **Fees**

[specify fees, based on Schedule 11 pricing]

7. **Payments**

Invoices shall be addressed and sent to Takeda Pharmaceuticals International AG, Thurgauerstrasse 130, 8152 Glattpark (Opfikon), Switzerland. Payment will be due within ninety (90) days of receipt of invoice.

Agreed

Place: _____

Place: _____

Date: _____

Date: _____

for and on behalf of
[insert Takeda affiliate]

for and on behalf of
Centogene GmbH

Exhibit 3
Monthly Diagnostic Test Reports

Form:

1. Monthly Diagnostic Test Report (one line per Test)*

Country	Disease tested	Test card type	Result	Gender	Age	Turnaround time [business days]	Invoice Date	Qty issues	Pre analytical failure	Expired card	Specialty
[*****]	[*****]	[*****]	[*****]	[*****]	[*****]	[*****]	[*****]	[*****]	[*****]	[*****]	
	[*****]	[*****]	[*****]	[*****]	[*****]			[*****]	[*****]	[*****]	
	[*****]	[*****]	[*****]	[*****]	[*****]						
	[*****]		[*****]	[*****]	[*****]						
	[*****]		[*****]		[*****]						
	[*****]		[*****]		[*****]						
	[*****]		[*****]		[*****]						
	[*****]		[*****]		[*****]						
	[*****]		[*****]		[*****]						
	[*****]		[*****]		[*****]						
	[*****]		[*****]		[*****]						
	[*****]		[*****]		[*****]						

* Data in the table are examples.

2. Biannual overview of the total number of analytical tests performed

Every [*****] months during the Term, Centogene will share with Takeda an overview of the total number of analytical tests performed under the Agreement for the respective [*****] period by type of analytical test performed. The report will be shared within [*****] after the end of the respective [*****] period. The first report will be shared in [*****] 2023 for the period [*****], 2022 to [*****], 2023, the second report will be shared in [*****] 2023 for the period [*****], 2023 to [*****], 2023, and so forth. Each report will contain the total number of analytical tests performed in the respective [*****] period for the Takeda reporting regions EUCAN and GEM split by the following analytical test categories: Genetic testing by gene sequencing, biochemical testing of metabolite by mass spectrometry, biochemical testing of enzyme activity, genetic testing for deletion/duplication analysis. The report will provide figures split at regional level (regions: EUCAN and GEM). Takeda will provide a table with the mapping of the countries and the regions EUCAN and GEM.

3. Monthly Expired Customized DBS Test Kit report (one line per country and disease on expired cards received)*

Country	Disease test requested for expired card	Month/year	Number of expired cards received	Positive outcome quality validation	Negative outcome quality validation
[*****]	[*****]	[*****]	[*****]	[*****]	[*****]
[*****]	[*****]	[*****]	[*****]	[*****]	[*****]
[*****]	[*****]	[*****]	[*****]	[*****]	[*****]
[*****]	[*****]	[*****]			
[*****]	[*****]	[*****]			

* Data in the table are examples.

Exhibit 4

Proforma Quarterly Transparency Report (one line per Test)

[*****]	[*****]	[*****]	[*****]	[*****]	[*****]	[*****]

*HCO name or institution ID in case no institution was provided

Exhibit 5
Communication to Physicians

Dear Dr. [●]

Thank you for choosing CENTOGENE as your genetic testing partner. We are pleased to confirm the arrival of the below sample.

Please, read the below information carefully. This document summarizes logistical information provided in your request forms. If necessary, please, contact us with any missing information or corrections via email CDM@centogene.com or fax +49 (0)381 80113 401.

Please note, the CentoCard® used for this sample has already exceeded its expiry date. We will nevertheless undertake our best efforts to ensure that the sample is processed in accordance with our required quality standards and will inform you if this is not possible. No new sample is requested at this time.

[Sample information]

[Sender information]

We prioritize the highest quality diagnostic processes and informed decision-making possible. Please, do not hesitate to contact us at CDM@centogene.com to discuss this order.

Sincerely,

[Signature]

Your Centogene Team

Exhibit 6
Data Protection Requirements

1. Warranties. Fair and Lawful Processing

- a) Centogene and Takeda shall each comply with their respective obligations under all Applicable Data Protection Laws in connection with this Agreement and each acts as a separate and independent Controller with regards to the Processing of Personal Data they each undertake.
- b) The Parties agree that it is Centogene's primary responsibility under this Agreement to act as Controller for Covered Personal Data of Patients and physicians and ensure that the Processing of Covered Personal Data complies with Applicable Data Protection Laws.
- c) Centogene shall ensure that:
 - (i) it, and any Centogene Affiliate or subcontractor, shall not disclose or make available to Takeda or any Takeda Affiliate, any **identifiable** Covered Personal Data, except where it is lawful and "De-Identified" and/or pseudonymized (as this term is defined in the Applicable Data Protection laws) in accordance with the terms of this Agreement. For the avoidance of doubt, "**De-identified**" Personal Data refers to data which has been stripped of all subject information that could reasonably identify a Data Subject and where the party that shares the data has no reasonable knowledge that the remaining information could be used to identify the individual on its own or in combination with other information that could be reasonably obtained;
 - (ii) any Covered Personal Data that is made available to Takeda and/or any Takeda Affiliate subject to section 1.c (i) above, has been processed by Centogene for lawful and legitimate purposes and that such Covered Personal Data may be made lawfully available to Takeda and/or any Takeda Affiliate in accordance with the Applicable Data Protection Laws. More specifically, Centogene shall ensure that it, and/or any Centogene Affiliate or subcontractor, as applicable, will provide an appropriate data privacy notice and obtain appropriate consent from the Patients that such notice and consent are in accordance with applicable Data Protection Laws and allows for the desired use of the Covered Personal Data. Should Centogene, its Affiliates or subcontractors learn that it has provided Covered Personal Data that may not be shared pursuant to a consent or notice, Centogene is responsible for promptly notifying Takeda so that the affected Covered Personal Data can be deleted as required;

2. Security of Processing and Security Incidents

Centogene shall implement and maintain, and require any Affiliate or subcontractor to implement and maintain, appropriate technical and organizational measures in compliance with the Applicable Data Protection Laws and reflective of current good industry practice and technological development to protect Covered Personal Data against Security Incidents.

These measures shall include, without limitation:

- a) Covered Personal Data is stored securely, using state-of-the-art software;
- b) limiting access to Covered Personal Data to personnel on a need-to-know basis;
- c) implementing appropriate security measures to avoid unauthorized access to or sharing of Covered Personal Data;
- d) ensuring that any deletion of Covered Personal Data is carried out in an irrevocable manner;
- e) maintaining appropriate backup and disaster recovery solutions;

- f) maintaining all appropriate certifications in relation to its information security management system, including ISO/IEC 27001:2017 and an appropriate Internet Privacy Standard (“**IPS**”) certification for its customer facing CentoPortal (which forms part of its information security management system and via which medical reports are being provided to the ordering health care professionals);
- g) to the extent that Centogene uses external data centres (including those located in Frankfurt am Main, Germany) to provide its core services (including CentoPortal), any such data centre provider shall ensure compliance with all applicable legislation (including, without limitation, the GDPR), and maintain an appropriate level of IT security and business continuity, including, without limitation:
 - (i) maintaining ISO 27001 certifications;
 - (ii) data encryption in transit (TLS 1.2) and at rest;
 - (iii) secure access by multi-factor-authentication;
 - (iv) centrally managed user-based data access (standardized authorization process, rule and permission concept);
 - (v) security tests on a regular basis (minimum once a year);
 - (vi) managed next-generation firewall; and
 - (vii) redundant operation in two different data centres.
- h) If Centogene becomes aware of, or reasonably suspects that there has been a Security Incident, it shall notify the competent supervisory authority, and impacted Data Subjects, in accordance with Applicable Data Protection Laws.
- i) To the extent that Centogene suffers a Security Incident affecting Covered Personal Data that has or could have an impact on the Services under the Agreement, Centogene shall without undue delay notify Takeda at PrivacyOffice@takeda.com about such Security Incident. Centogene shall, upon request in a timely manner:
 - (i) inform Takeda about the nature of the Security Incident, including where possible, the categories and approximate number of Data Subjects affected;
 - (ii) describe the likely consequences of the Security Incident, and
 - (iii) produce and provide to Takeda a report describing in detail the measures taken or proposed to be taken to address the Security Incident, including, where appropriate, measures to mitigate its possible effects; and
 - (iv) remedy any deficiencies identified within a reasonable period.

3. Data Protection Impact Assessments and Records

To the extent required by Applicable Data Protection Laws, Centogene shall:

- a) carry out data protection impact assessments and engage in prior consultations with the competent supervisory authorities in relation to the Processing of Covered Personal Data;
- b) maintain relevant records related to the Processing of Covered Personal Data, including any data protection impact assessments.

4. Transfers

Subject to and in compliance with the Applicable Data Protection Laws, Centogene may transfer Covered Personal Data to its Affiliates or subcontractors to the extent such Affiliates or subcontractors have a legitimate need to process the Covered Personal Data under this Agreement and always under appropriate contractual restrictions. Centogene shall not disclose or transfer Covered Personal Data to an Affiliate or a Subcontractor outside the European Economic Area without ensuring that adequate protections in accordance with the Applicable Data Protection Laws will be afforded to the Covered Personal Data under this Agreement. Such protections shall include, without limitation, standard contractual clauses for international transfers to the most recent EU standard, as well as other legitimate transfer mechanisms under applicable Data Protection Laws.

5. **Data Subject Requests and Third-Party Communications**

- a) The Parties agree that Centogene, as the only Party that has identifiable Covered Personal Data in its possession, is solely responsible for responding to Data Subjects Requests from Patients in accordance with the Applicable Data Protection Laws. Centogene shall make available its contact details for Patients, Physicians and other Data Subjects to facilitate the exercise of their rights under applicable Data Protection Laws in relation to the Processing of Covered Personal Data. Such contact details must also be inserted in relevant privacy notices and/or consents as described in section 1.c. (ii).
- b) The Parties agree to cooperate and provide reasonable notice and assistance to each other as necessary to enable them to (1) comply with the Applicable Data Protection Laws, (2) comply with Data Subject Requests and (3) respond to any other queries or complaints from any third party, including Data Subjects and regulatory authorities in relation to Personal Data under this Agreement.

6. **Management of Claims**

- a) Each Party undertakes and warrants, where it becomes aware that it will or may face a claim under the Applicable Data Protection Laws challenging the separate control over Personal Data as per Section 1.a. of this Exhibit 6 (Data Protection Requirements), it shall:
 - without undue delay inform the other Party of the claim or potential claim and provide, to the extent legally permissible, all material detail concerning the claim and the progress of the claim insofar as is known to it; and
 - provide, to the extent legally permissible, the other Party with all material detail concerning the underlying circumstances that gave rise to the claim or potential claim.
- b) Irrespective of its rights under the Applicable Data Protection Laws, each Party shall defend any such claim prudently, insofar as it relates to the area of responsibility of such Party.

Exhibit 7
Pricing

1. DEVELOPMENT SERVICES

a) **DEVELOPMENT FEES:**

- **A LUMP SUM FEE OF €[*****] PER SPECIFIC CUSTOMIZED DBS TEST KIT DEVELOPMENT PROJECT IF THE DEVELOPMENT SERVICES REQUIRE TRANSLATIONS INTO A NEW LANGUAGE (I.E., A LANGUAGE FOR WHICH CENTOGENE DOESN'T OFFER CUSTOMIZED DBS TEST KITS AT THE TIME OF TAKEDA'S RFQ).**
- **A LUMP SUM FEE OF €[*****] PER SPECIFIC CUSTOMIZED DBS TEST KIT DEVELOPMENT PROJECT IF THE DEVELOPMENT SERVICES DO NOT REQUIRE TRANSLATIONS INTO A NEW LANGUAGE.**

REGULATORY FEES: in ADDITION TO THE FEES UNDER SECTION 1A) ABOVE, CENTOGENE MAY INVOICE TAKEDA THE ACTUAL AND DOCUMENTED EXPENDITURES BY CENTOGENE TO OBTAIN REGULATORY APPROVALS, INCLUDING ANY THIRD-PARTY REGULATORY CONSULTANT FEES, PROVIDED HOWEVER THAT TAKEDA'S REIMBURSEMENT OF THOSE EXPENDITURES WILL BE CAPPED, DEPENDING ON THE RELEVANT COUNTRY, TO THE FOLLOWING AMOUNTS:

COUNTRIES	CAP ON REIMBURSEMENT OF REGULATORY FEES
ALL COUNTRIES	€[*****]

MANUFACTURE AND SUPPLY

[*****] EURO /CUSTOMIZED DBS TEST KIT

TESTING SERVICES

Takeda shall pay a Testing Services Fee for each Test in respect of which Testing Services are performed by Centogene in accordance with the terms of this Agreement during the Term, in accordance with the following table:

Tier	#tests from	#tests to	Price per test
1	[*****]	[*****]	[*****] Euro
2	[*****]	[*****]	[*****] Euro
3	[*****]	[*****]	[*****] Euro
4	[*****]	[*****]	[*****] Euro

The pricing bands in the first column of the above table are incremental.

For the avoidance of doubt, the Testing Services Fee includes all Testing Services as specified in Exhibit 9.

Exhibit 8
Testing Methodology

[*****]

(*) Gene sequencing takes place in two steps – Gene sequencing first and, if negative while biochemistry is positive, Del/Dup (deletion duplication) analysis is activated.

1. & 2. are sequential diagnosis steps (if available in multiple steps, only a positive step 1. will trigger step 2.).

Centogene is performing testing to exclude multiple sulfatase deficiency on an as needed basis.

Exhibit 9
Testing Services

1. The performance of Tests by Centogene, on DBS Cards (whether Centogene DBS Test Cards or Non-CG DBS Test Cards), whole blood Samples, plasma samples and upon specific request by Takeda and approval by Centogene buccal swabs, for the purpose of identifying Patients suffering from rare genetic diseases;
2. Quality testing of Customized DBS Test Kits and/or Non-CG DBS Test Kits received;
3. Monitoring of and ensuring compliance of manufacture, supply and provisions of any Customized DBS Test Kits or the provision of Services with Applicable Laws or Standards of the Territory, and informing Takeda of any changes to the Applicable Laws or Standards;
4. Reporting pursuant to Section 10 of the Agreement;
5. Regulatory services for maintaining relevant registrations in Existing Customized DBS Test Kit Countries in compliance with Applicable Laws or Standards;
6. Alliance management, including dedicated primary project manager contact and all costs of Centogene's Alliance Managers in participating in the Alliance Team and the Joint Steering Committee;
7. Importation activities required to import Customized DBS Test Kits into the relevant countries in accordance with Applicable Laws as far as not coordinated by Takeda pursuant to Exhibit 1 of the Agreement;
8. Operation and maintenance of CentoPortal;
9. Dispatch of digital medical reports via CentoPortal (or via postal mail if digital reports cannot be delivered);
10. Operation of Centogene email hotline including recording of the response time;
11. Country-specific support services provided through Centogene's corporate project management or local representatives;
12. At least [*****] ([*****]) CentoPortal training sessions for Takeda not exceeding a total of [*****] ([*****]) hours of such training per year;
13. Onboarding and strategic introductory meetings for Takeda medical lead and alliance management team;
14. Provision of testing methodology training materials pursuant to Section 8.5 of the Agreement;
15. Centralized invoicing;
16. Validating and qualifying the instruments and equipment used for the Tests (including, without limitation, conducting installation, operational and performance qualification) and maintaining all such instruments and equipment in a compliant state;
17. Notification of Contaminants in accordance with the Agreement;
18. Re-establishing any suspended Testing Services;
19. Audit support, audit follow-up actions.

LONG-TERM INCENTIVE PLAN
CENTOGENE N.V.

INTRODUCTION**Article 1**

1.1 This document sets out the Company's long-term incentive plan for employees, officers and other service providers who qualify as Eligible Participants.

1.2 The main purposes of this Plan are:

- 1.** to attract, retain and motivate Participants with the qualities, skills and experience needed to support and promote the growth and sustainable success of the Company and its business; and
- 2.** to incentivise Participants to perform at the highest level and to further the best interests of the Company, its business and its stakeholders.

DEFINITIONS AND INTERPRETATION**1**

1 In this Plan the following definitions shall apply:

Article	An article of this Plan.
Award	A grant under this Plan in the form of one or more Options, SGAs, SARs, Shares of Restricted Stock, RSUs, PSUs, Other Awards, or a combination of the foregoing.
Award Agreement	A written agreement between the Company and a Participant evidencing the grant of an Award to such Participant and containing such terms as the Committee may determine, consistent with and subject to the terms of this Plan.
Bad Leaver	A Participant who ceases to be an Eligible Participant for Cause.
Cause	With respect to a Participant, "cause" as defined in such Participant's employment, service or consulting agreement with the Company or a Subsidiary, or if not so defined (and unless determined otherwise in the applicable Award Agreement or otherwise by the Committee):

- a.** such Participant's indictment for any crime which (i) constitutes a felony, (ii) has, or could reasonably be expected to have, an adverse impact on the performance of such Participant's services to the Company and/or any Subsidiary or (iii) has, or could reasonably be expected to have, an adverse impact on the business and/or reputation of the Company and/or any Subsidiary;
 - b.** such Participant having been the subject of any order, judicial or administrative, obtained or issued by any governmental or regulatory body for any securities laws violation involving fraud, market manipulation, insider trading and/or unlawful dissemination of non-public price-sensitive information;
 - c.** such Participant's wilful violation of the Company's code of business conduct and ethics, insider trading policy or other internal policies and regulations established by the Company and/or any Subsidiary, in each case to the extent applicable to the Participant concerned;
 - d.** gross negligence or wilful misconduct in the performance of such Participant's duties for the Company and/or any Subsidiary or wilful or repeated failure or refusal to perform such duties;
 - e.** material breach by such Participant of any employment, service, consulting or other agreement entered into between such Participant on the one hand and the Company and/or any Subsidiary on the other;
 - f.** conduct by such Participant which should be considered as an urgent cause within the meaning of Section 7:678 DCC, irrespective of whether that provision applies to such Participant's relationship with the Company and/or any Subsidiary; and
 - g.** such other acts or omissions to act by such Participant as reasonably determined by the Committee,
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provided that the Committee may determine, at its absolute discretion, that occurrence of an event described in paragraphs c. through e. above shall only constitute Cause if and when such event has not been cured or remedied by the relevant Participant within thirty days after the Company has provided written notice to such Participant.

Change of Control

The occurrence of any one or more of the following events (in each case unless the Committee determines otherwise):

- a.** the direct or indirect change in ownership or control of the Company effected through one transaction, or a series of related transactions within a twelve-month period, as a result of which any Person or group of Persons acting in concert, directly or indirectly acquires (i) beneficial ownership of at least 50% of the Company's issued share capital and/or (ii) the ability to cast at least 50% of the voting rights in the General Meeting;
 - b.** at any time during a period of twelve consecutive months, individuals who at the beginning of such period constituted the Supervisory Board cease to constitute a majority of members of the Supervisory Board, provided that any new member of the Supervisory Board who was nominated for appointment by the Supervisory Board by a vote of at least a majority of the Supervisory Directors who either were Supervisory Directors at the beginning of such twelve-month period or whose nomination for appointment was so approved, shall be considered as though such individual were a member of the Supervisory Board at the beginning of such twelve-month period;
 - c.** the consummation of a merger, demerger or business combination of the Company or any Subsidiary with another Person, as a result of which the legal or beneficial ownership of the Shares outstanding immediately prior to the consummation of such transaction no longer represents (either by remaining outstanding or by being converted into, or exchanged for,
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voting securities of the surviving or acquiring Person or a parent thereof) (i) legal or beneficial ownership of at least fifty percent (50%) of all outstanding Shares, or at least fifty percent (50%) of the shares in the capital of such surviving or acquiring Person or parent, outstanding immediately after the consummation of such transaction or (ii) at least fifty percent (50%) of all voting rights attached to the securities referred to under (i) of this paragraph c.;

- d. the consummation of any sale, lease, exchange or other transfer to any Person or group of Persons acting in concert, not being Subsidiaries, in one transaction or a series of related transactions within a twelve-month period, of all or substantially all of the business of the Company and its Subsidiaries,

provided in each case that, under no circumstances, a delisting of the Shares in itself (i.e., without being combined with any of the events mentioned under paragraphs a. through d. above) will constitute a Change of Control.

Committee	Subject to Article 3.2, the Supervisory Board, acting at the recommendation of the Company's compensation committee.
Company	Centogene N.V.
Consultant	Any Person, other than a Managing Director, Supervisory Director or Employee, who is an adviser or consultant engaged by the Company and/or a Subsidiary to render bona fide services to the Company and/or a Subsidiary.
DCC	The Dutch Civil Code.
Eligible Participant	Any Managing Director, Supervisory Director, Employee or Consultant.
Employee	Any Person, other than a Managing Director or a Supervisory Director, who is an employee or officer of the Company and/or a Subsidiary.
Exercise Date	The date on which an Award is duly exercised by or on behalf of the Participant concerned.
Exercise Price	The exercise price applicable to an Award.

FMV	The volume weighted average closing price of a Share over a period of twenty trading days on the principal stock exchange where Shares have been admitted for trading, unless determined otherwise by the Committee.
General Meeting	The Company's general meeting of shareholders.
Good Leaver	A Participant who ceases to be an Eligible Participant and who is not a Bad Leaver.
Grant Date	The date on which the Committee decides to grant an Award, or such later effective date applicable to such Award as may be determined by the Committee.
Management Board	The Company's management board.
Managing Director	A member of the Management Board.
Option	The right to subscribe for, or otherwise acquire, one Plan Share.
Other Award	An Award which does not take the form of an Option, SGA, SAR, Share of Restricted Stock, RSU or PSU, and which may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on or related to Shares or factors which may influence the value of Shares, including financial instruments which are convertible into or exchangeable for Plan Shares.
Participant	The holder of an Award, including, as the context may require, the rightful heir(s) of a previous holder of such Award having acquired such Award as a result of the death of such previous holder.
Performance Criteria	The performance criteria applicable to an Award.
Person	A natural person, partnership, company, association, cooperative, mutual insurance society, foundation or any other entity or body which operates externally as an independent unit or organisation.
Plan	This long-term incentive plan.
Plan Share	A Share underlying an Award.
PSU	Any RSU in respect of which the vesting is conditioned in whole or in part on the satisfaction of Performance Criteria.
Replacement Award	An Award granted in assumption of, or in substitution or exchange for, long-term incentive awards previously granted by a Person acquired (or whose business is

acquired) by the Company or a Subsidiary or with which the Company or a Subsidiary merges or forms a business combination, as reasonably determined by the Committee.

Restricted Stock	Plan Shares subject to such restrictions as the Committee may impose, including with respect to voting rights and the right to receive dividends or other distributions made by the Company.
RSU	The right to receive one or more Plan Shares valued at FMV on the Exercise Date.
SAR	The right to receive, in the form of Plan Shares valued at FMV, the excess of the FMV of one Share on the applicable Exercise Date over the applicable Exercise Price.
SGA	The right to receive one Plan Share, which shall be settled automatically through the delivery of such Plan Share to the Participant once the Award becomes fully vested in accordance with its terms.
Section 409A IRC	Section 409A of the United States Internal Revenue Code of 1986, as amended, and the rules, regulations and guidance promulgated pursuant thereto.
Share	A share in the Company's capital.
Subsidiary	A subsidiary of the Company within the meaning of Section 2:24a DCC.
Supervisory Board	The Company's supervisory board.
Supervisory Director	A member of the Supervisory Board.

- 2 References to statutory provisions are to those provisions as they are in force from time to time.
- 3 Terms that are defined in the singular have a corresponding meaning in the plural.
- 4 Words denoting a gender include each other gender.
- 5 Except as otherwise required by law, the terms "written" and "in writing" include the use of electronic means of communication.

ADMINISTRATION

Article 2

- 1 This Plan shall be administered by the Committee. The Committee's powers and authorities under this Plan include the authority to perform the following matters, in each case consistent with and subject to the terms of this Plan:
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- 1 designating Persons to whom Awards are granted;
 - 2 deciding to grant Awards;
 - 3 determining the form(s), format(s) and type(s) of Awards being granted and setting the terms and conditions applicable to such Awards, including:
 - 1 the number of Plan Shares underlying Awards;
 - 2 whether, to which extent, and under which circumstances Awards may cancelled, forfeited or suspended;
 - 3 whether, to which extent and under which circumstances a Participant may designate another Person owned or controlled by him as recipient or beneficiary of his Awards;
 - 4 whether and to which extent Awards are subject to Performance Criteria and/or restrictive covenants (including non-competition, non-solicitation, confidentiality and/or Share ownership requirements);
 - 5 the method(s) by which Awards may be exercised, settled or cancelled;
 - 6 whether, to which extent and under which circumstances, the exercise, settlement or cancellation of Awards may be deferred or suspended;
 - 4 amending or waiving the terms applicable to outstanding Awards (including Performance Criteria), subject to the restrictions imposed by Article 9 and provided that no such amendment shall take effect without the consent of the affected Participant(s), if such amendment would materially and adversely affect the rights of the Participant(s) under such Awards, except to the extent that any such amendment is made to cause this Plan or the Awards concerned to comply with applicable law, stock exchange rules, accounting principles or tax rules and regulations;
 - 5 correcting any defect, supplying any omission or reconciling any inconsistency in the Plan or any Award Agreement;
 - 6 making any determination under, and interpreting the terms of, this Plan, any rules or regulations issued pursuant to this Plan and any Award Agreement;
 - 7 settling any dispute between the Company and any Participant (including any beneficiary of his Awards) regarding the administration and operation of this Plan, any rules or regulations issued pursuant to this Plan, and any Award Agreement entered into with such Participant; and
 - 8 making any other determination or taking any other action which the Committee considers to be necessary, useful or desirable in connection with the administration or operation of this Plan.
- 2 The Management Board is authorized to submit proposals to the Company's compensation committee for the grant of Awards to Eligible Participants who are not Managing Directors or Supervisory Directors, provided that (i) the Management Board may not grant more Awards to
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those Eligible Participants than an aggregate number of Awards approved by the Committee from time to time and (ii) when granting such Awards, the Management Board shall observe any other restrictions imposed by the Committee from time to time in connection with the administration or operation of this Plan. The Company's compensation committee may approve such proposals without further approval from the Supervisory Board.

- 3 The Committee may issue further rules and regulations for the administration and operation of this Plan, consistent with and subject to the terms of this Plan.
- 4 All decisions of the Committee shall be final, conclusive and binding upon the Company and the Participants (including beneficiaries of Awards).

AWARDS

Article 3

- 1 Awards can only be granted to Eligible Participants, unless the Committee decides otherwise.
 - 2 No Award is intended to confer any rights on the relevant Participant except as set forth in the applicable Award Agreement. In particular, no Award should be construed as giving any Participant the right to remain employed by or to continue to provide services for the Company or any Subsidiary.
 - 3 Awards can be granted for no consideration or for such minimal cash consideration as may be required by applicable law.
 - 4 Awards may be granted alone or in addition or in tandem with any other Award and/or any award under any other plan of the Company or any Subsidiary. Awards granted in addition or in tandem with any other Award and/or any award under any other plan of the Company or any Subsidiary may be granted simultaneously or at different times.
 - 5 Each Award shall be evidenced by an Award Agreement entered into between the Company and the Participant concerned. Until an Award Agreement has been entered into between the Company and the relevant Participant, no rights can be derived from the Awards concerned by such Participant.
 - 6 Plan Shares, including Awards in the form of SGAs or Shares of Restricted Stock, shall be delivered in book-entry form to the relevant Participant's account with the Company's U.S. transfer agent in such form(s) as may be determined by the Committee and shall be subject to such stop transfer orders and other restrictions as the Committee may deem required or advisable. Furthermore, the Committee may determine that certificates for such Shares shall bear an appropriate legend referring to the terms, conditions and restrictions applicable thereto. Plan Shares shall be delivered as promptly as reasonably practicable following the exercise or settlement of the relevant Award, but in no event later than 30 days following such exercise or settlement. Plan Shares shall be delivered through the records of the Company's transfer agent.
 - 7 The terms and conditions applicable to Awards, including the time(s) when Awards vest in whole or in part and any applicable Performance Criteria, shall be set by the Committee and may vary
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between Awards and between Participants, as the Committee deems appropriate. Without prejudice to the settlement of SGAs upon vesting, the Committee may also determine whether and under which circumstances other Awards shall be settled automatically upon vesting, without being exercised by the Participant.

- 8 The term of an Award shall be determined by the Committee, but shall not exceed ten years from the applicable Grant Date. Unless determined otherwise by the Committee, if the exercise or settlement of an Award is prohibited by applicable law or the Company's insider trading policy on the last business day of the term of such Award, such term shall be extended for a period of one month following the end of such prohibition.
- 9 Unless determined otherwise by the Committee, Awards cannot be transferred, pledged or otherwise encumbered, except by testament or hereditary law as a result of death of the Participant concerned. For the avoidance of doubt, Plan Shares delivered upon the exercise or settlement of an Award can be freely transferred, subject to restrictions under applicable law and the Company's insider trading policy.
- 10 If, as a result of changes in applicable law, accounting principles or tax rules and regulations, or due to a variation of the composition of the Company's issued share capital (including a share split, reverse share split, redenomination of the nominal value, or as a result of a dividend or other distribution, reorganization, acquisition, merger, demerger, business combination or other transaction involving the Company or a Subsidiary), an adjustment to this Plan, any Award Agreement and/or outstanding Awards is necessary to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under this Plan, the Committee may adjust equitably any or all of:
 - 1 the number of Plan Shares available under this Plan;
 - 2 the number of Plan Shares underlying outstanding Awards; and/or
 - 3 the Exercise Price or other terms applicable to outstanding Awards.
- 11 Any rights, payments and benefits under any Award shall be subject to repayment and/or recoupment by the Company in accordance with applicable law, stock exchange rules and such policies and procedures as the Company may adopt from time to time.
- 12 The Company shall report the additional income due to any grant of Awards and delivery of Plan Shares to a Participant in accordance with the prevailing income tax reporting requirements in the respective period. The taxable event in connection with any delivery of Plan Shares shall be considered to occur, to the extent permitted under applicable law, on the date of such delivery through the records of the Company's transfer agent and shall be reported by the Company in U.S. dollars, converted to the local currency applicable in the jurisdiction where the relevant Participant has his or her tax residency (if applicable).

TYPES OF AWARDS

Article 4

- 4.1 The Committee may grant Awards in the form of Options, SGAs, SARs, Shares of Restricted Stock, RSUs, PSUs, Other Awards or a combination of the foregoing.
- 4.2 Upon the exercise or settlement of vested Options, the Company shall be obliged to deliver to the Participant concerned (or the beneficiary of such Options, as applicable), the Plan Shares underlying such Options (unless otherwise set forth in the Award Agreement).
- 4.3 An SGA shall be settled in the form of the Plan Shares on the date that the SGA vests in accordance with its terms, with such Plan Shares to be delivered as soon as reasonably practicable after such vesting date, but in no event later than 30 days following such vesting date. Such settlement shall occur automatically and without the Participant exercising any discretion as to when the underlying Plan Shares are delivered.
- 4.4 Upon the exercise or settlement of vested SARs, the Company shall be obliged to pay to the Participant concerned (or the beneficiary of such SARs, as applicable) an amount equal to the number of Plan Shares underlying such SARs multiplied by the excess, if any, of the FMV of one Share on the applicable Exercise Date over the applicable Exercise Price. The Company shall satisfy such payment obligation in the form of Shares valued at FMV.
- 4.5 The exercise by a Participant of his rights attached to Shares of Restricted Stock shall be subject to such restrictions as the Committee may impose, including with respect to voting rights and the right to receive dividends or other distributions made by the Company. Upon the vesting of Shares of Restricted Stock, any such restrictions and conditions shall lapse with respect to those Shares. If an Award in the form of Shares of Restricted Stock is cancelled or otherwise terminated, the Participant shall be obliged to transfer all of his unvested Shares of Restricted Stock to the Company promptly and for no consideration.
- 4.6 Upon the exercise or settlement of vested RSUs or PSUs, the Company shall be obliged to pay to the Participant concerned (or the beneficiary of such RSUs or PSUs, as applicable) an amount equal to the number of Plan Shares underlying such RSUs or PSUs multiplied by the FMV of one Share on the applicable Exercise Date. The Company shall satisfy such payment obligation in the form of Shares valued at FMV.
- 4.7 The Committee may determine that a Participant holding one or more RSUs or PSUs is entitled to receive dividends and other distributions made by the Company on the Shares, as if such Participant held the Plan Shares underlying such RSUs or PSUs. The Committee may impose restrictions with respect to such entitlement.

PERFORMANCE CRITERIA

5

- 1 The Committee may condition the right of a Participant to exercise one or more of his Awards, and the timing thereof, upon the achievement or satisfaction of such Performance Criteria as may be determined by the Committee, within periods specified by the Committee.
 - 2 If an Award is subject to Performance Criteria which must be achieved or satisfied within a period
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specified by the Committee for that purpose, such Award can only be exercised or settled at or after the end of that period.

- 3 Performance Criteria may be measured on an absolute or relative basis and may be established on a Company-wide basis or with respect to one or more business units, divisions, Subsidiaries and/or business segments. Relative performance may be measured against a group of peer companies determined by the Committee, financial market indices and/or other objective and quantifiable indices. Performance Criteria may relate to performance by the Company and/or by the Participant concerned.
- 4 If the Committee determines that a change in the business, operations, group structure or capital structure of the Company, or other events or circumstances, render certain Performance Criteria applicable to outstanding Awards unsuitable or inappropriate, the Committee may amend or waive such Performance Criteria, in whole or in part, as the Committee deems appropriate.

PLAN SHARES AVAILABLE FOR AWARDS

Article 6

- 1 Subject to Articles 4.10 and 7.2, the maximum number of Plan Shares underlying Awards which are not Replacement Awards shall not exceed 13% of the Company's issued share capital immediately following the completion of the initial public offering of Shares, provided that, on January 1, 2020 and on January 1 of each calendar year thereafter, such maximum number shall be increased with an additional number of Shares equal to 3% of the Company's issued share capital on such date (or any lower number of Shares as determined by the Committee).
- 2 Plan Shares underlying Awards, except for Replacement Awards, which expire, which are cancelled or otherwise terminated, shall again be available under this Plan and shall not be counted towards the limit imposed by Article 7.1.

VESTING, EXERCISE AND SETTLEMENT

7

- 1 Each Award Agreement shall contain the vesting schedule, where relevant, delivery schedule (which may include deferred delivery later than the vesting dates) for the relevant Awards. Except with respect to Awards granted to Supervisory Directors, a one-year cliff vesting schedule shall apply to all Awards (i.e., the entire Award time-vests on the first anniversary of the Grant Date (or such other date as determined by the Committee instead of the Grant Date), subject to any Performance Criteria or other vesting conditions imposed by the Committee), provided that the Committee may decide to deviate from such one-year vesting schedule for specific Awards.
 - 2 Only vested Awards may be exercised or settled in accordance with their terms. An Award can only be exercised (to the extent it is not settled automatically) by or on behalf of the Participant holding such Award.
 - 3 An Award can only be exercised through the use of an electronic system or platform to be
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designated by the Committee (if and when such system or platform has been set up by the Company), or otherwise by delivering written notice to the Company in a form approved by the Committee.

- 4 Subject to Article 9.1, the Committee shall determine the Exercise Price, provided that the Exercise Price for an Award which can be exercised or settled in the form of Plan Shares shall not be less than the aggregate nominal value of such Plan Shares.
 - 5 Upon the exercise of an Award, the applicable Exercise Price must immediately be paid in cash, wire transfer of immediately available funds or by check payable to the order of the Company, provided that the Committee, subject to applicable law, may allow that such Exercise Price is satisfied on a cashless basis as follows:
 - 1 by means of an immediate sale of Plan Shares underlying the Award concerned, with sale proceeds equal to the Exercise Price being paid to the Company on behalf of the relevant Participant and any remaining sale proceeds (less applicable costs and taxes, if any) being paid to such Participant;
 - 2 as a result of the relevant Participant forfeiting his entitlement to receive part of the Plan Shares underlying the Award concerned at FMV on the Exercise Date and charging the aggregate nominal value of the remaining Plan Shares underlying such Award against the Company's reserves; and/or
 - 3 as a result of the relevant Participant surrendering and transferring Shares to the Company (which may include Plan Shares underlying the Award concerned) at FMV on the Exercise Date.
 - 6 The Company is authorized to withhold from any Award granted or any payment due or transfer made under any Award or under the Plan or from any compensation or other amount owing to a Participant the amount (in cash, Shares, other Awards, other property, net settlement or any combination thereof) of applicable taxes and fees incurred or due in respect of an Award, its exercise or settlement or any payment or transfer under such Award or under the Plan and to take such other action as may be necessary in the option of the Company to satisfy all obligations for the payment of such taxes
 - 7 When an Award is exercised or settled in the form of Plan Shares, the Company may, at the discretion of the Committee, subject to applicable law and the Company's insider trading policy:
 - 1 issue new Plan Shares to the relevant Participant; or
 - 2 transfer existing Plan Shares held by the Company to the relevant Participant,provided, in each case, that Plan Shares may be delivered in the form of book-entry securities representing those Plan Shares (or beneficial ownership of those Plan Shares entitling the holder to exercise or direct the exercise of voting rights attached thereto) credited to the securities account designated by the relevant Participant.
 - 8 If an Award is exercised or settled in the form of Plan Shares and such Award does not relate to a whole number of Plan Shares, the number of Plan Shares underlying such Award shall be rounded
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down to the nearest integer.

PRICING RESTRICTIONS FOR OPTIONS AND SARs

Article 8

- 1 Except for Replacement Awards, the Exercise Price for an Option or SAR shall not be less than the higher of:
 - 1 the FMV of a Plan Share on the applicable Grant Date and, in case of a SAR being granted in connection with an Option, on the Grant Date of such Option; or
 - 2 the nominal value of a Plan Share (i.e., EUR 0.12).
- 2 Except as provided in Article 4.10, the Committee may not, without prior approval of the General Meeting, seek to effect any re-pricing of any outstanding "underwater" Option or SAR by:
 - 1 amending or modifying the terms of such Award to lower the Exercise Price;
 - 2 cancelling such Award and granting in exchange either (i) replacement Options and/or SARs having a lower Exercise Price, or (ii) Restricted Stock, RSUs, PSUs or Other Awards; or
 - 3 cancelling or repurchasing such Award for cash, assets or other securities.
- 3 Options and SARs will be considered to be "underwater" within the meaning of Article 9.1 at any time when the FMV of the Plan Shares underlying such Awards is less than the applicable Exercise Price.

U.S. PARTICIPANTS

Article 9

- 1 With respect to any Award subject to Section 409A IRC, this Plan and the applicable Award Agreement are intended to comply with the requirements of Section 409A IRC, the provisions of this Plan and such Award Agreement shall be interpreted in a manner that satisfies the requirements of Section 409A IRC, and this Plan shall be operated accordingly. If any provision of this Plan or any term or condition of any Award subject to Section 409A IRC would otherwise frustrate or conflict with this intent, the provision, term or condition will be interpreted and deemed amended so as to avoid this conflict.
 - 2 If all or part of any payments made, or other benefits conferred, under any Award subject to Section 409A IRC constitutes deferred compensation for purposes of Section 409A IRC as a result of a "separation from service" of the relevant Participant (other than due to his death) within the meaning of Section 409A IRC while such Participant is a "specified employee" under Section 409A IRC, then such payment or benefit shall not be made or conferred until six months and one business day have elapsed after the date of such "separation from service", except as permitted under Section 409A IRC.
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- 3 If an Award subject to Section 409A IRC includes a "series of installment payments" within the meaning of Section 1.409A-2(b)(2)(iii) of the United States Treasury Regulations, the right of the relevant Participant to such series of installment payments shall be treated as a right to a series of separate payments and not as a right to a single payment, and if such an Award includes "dividend equivalents" within the meaning of Section 1.409A-3(e) of the United States Treasury Regulations, the right of the relevant Participant to such dividend equivalents shall be treated separately from the right to other amounts or other benefits under such Award.
- 4 For any Award subject to Section 409A IRC that provides for accelerated distribution on a Change of Control of amounts that constitute "deferred compensation" as defined in Section 409A IRC, if the event that constitutes such Change of Control does not also constitute a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets (in either case, as defined in Section 409A IRC), such amount shall not be distributed on such Change in Control but instead shall vest as of the date of such Change of Control and shall be paid on the scheduled payment date specified in the applicable Award Agreement, except to the extent that earlier distribution would not result in the relevant Participant incurring any additional tax, penalty, interest or other expense under Section 409A IRC.
- 5 Notwithstanding the foregoing in this Article 10, the tax treatment of the benefits provided under this Plan or any Award Agreement is not warranted or guaranteed, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by a U.S. Participant on account of non-compliance with Section 409A IRC.
- 6 A U.S. Participant is not eligible to receive Awards in the form of RSUs or PSUs.

LEAVER

Article 10

- 10.1 If a Participant becomes a Good Leaver, unless otherwise determined by the Committee or set forth in an Award Agreement:
 1. all vested Awards that have not yet been exercised or settled must be exercised or settled in accordance with their terms within a 6-month period and, if such Awards are not exercised or (through no fault of the Participant concerned) not settled within such period, they shall be cancelled automatically without compensation for the loss of such Awards; and
 2. all unvested Awards of such Participant shall be cancelled automatically without compensation for the loss of such Awards, unless the Committee decides otherwise.
 - 10.2 If a Participant becomes a Bad Leaver, all vested Awards of such Participant which have not been exercised or settled, as well as all unvested Awards of such Participant, shall be cancelled automatically without compensation for the loss of such Awards.
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CHANGE OF CONTROL

Article 11

- 11.1** If long-term incentive awards are granted in assumption of, or in substitution or exchange for, outstanding Awards in connection with a Change of Control and the Committee has determined that such awards are sufficiently equivalent to the outstanding Awards concerned, then such outstanding Awards shall be cancelled and terminated upon the replacement awards being granted to the Participants concerned.
- 11.2** If, in connection with a Change of Control, outstanding Awards are not replaced by long-term incentive awards as described in Article 12.1, or are replaced by long-term incentive awards which the Committee does not consider to be sufficiently equivalent to such outstanding Awards, then such Awards shall immediately vest and, where relevant, settle in full, unless the Committee decides otherwise.

LOCK-UP

Article 12

In connection with any registration of the Company's securities, to the extent requested by the Company or the underwriters managing any public offering of the Company's securities, and except (a) as otherwise approved by the Committee, or (b) pursuant to any exceptions approved by the underwriters, Shares acquired by a Participant pursuant to the issuance, vesting, exercise, or settlement of any Award granted hereunder may not be sold, transferred, or otherwise disposed of prior to such period following the effective date of such registration as designated by the underwriters, not to exceed 180 days following such registration (the "**Lock-Up Period**"). The Company may impose stop-transfer instructions with respect to the Shares subject to the foregoing restriction until the end of such Lock-Up Period.

DATA PROTECTION

Article 13

- 13.1** The Company may process personal data relating to the Participants in connection with the administration and operation of this Plan. The personal data of the Participants which may be processed in this respect may include a copy of an identification document, contact details and bank and securities account numbers. Each Participant's personal data shall be stored by the Company for such time period as is necessary to administer such Participant's participation in the Plan or as otherwise permitted under applicable law.
- 13.2** Each Participant's personal data shall be handled by the Company in a proper and careful manner in accordance with applicable law, including the General Data Protection Regulation (GDPR) and the rules and regulations promulgated pursuant thereto. Participants have the right to lodge complaints with an applicable supervisory authority regarding the Company's processing of personal data pursuant to this Plan.
- 13.3** The Company shall implement technical and organisational measures designed to protect
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personal data processed pursuant to Article 14.1. Personnel or third parties that have access to such personal data shall be bound by confidentiality obligations.

- 13.4** The Company shall abide by any statutory rights the Participants may have regarding their respective personal data processed pursuant to Article 14.1, which includes the right to access, rectification, erasure, restriction of processing, objection to processing and portability of such personal data.
- 13.5** In connection with the administration and operation of this Plan, the Company may transfer personal data processed pursuant to Article 14.1 to one or more third parties, provided that there is a legitimate interest in doing so. Where such third parties are located outside the European Economic Area in countries that are not considered to provide for an adequate level of data protection, the Company shall ensure that sufficient data protection safeguards are put in place, failing which explicit consent for such transfer shall be obtained from the Participant(s) concerned.
- 13.6** The Company may establish one or more privacy policies providing further information on data protection and applying to the processing of personal data of the Participants by the Company in connection with the administration and operation of this Plan.

INSIDER TRADING

Article 14

All transactions in connection with the operation of this Plan are subject to the stipulations set forth in the Company's Insider Trading Policy as well as applicable laws, regulations and stock exchange rules.

AMENDMENT AND TERMINATION

Article 15

Pursuant to a resolution to that effect, the Supervisory Board may amend, supplement or terminate this Plan, provided that no such amendment, supplement or termination shall take effect without:

1. approval of the General Meeting, if such approval is required by applicable law or stock exchange rules; and/or
2. the consent of the affected Participant(s), if such action would materially and adversely affect the rights of such Participant(s) under any outstanding Award, except to the extent that any such amendment, supplement or termination is made to cause this Plan to comply with applicable law, stock exchange rules, accounting principles or tax rules and regulations.

GOVERNING LAW AND JURISDICTION

Article 16

This Plan shall be governed by and shall be construed in accordance with the laws of the Netherlands.

Subject to Article 3.1 paragraph g., any dispute arising in connection with these rules shall be submitted to the exclusive jurisdiction of the competent court in Amsterdam, the Netherlands.

List of subsidiaries

Subsidiaries of the Registrant	
Entity name	Jurisdiction of organization
Centogene GmbH	Germany
Centogene FZ-LLC	United Arab Emirates
Centogene US, LLC	Delaware, USA
Centogene GmbH	Austria
Centogene India Pvt. Ltd	India
Centogene Switzerland AG	Switzerland
Centosafe B.V.	Netherlands
Centogene d.o.o Belgrade	Serbia

**CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Kim Stratton, certify that:

1. I have reviewed this Annual Report on Form 20-F of Centogene N.V.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: May 16, 2023

/s/ Kim Stratton
Kim Stratton
Chief Executive Officer

**CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Miguel Coego Ríos, certify that:

1. I have reviewed this Annual Report on Form 20-F of Centogene N.V.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: May 16, 2023

/s/ Miguel Coego Ríos

Miguel Coego Ríos
Chief Financial Officer

**CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 20-F of Centogene N.V. (the "Company") for the fiscal year ended December 31, 2022 (the "Report"), I, Kim Stratton, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 16, 2023

/s/ Kim Stratton

Kim Stratton
Chief Executive Officer

**CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 20-F of Centogene N.V. (the “Company”) for the fiscal year ended December 31, 2022 (the “Report”), I, Miguel Coego Ríos, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 16, 2023

/s/ Miguel Coego Ríos

Miguel Coego Ríos
Chief Financial Officer

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-234551) pertaining to the Centogene N.V. Long-Term Incentive Plan of our report dated May 15, 2023, with respect to the consolidated financial statements of Centogene N.V. included in this Annual Report (Form 20-F) for the year ended December 31, 2022.

/s/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Berlin, Germany

May 16, 2023
