BIOCARTIS

ANNUAL REPORT 2022

BIOCARTIS GROUP NV

Part 1
At a glance

Part 2
Strategy

Part 3
Sustainability

Part 4
Corporate governance report

Part 5
Financial report

Part 6
Glossary & bibliography

1 At a glance

Biocartis' **vision** is to enable universal access to **personalized medicine** for patients around the world.

Our **mission** is to make **molecular testing** convenient, fast and suitable for any lab

Idylla™
a revolutionary,
molecular testing system designed to offer biomarker results within 3 hours for faster treatment decisions.
Suitable for any lab.

About this report

The board of directors of Biocartis Group NV (the 'Company') is responsible for the contents of this document and declares that, having taken all reasonable care to ensure that such is the case, the information contained in this Biocartis annual report 2022 is, to the best of its knowledge, in accordance with the facts, contains no omissions likely to affect it materially and contains the required information in accordance with applicable Belgian Law. In accordance with Article 3:32 of the Belgian Code of Companies and Associations, the annual reports on the statutory and consolidated annual accounts have been combined.

As a company with less than 500 employees in 2022, Biocartis is not yet legally required to report on its environmental, social and governance (ESG)/sustainability performance according to the EU Corporate Sustainability Reporting Directive (CSRD) and EU Taxonomy Regulation. Since 2020, Biocartis has been gradually expanding its disclosures on sustainability and in 2022 it performed a materiality analysis. Sustainability disclosures in this report are based, similar to previous years, on the Sustainable Development Goals (SDG), the Global Reporting Initiative (GRI) guidelines as well as the SASB (Sustainability Accounting Standards Board) framework and several principles of the Taskforce on Climate-Related Financial Disclosures.

According to the European Single Electronic Format issuers on EU regulated markets are required to prepare their annual financial reports in an electronic reporting format with the intention to make reporting easier for issuers and to facilitate accessibility, analysis, and comparability of annual financial reports. This annual report was prepared both in XHTML format (Inline XBRL technology with XBRL tagged data) and in PDF. In case of differences between both versions, the formal XBRL version shall prevail. According to the According to Belgian law, Biocartis must publish its annual report in Dutch. Biocartis also provides an English version. In case of differences between both versions, the English version shall prevail. An electronic version of the annual report 2022 is available on http://investors.biocartis.com/en. Except if information is explicitly incorporated herein by reference, other information on the website of Biocartis or on other websites is not a part of this annual report. The annual report reflects the performance and results of Biocartis in the period between 1 January 2022 and 31 December 2022. An overview of the securities legislation and listed company reporting requirements can be found on the website of the Financial Services and Markets Authority, www.fsma.be.

This report is not for distribution, directly or indirectly, in any jurisdiction where to do so would be unlawful. Any persons reading this report should inform themselves of and observe any such restrictions. Biocartis takes no responsibility for any violation of any such restrictions by any person. This report does not constitute an offer or invitation for the sale or purchase of securities in any jurisdiction. No securities of Biocartis may be offered or sold in the United States of America absent registration with the United States Securities and Exchange Commission or an exemption from registration under the U.S. Securities Act of 1933, as amended.

About Biocartis

Biocartis Group NV is a limited liability company organized under the laws of Belgium and has its registered office at Generaal de Wittelaan 11 B, 2800 Mechelen, Belgium. Throughout this report, the term 'Biocartis NV' refers to the Belgian subsidiary on a standalone basis and references to 'the Group' or 'Biocartis' include Biocartis Group NV together with its subsidiaries.

Forward-looking statement

Certain statements, beliefs and opinions in this report are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events

such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this report regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this report, those results or developments may not be indicative of results or developments in future periods. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this report as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person’s officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this report or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this report.

Use of the Idylla™ trademark, logo and product labelling

Biocartis and Idylla™ are registered trademarks in Europe, the United States and other countries. The Biocartis trademark and logo and the Idylla™ trademark and logo are used trademarks owned by Biocartis. Please refer to the product labelling for applicable intended uses for each individual Biocartis product.

1.1. Message from the Chairman and the CEO

"2022 was a successful year, both operationally and financially. In a troubled macroeconomic environment, we continued to scale our core oncology business and delivered on our financial objectives with strong 30% growth of oncology revenues, a doubling of the gross margin on product sales to 34%, and a sizeable EUR 18.1m or 32% reduction of our operating cash burn. Furthermore, we laid solid foundation for continued future growth. The regulatory approval of the Idylla™ instrument in China and of the Idylla™ MSI Test as a companion diagnostic test (CDx) in Japan will broaden our global commercial footprint. The extension of the collaboration with AstraZeneca aimed at developing a CDx for Tagrisso® and the commercialization of SkylineDx's Merlin™ Assay and Ophiomics' HepatoPredict show that partnerships are a powerful means to rapidly expand the menu of oncology tests and to make it available to any lab. Now that we also successfully recapitalized the company with EUR 66m of gross cash proceeds and a strengthened capital structure, we are in a strong position to take another significant step towards profitability. Several new regulatory approvals and new product launches are planned for 2023, including the launch of the Idylla™ IDH1-2 Mutation Assay Kit (RUO), the first assay developed with our new Idylla™ FLEX technology that significantly shortens development times and that will allow us to bring more tests to the market faster. While we are likely to operate in a continued unstable economic climate, we took measures towards the end of 2022 to weather the impact of significant cost inflation, and we are confident that in 2023 we will continue to grow product related revenues, again improve the gross margin on product sales and further reduce the operating cash burn."

Strong operational performance in a troubled economic environment

Following two years of COVID-19 pandemic, during which global cancer care was often severely hampered and we endured the global shortage of reagent supplies, we were committed to continue to grow and scale on our journey towards profitability. The war in Ukraine very rapidly brought on renewed economic uncertainty. In today's world, our partners and customers thread carefully when taking decisions to invest in the development of new diagnostic tests or to onboard our Idylla™ technology. We nevertheless honored our commitment and delivered very strong operational and financial performance that demonstrated our ability to grow and scale at a continuously high pace. Revenues in our core oncology business grew 30%, only partly offset by logically decreasing sales of the Idylla™ SARS-CoV-2 Test and the Idylla™ SARS-CoV-2 Panel. In addition to additional cartridge volumes in oncology, the average selling price of our tests continued to increase thanks to the growing contribution of sales in de US and the addition of higher-priced tests with high clinical value such as our CE-marked IVD Idylla™ GeneFusion Panel. In 2022, we also demonstrated that we can deliver profitable growth. The increased utilization of our automated high-throughput manufacturing line ML2 allowed us to more than double the gross margin on products from 16% in 2021 to 34% in 2022. In 2023, we will decommission our older manufacturing line ML1 and exclusively produce on ML2, which will cater for the further improvement of our gross margins in 2023 and beyond. Finally, we rigorously managed our available cash, and reduced the operating cash burn[1] to EUR 38.5 million, beyond an initial expectation of EUR 41 million to EUR 47 million.

Continued menu expansion

While focusing on improving our financial performance in 2022, we also continued to lay a solid foundation for future growth. Partnerships remain a key attribute of our strategy to expand our menu of tests and making it available to any lab. In 2022, we expanded our collaboration with AstraZeneca aimed at developing a companion diagnostic test (CDx) for use with Tagrisso®. We also started the commercialization of SkylineDx's Merlin assay, ahead of the launch of an Idylla™ version of the assay, and Ophiomics' HepatoPredict[2]. Building menu across various cancer programs is essential to future growth with both existing as well as new customers. Over the past two years we have focused on the new Idylla™ FLEX technology that significantly reduces development times and that will allow us to bring more tests to the market faster. The technology combines a generic Idylla™ cartridge, which can be mass-manufactured on Biocartis' high-throughput manufacturing line at low cost, with the test-specific components that are provided in a separate vial of which the content can be added into the generic Idylla™ cartridge by the user together with the sample. We recently launched the Idylla™ IDH1-2 Mutation Assay Kit (RUO), the first assay ever developed with

this new technology. Ultimately, we believe that the off-line customization of the Idylla™ cartridge has significant potential to be deployed in the vast market of frequent and repeated liquid biopsy-based testing of patients.

Successful refinancing

In very challenging financial markets, we managed to implement a comprehensive recapitalization that not only strengthened our cash resources with EUR 66 million of gross proceeds, but also improved our financing structure by pushing out the maturity date of the convertible debt. In a fundamental rehaul, the existing convertible debt of EUR 135 million was first extended and reduced through a partial equitization and repurchase at significant discounts, to then be exchanged for a new and upsized new convertible bond. Together with a new secured convertible term loan, the bond restructuring brought EUR 41 million of newly available cash and was complemented by new equity of EUR 25 million. This refinancing will support our future growth for the foreseeable future.

Making a mark in molecular diagnostics

After a successful year 2022, we have deployed a broad menu of 13 oncology tests on a global installed base of 2,085 Idylla™ instruments. The future looks bright. Not only will we launch an increasing number of novel high value-added tests, but the new Idylla™ FLEX technology will increase the pace at which we build out our franchise of decentralized molecular testing in oncology. We will continue to build on those fundamentals and are confident that in 2023 we will grow revenues, improve gross margins and further reduce our cash burn on our way to profitability.

Yours sincerely,

DocuSigned by:
Herman Verrelst
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Herman Verrelst

CEO

DocuSigned by:
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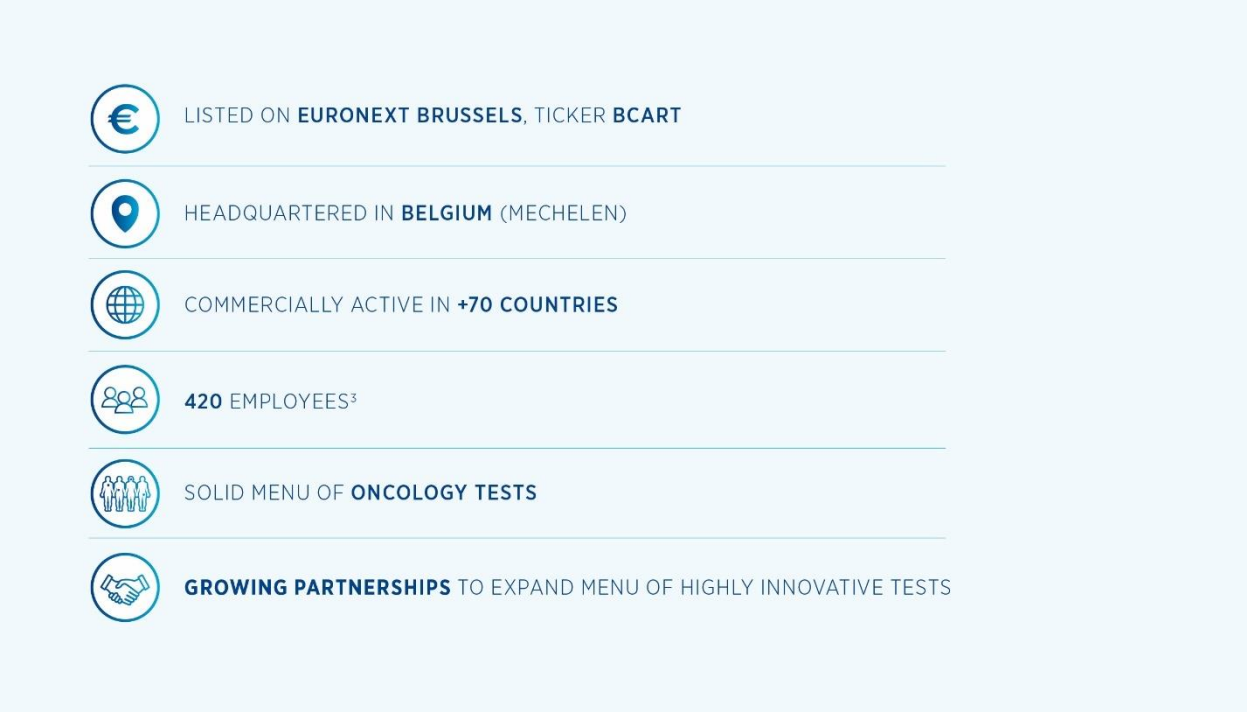
Christian Reinaudo

Chairman of the Board of Directors

1.2. Who we are

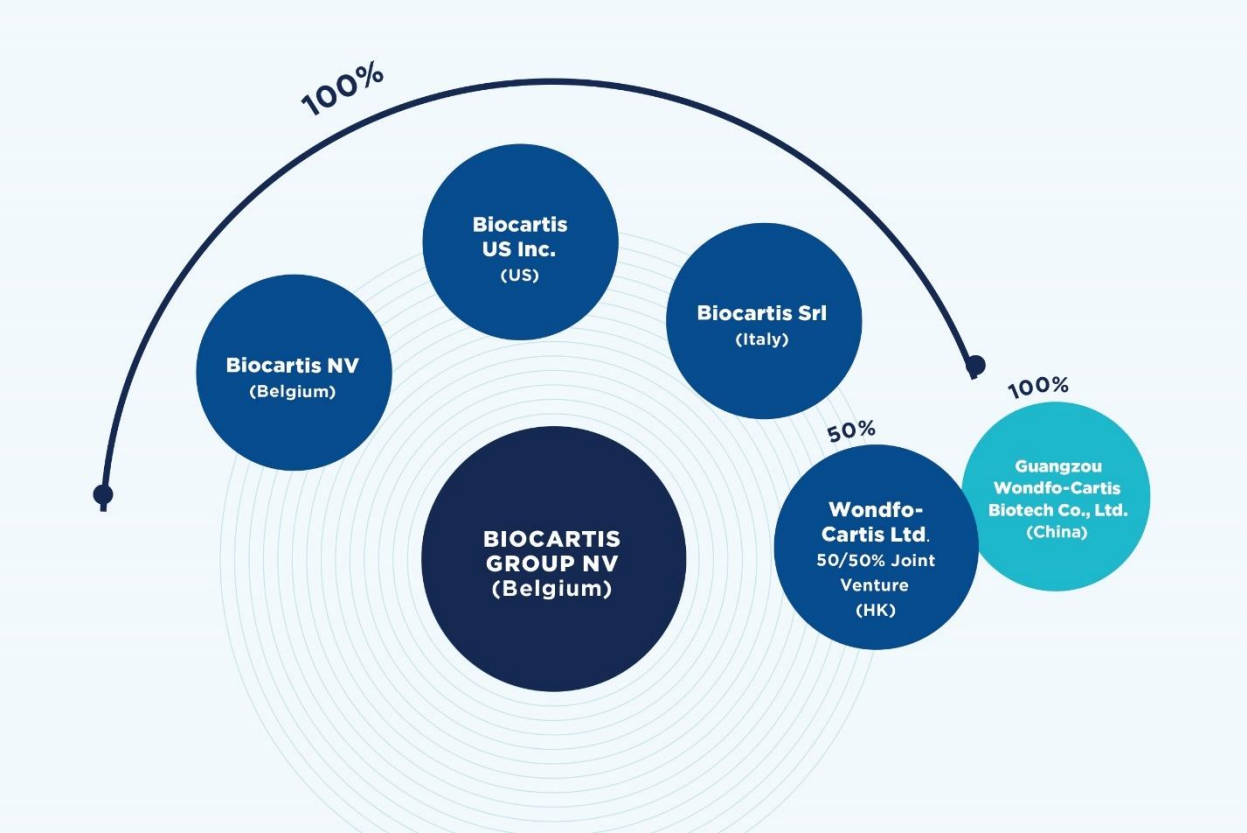
Biocartis is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions with its unique proprietary Idylla™ platform, aimed at improving clinical practice for the benefit of patients, clinicians, payers and the healthcare industry.

Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample, in virtually any setting, allowing fast and effective treatment selection and treatment progress monitoring.



Biocartis' vision is to enable universal access to personalized medicine for patients around the world. Our mission is to make molecular testing actionable, convenient, fast and suitable for any lab. Biocartis was founded in Switzerland in 2007 and acquired its technology in 2010 from Koninklijke Philips NV. In 2011, Biocartis moved to Mechelen, Belgium from where it launched its first commercial products in December 2014, the Idylla™ platform (CE-IVD) and its first Idylla™ BRAF Mutation Test (CE-IVD). In April 2015, Biocartis launched its Initial Public Offering (IPO) and is since then listed on Euronext Brussels. In 2017, Biocartis US, Inc. was established in the US. While Biocartis has mainly focused its efforts on developing and commercializing oncology tests, the 2020 pandemic clearly showed opportunities to grow in infectious diseases for which the speed and simplicity of Idylla™ equally make a true difference.

The structure of the Biocartis group consisting of the holding company, Biocartis Group NV, and three wholly owned subsidiaries as of 31 December 2022 is as follows:

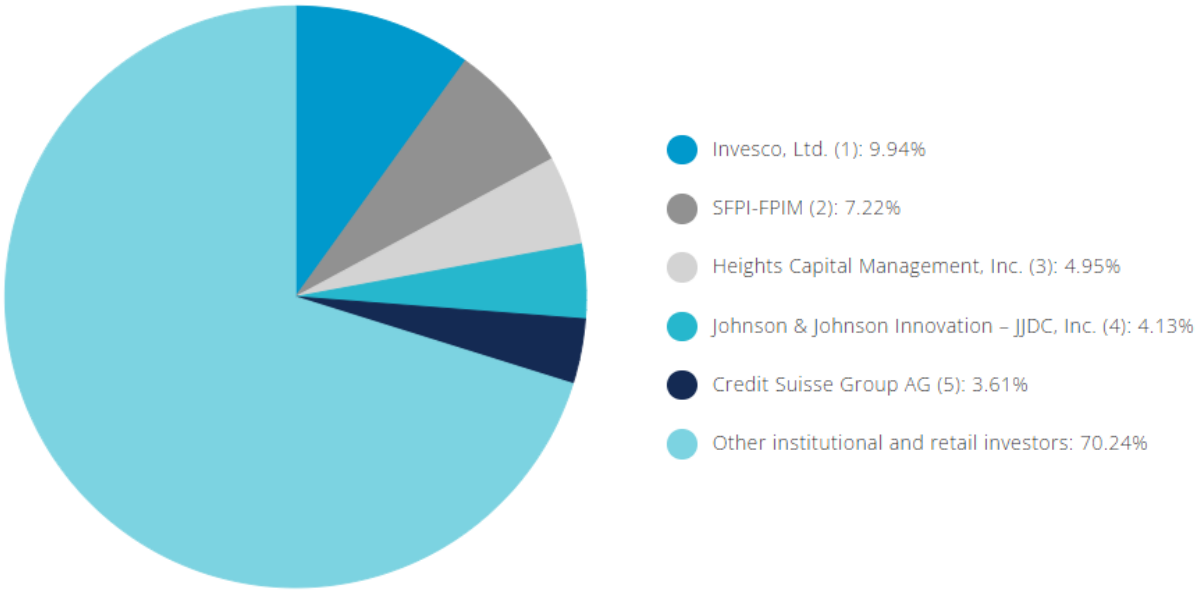


The headquarters of Biocartis Group NV are located in Mechelen, Belgium. The Company was incorporated on 24 November 2014 and is registered in Belgium under enterprise number 0505.640.808 (register of legal entities Antwerp, division Mechelen). The majority of operational activities are centralized in Mechelen (Belgium). In addition, Biocartis has a team in the US to support its US commercialization and which provides amongst others regulatory and clinical support. Furthermore, Biocartis' joint venture, WondfoCartis Ltd., was established in 2018 as a joint venture owned 50% by Biocartis Group NV and 50% by Wondfo Biotech (HK) Co., Ltd.

1.3. Share and share capital

Major shareholders

Biocartis has an international shareholder structure with both large and smaller specialized shareholders in healthcare and life sciences, and a broad base of retail investors. Based on the number of shares as of 31 December 2022 and the transparency notifications received until that date, the shareholder structure of the Company was as follows:



(1) Invesco, Ltd. is not a controlled entity
(2) SFPI-FPIM is 100% controlled by the Belgian State.
(3) Heights Capital Management, Inc. controls CVI Investments, Inc. Heights Capital Management Inc. is not a controlled entity.
(4) Johnson & Johnson Innovation-JJDC, Inc., is a wholly owned subsidiary of Johnson & Johnson. Johnson & Johnson is not a controlled entity
(5) Credit Suisse Group AG controls Credit Suisse Group AG, Credit Suisse AG, Credit Suisse AG, Dublin Branch / Credit Suisse Group AG, Credit Suisse AG, Credit Suisse Asset Management International Holding Ltd., Credit Suisse Asset Management & Investor Service (Schweiz) Holding AG, Credit Suisse Fund Management S.A. / Credit Suisse Group AG, Credit Suisse AG, Credit Suisse International

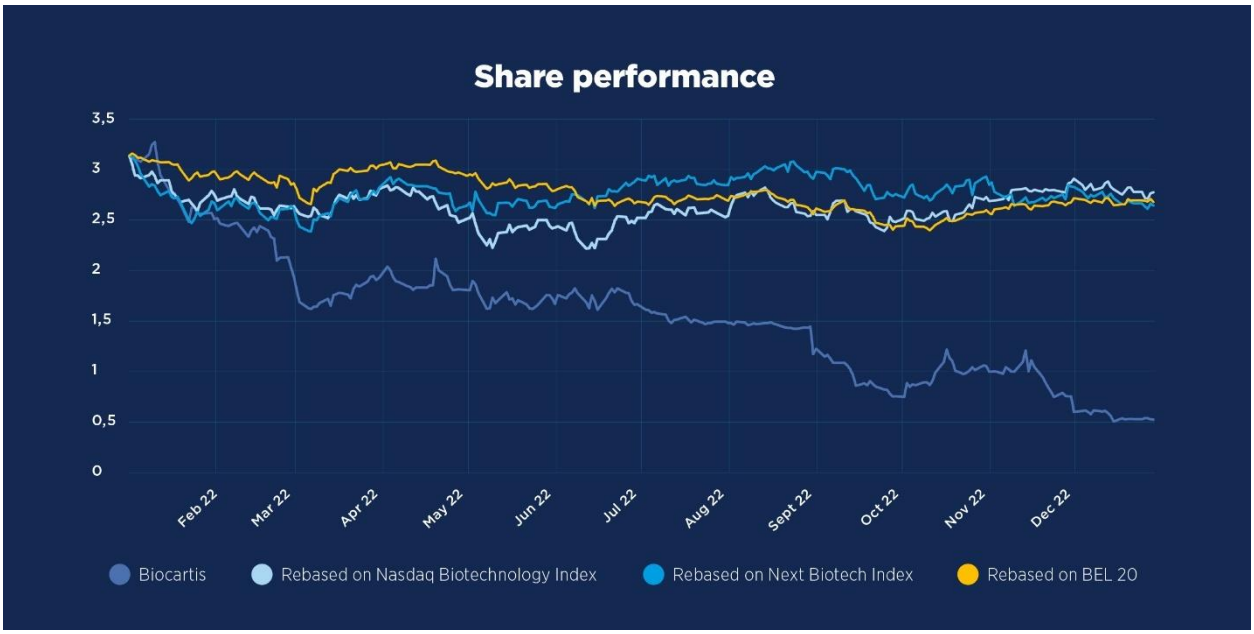
The articles of association of Biocartis Group NV provide for shareholders notification threshold of 3%, 5% or a multiple of 5% (i.e. 10%, 15%, 20%, etc.) of the total number of existing voting rights. All transparency notifications are available under the 'investor relations' section on www.biocartis.com. More details on the outstanding shares, share capital and stock-based incentive plans can be found in the Corporate Governance Statement.

Share performance

Below is an overview of Biocartis' share price performance compared to three relevant stock indices:

- Nasdaq Biotechnology Index (US focused)
- Next Biotech Index (European focused)
- BEL20 Index (Belgium focused)

Biocartis' closing share price on 30 December 2022 was EUR 0.53.



Trading volume

Below is a summary of the 2022 trading volumes of Biocartis' share.

BCART	2022	2021	Change %
Average daily volume	132,422	81,743	62%
Average daily value	1,57	4.11	-62%
Total traded volume	34,429,824	21,089,678	63%
Total traded value	49,755,443	89,305,435	-31%

Source: Bloomberg

Analyst coverage

The Biocartis share was covered by four analysts end of 2022. For more recent information about financial analyst ratings, please see the Biocartis investor website.

Broker	Analyst	Rating end 2022
Degroof Petercam	Laura Roba	Hold
KBC Securities	Thomas Vranken	Buy
Van Lanschot - Kempen	Suzanne van Voorthuizen	Neutral
Bryan-Garnier	Alexandru Cogut	Neutral

Financial calendar 2023

Date	Event
23 February 2023	Full year results 2022
11 April 2023	Publication Annual Report 2022
20 April 2023	Q1 2023 Business Update
12 May 2023	Annual General Meeting Biocartis Group NV
31 August 2023	H1 2023 results
9 November 2023	Q3 2023 Business Update

Investor relation details

For any investor relation related questions, please contact Biocartis Group, Generaal de Wittelaan 11B, 2800 Mechelen (Belgium), tel. +32 15 632 600, ir@biocartis.com.

1.4. Key achievements in 2022

- Continued strong growth of product revenues in the core oncology business
  - Product revenue amounted to EUR 45m, of which EUR 35.9m from 334k cartridges sold and EUR 9.2m from instrument rentals and sales
  - EUR 31.3m cartridge revenue in oncology, a 30% year-on-year increase, double-digit growth across all regions, led by the US, both in cartridge volumes and in average selling price (ASP)
  - Continued increase of ASP per commercial cartridge to EUR 106 (2021: EUR 96). Oncology ASP at EUR 116 (+11%)
  - Global Idylla™ installed base of 2,085 instruments, 173 net new instruments placed
- Significant economies of scale unlocked on the automated manufacturing line ML2
  - Transfer of more than 90% of all assays transferred to ML2
  - Gross profit on product sales increased by 132% from EUR 6.6m in 2021 to EUR 15.2m 2022
  - Gross margin on product sales doubled from 16% in 2021 to 34% in 2022
- Cash runway extended
  - Operating cash burn reduced by EUR 18.1m to EUR 38.5m
  - Comprehensive recapitalization: EUR 66m additional gross cash proceeds and restructuring of the convertible debt, which was extended by 2.5 years
- New tests, partnerships and regulatory approvals lay solid foundation for continued growth
  - Extended collaboration with AstraZeneca aimed at developing a new companion diagnostic test for use with Tagrisso® (osimertinib), AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment[3]
  - Start of commercialization of SkylineDx's Merlin Assay as a CE-IVD, ahead of the launch of an Idylla™ version of the Assay
  - Launch of the CE-marked IVD Idylla™ GeneFusion Panel
  - Regulatory approval of the Idylla™ instrument in China and the Idylla™ MSI test as a CDx in Japan
  - New Idylla™ FLEX technology: first assay launched (Idylla™ IDH1-2 Mutation Assay Kit (RUO))

Commercial highlights

- 334k cartridges sold in 2022, compared to 326k in 2021: 14% year-on-year growth in oncology, offset by the continued decrease of COVID-19 testing, causing volumes in infectious disease to decrease by 36% year-on-year
- Oncology cartridge revenues grew 30% in 2022: double-digit growth of cartridge volumes across all regions coupled with a consistently increasing ASP of EUR 116 (+11%):

- Sustained growth across Europe with growing adoption of the higher-priced Idylla™ GeneFusion Panel in routine clinical use since its launch in June 2022
- The US continues to combine the highest growth of oncology cartridge volumes with sustained pricing discipline. Several new customers among the top 10 cancer centers adopted Idylla™ in 2022. The ASP in oncology, traditionally higher in the US than in our other markets, benefitted from a favorable product mix and a smaller proportion of free-of-charge cartridge volumes for market seeding and the initial validation of assays
- Strong performance of the distributor markets supported by the commercial agreement with AstraZeneca aimed at increasing access to Idylla™ EGFR testing products for patients with non-small cell lung cancer

- Total revenue from Idylla™ instruments increased by 3% to EUR 9.2m in 2022, including instruments sold to content partners:
  - Revenue generated from instrument placements at end customers increased by 36% year-on-year, against a 9% increase of the installed base of Idylla™ instruments, which is evenly split between sold and rented instruments
  - Certain clinical trials that were planned to start in 2022 and requiring the sale of a significant number of Idylla™ instruments were delayed by our content partners in light of the uncertain economic environment
  - Instrument revenue in the US more than doubled, even though several new customers deferred the investment decision and adopted Idylla™ through Biocartis' free-of-charge evaluation program under which they can temporarily use the instrument while only paying for the cartridge consumption. Subject to the favorable outcome of the evaluation, revenues from the ultimate sale or rental of such instruments are therefore delayed by 6 months on average
  - 173 net new instruments placed. Several instruments were reclaimed following a focused review of non-performing reagent rental agreements to eliminate non-profitable investments in capital expenditure

Test menu and partnership highlights

Test menu:

- Launch of the fully automated, CE-marked IVD Idylla™ GeneFusion Panel[4] on 20 June 2022
- Launch of new SeptiCyte RAPID®[5] (CE-IVD) EDTA[6] blood compatible cartridges by Biocartis' partner Immunexpress[7] on 23 August 2022
- Start of the commercialization on 1 September 2022 in Europe of SkylineDx's innovative Merlin test as a CE-IVD marked manual kit, ahead of the launch of an Idylla™ version of the test. The test aims at predicting a patient's risk of nodal metastasis in melanoma

Product registrations:

- Japan – On 29 August 2022, Nichirei Biosciences, Biocartis' distribution partner in Japan, received approval by the Japanese regulatory authorities (Ministry of Health, Labor and Welfare) for the commercialization of the Idylla™ MSI Test in Japan. Nichirei Biosciences plans the commercial launch of the Idylla™ MSI Test as a CDx in Japan in Q1 2023
- China – Regulatory approval of the Idylla™ instrument on 16 September 2022 by the Chinese regulatory authorities NMPA, an important step towards the further regulatory and commercialization of Idylla™ assays in China

Partnerships:

- Announcement of a new partnership on 8 February 2022 between Biocartis and Ophiomics, a Lisbon (Portugal) based biotech company with an initial focus on the commercialization of HepatoPredict. The commercialization in Europe of the test as a CE-marked IVD kit started on 10 October 2022

- Announcement of an extension of the collaboration with AstraZeneca on 22 June 2022 highlighting the development and planned premarket submission to the US FDA of a novel CDx test on the Idylla™ platform for AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment

Publications - During 2022, 42 new papers with excellent data were published on several new Idylla™ studies, including:

- A study[8] (announced 4 May 2022) by Memorial Sloan Kettering Cancer Center (NY, US), in the Journal of Molecular Diagnostics on the Idylla™ GeneFusion Assay (RUO), highlighting the quicker turnaround and the lower tissue requirements compared to immunohistochemistry and molecular methods, while also circumventing the infrastructure dependencies associated with NGS and fluorescence in situ hybridization

- A large prospective study[9] (announced 8 November 2022) demonstrating that the Idylla™ EGFR Mutation Test (CE-IVD) leads to the significant reduction of the time-to-treatment by on average 16.8 days or 48% compared to NGS testing for EGFR positive patients

Organizational and operational highlights

- Commercial milestones – Double milestone announced on 15 June 2022 with the selling of the 1,000,000th commercial Idylla™ cartridge and the placement of the 2,000th Idylla™ instrument since commercial launch

- Shareholders' Meetings – All agenda items were approved during the ordinary shareholders' meeting held 13 May 2022 and the extraordinary shareholders' meeting held 14 November 2022 which approved the various components of the Company's comprehensive recapitalization

- Cartridge manufacturing – Except for the SeptiCyte RAPID® test, the transfer of all assays to the second cartridge manufacturing line ('ML2') was completed during 2022, further unlocking economies of scale and reducing manufacturing costs

- ISO 27001 certification – ISO 27001 certification of Biocartis announced on 24 August 2022 for the design, development, maintenance, service provision and support of the Idylla™ platform and associated customer-facing software

- Management team – Biocartis aligned its organizational structure to deliver on its strategic priorities and has appointed, effective as from 1 September 2022:

    - Global Head of Partnering: Madhushree (Madhu) Ghosh, PhD, MS, joined Biocartis as Global Head of Partnering. Dr. Ghosh brings a wealth of experience to successful commercial and strategic team leadership in global strategic alliance management, P/L business unit leadership and IVD and CDx product development for more than 20 years spent in molecular diagnostics and clinical assay development with a focus on Next Generation Sequencing, real-time PCR, multiplex PCR, oncology and infectious disease diagnostics. Previously, Dr. Ghosh held senior roles at Thermo Fisher Scientific, NeoGenomics Laboratories Inc., QIAGEN, and AltheaDx.

    - Global Head of Sales: David Dejans, previously Head of Sales Europe and Distributor markets, moved into the role of Global Head of Sales

- In Q4 2022, the organization was streamlined across all areas of the business to withstand the impact of the significant cost inflation. Compared to 31 December 2021, the workforce decreased by 16%

Financial highlights

- Total operating income – Total operating income amounted to EUR 58m, compared to EUR 54.9m in 2021, and included EUR 45m from product sales (2021: EUR 40.5m; +11%), EUR 11.1m from various collaborations with partners (2021: EUR 6.1m; +83%), EUR 1.4m from instrument servicing (2021: EUR 1.7m; -20%) and EUR 0.5m other income (2021: EUR 6.6m; -93%)
    - Revenues from cartridge sales grew 13% year-on-year to EUR 35.9m. Cartridge sales in the core oncology business increased by 30%, while sales of the SARS-CoV-2 cartridges decreased by 49% and only represented 7.7% of total product revenues. 334k cartridges were sold in 2022 (2021: 326k) at an ASP of EUR 106 (2021: EUR 96)
    - The strong 30% growth of oncology cartridge revenue resulted from growing cartridge volumes (+14% year-on-year) and an increased ASP of EUR 116, compared to EUR 105 in 2021. The ASP in oncology continues to develop favorably as the contribution from high value-adding assays such as the Idylla™ GeneFusion Assay (RUO) continues to increase. A continued focus on pricing discipline and a gradually increasing contribution from sales in the US where prices are generally higher than in Europe and other parts of the world, also support the steady increase of the cartridge ASP. Conversely, the fading COVID-19 testing need resulted in 36% lower cartridge volumes in infectious diseases, while the ASP of EUR 63 also decreased 18% year-on-year
    - Revenues from the sale and rental of the Idylla™ instrument amounted to EUR 9.2m, a 3% increase year-on-year. The installed base grew with 173 instruments to 2,085 instruments, net of conversions from instruments previously placed free-of-charge under short-term evaluation programs and returns of non-performing instruments under reagent rental agreements aimed at reducing non-profitable capital investments. As a direct result of the uncertain economic climate, the planned sale of a significant number of instruments was delayed following the decision by certain content partners to delay clinical trials that were planned to start in 2022
    - Income from collaborations amounted to EUR 11.1m compared to EUR 6.1m in 2021, and mainly included R&D services provided to our pharma and content partners, aimed at expanding the Idylla™ test menu and at developing companion diagnostic tests that will unlock additional market potential in the US and in other markets
    - Other income of EUR 0.5m related to grants received in connection with the development of the new Idylla™ FLEX technology that is expected to facilitate the use of Idylla™ tests in therapy decisions and molecular surveillance. The first product that is based on this Idylla™ FLEX technology, the Idylla™ IDH1-2 Mutation Assay Kit (RUO), was launched in 2023. In 2021, other income included an insurance claim of EUR 4.6m for damages caused by the fire in a warehouse in July 2021
- Cost of goods sold – Cost of goods sold decreased by 12% to EUR 29.8m, while cartridge volumes and the number of newly placed instruments remained comparable to 2021. Contrary to 2021, a year of disrupted reagent supply and the temporary unavailability of manufacturing capacity caused by the fire in one of Biocartis' warehouses, most cartridges were produced on the high-throughput automated manufacturing line ML2 in 2022, unlocking significant economies of scale. The gross margin on product sales more than doubled from 16% in 2021 to 34% in 2022, as a

direct result of lower manufacturing costs per cartridge and the lower contribution of low-priced SARS-CoV-2 tests. In the first quarter of 2023, more than 90% of the commercial cartridge production will have been transferred to ML2 and a plan to fully decommission ML1 will be implemented over the year

- OPEX – Total operating expenses, excluding the cost of goods sold, decreased 10% year-on-year from EUR 83.6m to EUR 75.2m. Apart from the fire damages of EUR 3.2m incurred in 2021, operating expenses decreased by EUR 5.2m, despite the impact of global inflation. Investments in various R&D programs were cut back by EUR 9.7m. The increase of EUR 3.8m in sales & marketing reflected normalized commercial activities post the pandemic and the full year impact of the restructuring of the US commercial operations implemented at the end of 2021. General & administrative spending levels remained stable at EUR 16.2m, an increase of 4% year-on-year that merely reflected cost inflation. In Q4 of 2022, the organization was streamlined to offset the expected continued inflation of costs in 2023, including the mandatory indexation of salaries in Belgium of 11%, effective January 2023. Among others, the workforce was reduced by 16% across the entire organization since 31 December 2021

- Recapitalization – On 1 September 2022, Biocartis launched a comprehensive recapitalization, providing EUR 66m of gross proceeds and comprising:

  - The amendment of the existing 4% convertible bonds of EUR 135m, including a.o. the mandatory conversion of 10% of these convertible bonds into common shares at the conversion rate of EUR 12.89 and the extension of the maturity date until 9 November 2027
  - A new first lien secured convertible term loan of EUR 30.1m, partly used for the buy-back of EUR 16.3m of existing 4% convertible bonds for EUR 13.7m in cash
  - An offer to exchange the amended existing convertible bonds for new 4.5% second lien secured convertible bonds, subject to the subscription of EUR 25m of additional newly issued 4.5% convertible bonds
  - A rights offering with extra-legal preferential rights for the existing shareholders of the Company of EUR 25.1m

  On 31 December 2022, the recapitalization transactions were partly completed. Following the amendment, the buy-back and the exchange offer, EUR 14.8m of existing 4% convertible bonds remained outstanding and EUR 92.1m of these convertible bonds had been exchanged for the new 4.5% convertible bonds. EUR 18.1m was drawn under the new convertible term loan and 33,476,932 new shares were issued on 2 December 2022 through a rights offering of EUR 25.1m. Post year-end, the recapitalization completed on 16 January 2023 with the second drawdown of EUR 12m under the new convertible term loan and the funding of the additional new 4.5% convertible bonds for EUR 25m

- Financial results – The net financial expense of EUR 17.7m included the impact of the recapitalization. In accordance with IFRS, the amendment and the exchange were considered as an extinguishment of the existing 4% convertible bond and the issuance of the new 4.5% convertible bond. The difference between the derecognition of the existing convertible bond and the new convertible bond was recorded as a loss of EUR 7.3m in the income statement including transaction expenses of EUR 6.5m. The interest and debt appreciation expense associated with the convertible term loan and the two convertible bonds amounted to EUR 10.2m

- Cash flows and cash balance – The cash flow from operating and investing activities amounted to EUR -50.3m, a significant reduction of EUR 19.2m compared to EUR 69.5m in 2021. The reduction resulted from a.o. (a) EUR 15.6m improvement of the operating result, (b) EUR 5.8m lower investments in working capital, (c) EUR 1.8m lower capital expenditure, offset by (d) investments in the Chinese joint venture Wondfo-Cartis (EUR 1m) and in a convertible note issued by SkylineDx (of which EUR 2.5m was already made available by Biocartis). The net proceeds from financing activities of EUR 22.5m reflected (a) a net new drawdown of EUR 9m on working capital facilities from KBC Bank, (b) EUR 18.1m proceeds from the first drawdown under the new convertible term loans, (c) the cash buy-back of existing convertible bonds for EUR 13.7m, (d) the scheduled reimbursement of EUR 6.6m of lease obligations, € EUR 25.1m proceeds of the rights issue, net of (f) EUR 9.6m fees associated with the recapitalization transactions. The cash and cash equivalents at 31 December 2022 amounted to EUR 26.1m

  Post year-end, the recapitalization transaction was completed on 16 January 2023, adding EUR 36.1m of net cash, from the second drawdown on the convertible term loan and the issuance of EUR 25m of additional 4.5% convertible bonds

- Balance sheet – In accordance with IFRS 9, the new 4.5% convertible bonds were partly recorded as a liability and partly as equity. Following the recapitalization transactions, the financial indebtedness at 31 December 2022 amounted to EUR 122.4m compared to EUR 154.2m at 31 December 2021. The shareholders' equity increased by EUR 3.6m as a result of a.o. (a) the recognition of EUR 33.1m equity value attributed to the new convertible bond, (b) the issuance of new shares for EUR 23m, net of fees, following the rights offering and (c) the loss for the year of EUR 63.4m

Key figures 2022

The tables below show an overview of the key figures and a breakdown of operating income for 2022. A consolidated income statement, balance sheet, cash flow statement and statement of changes in shareholder equity of Biocartis Group NV is presented in part 5, Consolidated financial accounts.

Key figures (EUR 1,000)	2022	2021	% Change
Total operating income	57,976	54,898	6%
Cost of sales	-29,799	-33,922	-12%
Research and development expenses	-38,393	-48,054	-20%
Sales and marketing expenses	-20,595	-16,763	23%
General and administrative expenses	-16,236	-15,560	4%
Other expenses	-	-3,244	
Operating expenses	-105,023	-117,543	-11%
Operating result	-47,047	-62,645	-25%
Net financial result	17,690	-8,411	-100%
Share in the result of associated companies	-884	-659	34%
Income tax	240	243	-1%
Net result	-65,381	-71,472	-33%
Cash flow from operating activities	-44,855	-65,716	-32%
Cash flow from investing activities	-5,431	-3,748	45%
Cash flow from financing activities	22,463	-1,204	-1,965%
Net cash flow [1]	-27,823	-70,668	-61%
Cash and cash equivalents[2]	26,125	53,522	-51%
Financial debt	122,356	154,162	-21%

1 Excludes the effect of exchange rate differences on the cash balances held in foreign currencies

2 Including EUR 1.2m of restricted cash in 2022 and 2021

Operating income (EUR 1,000)	2022	2021	% Change
Collaboration revenue	11,068	6,053	83%
Idylla™ system sales and rentals	9,172	8,869	3%
Idylla™ cartridge sales	35,864	31,618	13%
Product sales revenue	45,036	40,486	11%
Service revenue	1,377	1,730	-20%
Total revenue	57,481	48,269	19%
Grants and other income	495	6,629	-93%
Total operating income	57,976	54,898	6%

Income statement

Total operating income increased by EUR 3.1m to EUR 58m in 2022. Collaboration revenue increased by EUR 5m, or 83% to EUR 11.1m and predominantly consisted of development services provided to partners. Revenue from such services amounted to EUR 10.5m compared to EUR 5.9m in 2021, an increase of 79%. Collaboration income further included license revenue of EUR 0.1m and EUR 0.5m related to certain development milestones achieved in 2022.

Revenue from product sales amounted to EUR 45m and increased with EUR 4.6m or 11% from EUR 40.5m in 2021. Within revenue from product sales, cartridge sales accounted for EUR 35.9m and the sale and rental of Idylla™ systems represented EUR 9.2m. The revenue from the sale of 334k cartridges increased by EUR 4.2m or 13% from EUR 31.6m in 2021. The strong increase in the sale of cartridges in the core oncology business of 30% was partly offset by a decrease of the sale of the Idylla™ SARS-CoV-2 test as a direct result of fading global COVID-19 testing needs. The increase in oncology cartridge revenue was driven by increasing cartridge volumes (+14%) and an average selling price (ASP) that increased from EUR 105 in 2021 to EUR 116 in 2022. Oncology cartridges represented EUR 31.3m or 87% of total cartridge revenue. The revenue from the sale and rental of Idylla™ systems increased from EUR 8.9m to EUR 9.2m and reflected the increase of the installed base from 1,912 on 31 December 2021 to 2,085 on 31 December 2022. Included in the system revenues is the income from the rental of Idylla™ systems for a total amount of EUR 5m, an increase of 31% compared to EUR 3.8m in 2021. The revenue from servicing the Idylla™ systems decreased from EUR 1.7m in 2021 to EUR 1.4m in 2022.

Grant income decreased to EUR 0.5m in 2022 compared to EUR 2.1m in 2021, and related to the recognition of subsidies awarded in relation to the highly innovative Idylla™ FLEX technology to be deployed on the Idylla™ platform aimed at enabling the off-line customization of the Idylla™ cartridge. A first assay developed with this new technology, the Idylla™ IDH1-2 Mutation Assay Kit was launched among selected customers as a Research Use Only product and will be made available globally during the second half of 2023. In 2021, other income included a EUR 4.6m insurance claim for damages caused by the fire on 30 July 2021.

Total operating expenses decreased from EUR 117.5m in 2021 to EUR 105m in 2022. Within operating expenses, the cost of goods sold decreased by EUR 4.1m or 12% from EUR 33.9m in 2021 to EUR 29.8m in 2022, while product revenue increased by 11%. The decrease of the cost of goods sold is attributable to economies of scale resulting from the increased utilization of the automated high-throughput manufacturing line ML2. In 2021, production on the ML2 line was constrained because of the global shortage of reagents during the first half of the year caused by the pandemic, and because of the forced 2-month production stop after the fire in one of the warehouses in July 2021. Following this fire, the production of certain assays was transferred to the ML1 line to preserve customer supply as much as possible, but the manufacturing capacity on the ML1 line is significantly lower and the manufacturing cost significantly higher than on the ML2 line. In 2022, more than 90% of all assays were transferred from the older manufacturing line ML1 to ML2, resulting in a significant reduction of the manufacturing cost per cartridge. In 2023, ML1 will be decommissioned. Together with the increasing ASP, the decrease of the manufacturing cost of cartridges, resulted in an increase of the gross margin on product sales from 16% in 2021 to 34% in 2022.

Total operating expenses, excluding the cost of goods sold, decreased by EUR 8.4m or 10% from EUR 83.6m in 2021 to EUR 75.2m in 2022. R&D expenses amounted to EUR 38.4m, a decrease of EUR 9.7m compared to 2021. 2021 was a year of exceptional investment in R&D, in part because of the carry-over of projects that were delayed in 2020 following the pandemic outbreak, but

also because of increased investments in further menu expansion and diversification, including a.o. the development of the Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD) and the continued investment in the transfer of assays from the ML1 line to the ML2 line. In 2022, investments in R&D were cut back and included the development and the launch of the CE-IVD Idylla™ GeneFusion panel, the Idylla™ IDH1-2 Mutation Assay Kit (RUO) and certain content partner tests. S&M expenses increased by EUR 3.8m to EUR 20.6m because of the post-pandemic normalization of commercial activities and the full year impact of the restructuring of the US commercial operations implemented at the end of 2021. The increase of EUR 0.7m in G&A expenses from EUR 15.6m in 2021 to EUR 16.2m in 2022 is largely attributable to inflation. At the end of 2022, the organizational structure was streamlined to withstand the impact of the expected continued cost inflation in 2023.

The operating result for 2022 improved by EUR 15.6m from EUR -62.6m in 2021 to EUR -47m in 2022, as a result of the significantly improved gross profit and the decrease of operating expenses.

In addition to interest and other financial expenses of EUR 3.5m, the financial result the impact of the recapitalization transactions. The recapitalization included the partial equitization of 10% of the 4% convertible bonds (10%), the buy-back of EUR 16.3m of the 4% bonds for cash consideration of EUR 13.7m and the exchange of EUR 92.1m of such convertible bonds for new 4.5% convertible bonds. In accordance with IFRS 9, this exchange was accounted for as an extinguishment of the existing convertible bonds and the recognition of the new convertible bonds, resulting in a loss of EUR 7.3m in the income statement.. The recapitalization included the partial equitization of 10% of the 4% convertible bonds (10%), the buy-back of EUR 16.3m of the 4% bonds for cash consideration of EUR 13.7m and the exchange of EUR 92.1m of such convertible bonds for new 4.5% convertible bonds. These transactions were recorded as an extinguishment of the 4% convertible bonds and the resulting derecognition of such bonds resulted in a loss of EUR 7.3m. Interest expenses in 2022 amounted to EUR 11.2m, an increase of EUR 1.9m compared to 2021, reflecting the net drawdown of EUR 9m on working capital facilities, the first drawdown of a new convertible term loan for an amount of EUR 18.1m and the increased interest expense on the convertible bonds following the exchange of the existing 4% convertible bonds for new 4.5% convertible bonds. The net financial expenses also included EUR 0.8m of foreign currency exchange gains.

Balance sheet

On 31 December 2022, total assets amounted to EUR 114.3m, a decrease of EUR 28.2 m from EUR 142.5m on 31 December 2021. Non-current assets decreased by EUR 3m as a result of the net reduction of intangible assets and property, plant and equipment of EUR6m, offset by an investment of EUR 2.5m in a convertible note issued by SkylineDx. The company agreed to invest up to EUR 10m in SkylineDx's convertible notes as part of the collaboration announced on 22 April 2021. The investment will be made available in different project-based milestones throughout the collaboration. The investment in the China joint venture Wondfo-Cartis amounted to EUR 2.5m compared to EUR 2.3m on 31 December 2021 following an additional capital injection of EUR 1m, which was offset by Biocartis' share of EUR 0.9m in the joint venture's loss of 2022.

Current assets at the end of 2022 amounted to EUR 69.9m, a decrease of EUR 25.2m from EUR 95.1m in 2021, driven by a reduction in cash and cash equivalents of EUR 27.4m. Trade receivables and inventories increased by EUR 3.3m, an increase which is fully in line with the growing commercial activity. Other receivables decreased by EUR 4.3m from EUR 6.6m in 2021 to EUR 2.2m in 2022, mostly reflecting the collection of the remaining balance of EUR 3.8m of insurance claims for fire damages. Other current assets increased by EUR 3.2m to EUR 6m following the deferral of costs related to the issuance of new 4.5% convertible bonds and the second drawdown of the new convertible term loan which only completed on 16 January 2023. These costs will be capitalized as part of the recognition of these financial obligations in 2023.

The financial debt reduced from EUR 154.2m at the end of 2021 to EUR 122.4m on 31 December 2022. On 1 September 2022, Biocartis launched a comprehensive recapitalization, which included the restructuring of the existing convertible debt and the provision of new convertible debt, summarized as follows:

- The amendment of the existing 4% convertible bonds of EUR 135m, including a.o. the mandatory conversion of 10% of these convertible bonds into common shares at the conversion rate of EUR 12.89 and the extension of the maturity date until 9 November 2027.

- A new first lien secured convertible term loan of EUR 30.1m, partly used for the buy-back of EUR 16.3m of existing 4% convertible bonds for EUR 13.7m in cash.

- An exchange of the amended existing convertible bonds for new 4.5% second lien secured convertible bonds, subject to the subscription of EUR 25m of additional newly issued 4.5% convertible bonds.

On 31 December 2022, the recapitalization transactions were partly completed. Following the amendment, the buy-back and the exchange offer, EUR 14.8m of existing 4% convertible bonds remained outstanding and EUR 92.1m of these convertible bonds had been exchanged for the new 4.5% convertible bonds. EUR 18.1m was drawn under the new convertible term loan. In accordance with IFRS 9, the convertible bonds have been partly recorded as a liability and partly as equity to reflect the value of the embedded derivative. The liability associated with both convertible bonds and the new convertible term loan amounted to EUR 92.7m. In addition to the convertible debt, total financial liabilities of EUR 122.4m included EUR 14.6m lease obligations (2021: EUR 20m) and EUR 15m of bank debt (2021: 6m). Post year-end, the recapitalization completed on 16 January 2023 with the second drawdown of EUR 12m under the new convertible term loan and the funding of the additional new 4.5% convertible bonds for EUR 25m.

Trade payables of EUR 11.7m only marginally increased by EUR 0.2m, while other current liabilities, which mainly include payroll related obligations such as vacation pay and year-end premiums, increased from EUR 8.4m at the end of 2021 to EUR 8.9m at the end of 2022.

Cash flow statement

The cash flow from operating activities in 2022 benefitted from the improved operating result and reduced by EUR 20.9m from EUR -65.7m in 2021 to EUR -44.9m in 2022. Investments in working capital decreased from EUR 9.6m in 2021 to EUR 3.9m in 2022. The decrease related to the reduction of trade and other receivables of EUR 7.5m (of which EUR 3.8m related to the collection of the outstanding balance of the insurance claim for fire damages), an increase in trade and other payables with EUR 2.1m, partly offset by increased investments in the replenishment of inventories by EUR 2.6m that were depleted following the fire in 2021.

The cash flow from investing activities in 2022 amounted to EUR -5.4m, compared to EUR -3.7m in 2021. The increase resulted from the investments in the convertible note issued by SkylineDx (EUR 2.5m) and in Wondfo-Cartis (EUR 1m), offset by EUR 1.8m lower investments in property, plant and equipment and intangible assets.

The cash flow from financing amounted to EUR 22.5m as a result of the net repayment of lease and other obligations for EUR 11.3m, offset by the net proceeds of the rights offering and the first drawdown under the new convertible term loan for EUR 33.8m in aggregate.

The total cash flow for 2022 amounted to EUR -27.8m compared to EUR -70.7m in 2021 and resulted in cash and cash equivalents of EUR 26.1m on 31 December 2022.

1.5. Macroeconomic environment

While still recovering from the impact of more than two years of COVID-19 pandemic, the macroeconomic environment was significantly impacted by the war in Ukraine. The war in Ukraine added to the disruption in supply of multiple materials initially caused by pent up demand in the aftermath of the pandemic. Soaring commodity and energy prices and an increasingly uncertain economic outlook led to extremely high inflation rates. Global cancer care normalized to pre-pandemic levels with few and sporadic restrictions to patient access to hospitals. While our core oncology business therefore strongly grew, the overall economic environment impacted us in various respects.

COVID-19

In 2020, as a direct result of the outbreak of the COVID-19 pandemic, cancer care was significantly disrupted, and customer prospection severely hampered. Patient access to hospitals was restricted and the surge of COVID-19 cases resulted in an overburdened healthcare system, requiring cancer diagnosis and treatment to be delayed.

The pandemic also brought an opportunity to strengthen our offering in infectious diseases. In order to respond to our customers' needs for COVID-19 testing, and to bridge the shortfall in oncology testing, we developed the Idylla™ SARS-CoV-2 Test (CE-IVD). The demand for this Test was particularly strong during the fourth quarter of 2020 in the US. In 2021, we upgraded the test and launched the Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD) which detects, in one single cartridge, SARS-CoV-2, Flu A/B and RSV[10] nucleic acids. In 2022, the demand for both tests gradually decreased following the fading need for COVID-19 testing. Moreover, the average selling price of the tests eroded because there was more than enough testing capacity. In 2022, the revenue from the sale of the Idylla™ SARS-CoV-2 Test (CE-IVD) and the Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD) decreased to EUR 3.5 million, representing less than 8% of total product revenues, compared to EUR 6.8 million, or 17% in 2021. In light of the gradually reducing gross margins on the sale of both tests, the prospection of new customers was deprioritized in 2022 and the contribution of both tests to product revenue is expected to further decrease in 2023. Nevertheless, the pandemic is expected to have continued long-term impact:

- The pandemic clearly demonstrated the need for more, better and faster diagnostic testing. With the spread of COVID-19, the demand for molecular assays, particularly those involving PCR, has exploded and is expected to keep growing. In response to faster screening, the volume of point-of-care testing has also significantly risen. The pandemic may therefore lead to the broader adoption of decentralized PCR testing, and positively impact the demand for Idylla™, a fully automated platform with rapid turn-around time and unmatched ease-of-use. Idylla™ is ideally suited to capitalize on the trend for more personalized medicine in oncology while addressing the need for fast-response infectious disease testing in acute settings at the same time

- The growing demand for PCR testing has led to a significant expansion of testing capacity, which will likely remain in place as the pandemic subsides. Furthermore, the shortage of reagent supplies and the growing demand have garnered regulatory support for the use of new technologies as an alternative to PCR-based COVID-19 testing, including NGS. Both could lead to increased competition, including in our core oncology activities, as the additional capacity and new technologies search for alternative ways of deployment in a post-pandemic environment

- The pandemic has made Biocartis more resilient and efficient. Among others, the afore-mentioned positive environmental and social impact is expected to have a sustainable long-term impact on how we operate. The pandemic increased awareness in multiple areas such as business risk, mental well-being, cost-effective ways of working, supply continuity, etc. Many business practices and processes have developed throughout the pandemic and are expected to improve our ability to adapt to rapidly changing circumstances and more adequately respond to crisis

Supplier impact

Even though we raised our efforts at the start of the pandemic to strengthen our supply chain and mitigate the risk of disruptions that could affect the supply of Idylla™ products to our customers, we were nevertheless affected in 2021 by the worldwide shortages of reagent supply caused by the growing and worldwide need for COVID-19 PCR testing, one of the most effective components in the fight against the pandemic. The shortfall in critical reagents constrained our production capacity during the first half of 2021. Furthermore, a fire in one of our warehouses destroyed a significant part of reagent inventory that was difficult to replenish. As such, we were not able to serve all customer demand in 2021. Despite the additional impact of the war in Ukraine on global supply, the supply of raw material was largely undisrupted in 2022 as we benefitted from several actions taken in 2021, including:

- Improvement of internal communications between sales and manufacturing teams to better align supply and demand
- Increase of inventory levels where possible to ensure availability of raw materials by working closely with existing suppliers and by identifying new suppliers
- Increase of safety stock levels of finished goods, where possible
- Close collaboration with preferred transportation partners to continue shipments to our partners and customers across the globe
- Heightened supply chain monitoring systems with weekly and even daily updates by our supply chain teams
- Interaction with main suppliers to further improve our ability to respond quickly to changing demand

Biocartis had one indirect supplier for Idylla™ instrument sub-parts based in Russia. An alternative supplier was identified and qualified in 2022 to ensure the continued supply of instruments.

Inflationary impact

The Russian invasion of Ukraine magnified the impact from pent-up demand following more than two years of pandemic, resulting in a very significant increase of the price of commodities and causing soaring global inflation. Biocartis' costs predominantly consist of personnel costs, raw materials used in the manufacturing of the Idylla™ instrument and the Idylla™ cartridges and energy costs. In 2022, Biocartis took several measures to withstand the impact of inflation, such as the mandatory indexation of Belgian salaries and increased manufacturing costs:

- Selling prices of Biocartis' products were increased within the boundaries of existing levels of reimbursement and to the extent price increase are contractually allowed.
- Biocartis streamlined its organization and reduced its workforce. The number of employees on 31 December 2022 was reduced by 16% compared to 31 December 2021.

Commercial impact of the war in Ukraine

Biocartis has no sales in Ukraine. In Russia, we operate through a local sales distributor who realized first sales in 2021 following the completion of the first product registrations in Russia. Sales in Russia are not subject to sanctions taken against Russia. Sales amounted to EUR 0.3 million in 2022 and are subject to prepayment before delivery.

Government support measures

In 2020, our US subsidiary, Biocartis US Inc., received a loan of USD 1m under the US Paycheck Protection Program ('PPP'), established as part of the Coronavirus Aid, Relief and Economic Security Act ('CARES Act'). On 29 October 2020, Biocartis US Inc. submitted a loan forgiveness application for the full amount of the loan plus applicable interest to its lender. The lender approved the forgiveness application and recommended full forgiveness to the Small Business Administration ('SBA'). On 31 March 2021, the loan was effectively forgiven. Biocartis US Inc. also applied for an Employee Retention Tax Credit under the CARES Act in 2021, aimed at encouraging companies to retain employees on their payroll to compensate for business losses. A tax credit of USD 223 thousand was approved and collected in 2022.

2.1. Market of molecular diagnostics

What is molecular diagnostics?

The study of diseases has led to the discovery of macromolecules associated with specific diseases or treatment response. These macromolecules can be used as biomarkers and can be detected in patient samples such as blood, urine, sputum, saliva or tissue such as tumor tissue. Molecular testing or diagnostics (MDx) is the primary tool used to identify the presence of molecular biomarkers in these patient samples. In cancer, measuring the presence of a biomarker associated with a patient's tumor can provide crucial information on the applicability of a new generation of more effective targeted treatments, providing an opportunity for better health outcomes and reduced healthcare costs. Tailoring treatment to the genetic profile of a patient is part of a trend towards personalized medicine.

Speed is of the essence. Rapid access to accurate data about the relevant pathogens in infectious diseases, or about the relevant cancer mutations or treatment resistance in oncology, is vital. Early disease interception[11] reduces the anxiety while waiting for results and the time before starting the best possible treatment. In molecular diagnostics, current technologies are often complex, require a lot of hands-on time and are difficult to implement in the local laboratory. As a consequence, most laboratories do not perform molecular tests in-house, but send samples out to specialized centers, where they are batched in order to optimize costs[12]. This delays the fast delivery of results, preventing rapid initiation of the most beneficial therapy.

In the case of cancer, this means the tumor has time to grow or spread. Fast initiation of immunotherapy or targeted therapy as first-line treatment is crucial for cancer patients, as it increases overall survival rates[13]. Timely detection of biomarkers therefore is very important. Today, turnaround times of reference technologies are on average 18 days, with 14% of patients waiting longer than a month to be able to start treatment. 95% of the patients must wait more than a week in order to receive the biomarker results[14]. This means that precious time is lost whereas treatment initiation could have been started and unnecessary use of chemotherapy with its side effects could have been avoided.

Vast addressable market

The worldwide COVID-19 pandemic has created an increased demand for molecular diagnostic testing. The global molecular diagnostics market, estimated at USD 17.2bn in 2022, is expected to grow at a 7.7% compound annual growth rate (CAGR)[15] between 2021-2026. Oncology reached a value of USD 3.2bn in 2022 and is expected to reach USD 7.3bn by 2027, exhibiting a CAGR of 14.7%[16].

Biocartis' oncology products target a large, global customer base of pathology labs with the opportunity to unlock new customer segments. The current on-market Idylla™ test menu serves a market of nearly 6 million tests per annum[17], increasing to at least 10 million by 2026 with tests in the pipeline. The market potential is vast[18]:

- Therapy selection market of USD 6bn
- Recurrence monitoring market of USD 15+bn

- Early detection (screening) market of USD 50bn

This is complemented with the ongoing expansion of the oncology test menu through novel gene signature tests and liquid biopsy based personalized patient monitoring tests.

The global infectious disease diagnostics market is estimated at USD 35.5bn in 2022. Market growth, which is expected to stabilize towards 2027, is driven by the global prevalence of infectious diseases and the growing awareness for early diagnosis and a shift in focus from centralized laboratories to decentralized point-of-care testing[19]. Thanks to the build out of its pandemic response test menu, Biocartis developed a proven market access to the infectious disease market and is now broadening its test menu with a focus on COVID-19 and sepsis testing to support patient journey in hospital ICU. Longer term opportunities exist for partner collaboration around the development of broad syndromic panels leveraging the unique multiplexing-related capacity of Idylla™.

Within the market of infectious diseases, sepsis testing represents a high unmet need, as current markers are not rapid (blood cultures) or are non-specific (PCT, CRP)[20]. Since sepsis is the final common pathway to death from most infectious diseases worldwide, including viral infections such as SARS-CoV-2 (COVID-19) there is an increased risk in pandemic times. Fast clinical decisions are essential for a positive impact on the patient's outcome, which matches Idylla™'s key characteristics.

Sepsis arises when the body's response to an infection injures its own tissues and organs. It may lead to shock, multi-organ failure, and death – especially if not recognized early and treated promptly. Sepsis is responsible for an estimated 11 million deaths/year globally[21], with annual healthcare costs estimated at over USD 65 billion in the US alone[22].

2.2. Product strategy

Biocartis' vision is to enable universal access to personalized medicine for patients around the world. Our mission is to make molecular testing convenient, fast and suitable for any lab.

MDx testing today still suffers from many inefficiencies, which delay results and impacts patients. The Idylla™ platform provides a unique solution offering results available in minutes or hours instead of days or weeks, a fully automated workflow with little to no hands-on time and superior performance in a single proprietary and versatile platform that can be used both in oncology and infectious diseases. Biocartis has a focus in oncology since 2017 where Idylla™ can make the biggest difference because of its unique features including:

- Rapid and fully automated testing
- Decentralized testing with the performance of lab reference testing
- On both solid and liquid biopsies

"Idylla™ is a revolutionary, fully automated system that makes molecular testing convenient, affordable & exceptionally fast. Suitable for any lab."

Idylla™ platform and Idylla™ technology

Robust technology with validated performance

The Idylla™ platform is a fully automated, real-time PCR-based molecular diagnostics system that provides same-day results enabling physicians to make timely decisions on patients' therapy. Idylla™ can be used with multiple sample types, including solid and liquid biopsies.

This flexibility allows use of Idylla™ for diagnosis, research or possibly future monitoring applications with its compact scalable design and outstanding ease-of-use, Idylla™ overcomes the traditional barriers of molecular diagnostics, allowing it to be used in virtually any laboratory setting. The simplified four-step Idylla™ workflow drastically limits the number and duration of operator steps that have traditionally led to high labor costs and risks of errors for MDx tests, and generally take no longer than two minutes:

- The Idylla™ platform is composed of a console (display), an instrument (stackable up to eight) and a disposable cartridge, a plastic consumable with all necessary reagents on board to process a clinical sample and to detect the molecular biomarkers of interest. All cartridges share a common hardware design but are made application-specific by their reagent content, test execution protocol (software) and labeling

- The Idylla™ platform in combination with the Idylla™ assays or tests differs from other technologies in its outstanding ease-of-use, leading to an unsurpassed level of standardization, short turnaround time, enabling fast results and allowing a more rapid start of the appropriate targeted therapy

The Idylla™ technology has been validated by 42 new published Idylla™ papers in 2022, bringing the total number of Idylla™ papers to 166 end of 2022.

The new Idylla™ FLEX technology

In recent years, Biocartis has continued to invest in its technology and developed the new Idylla™ FLEX technology that separates the generic components of an Idylla™ test from the test-specific components. The Idylla™ FLEX technology shortens the development time of new Idylla™ assays, allowing to bring them to the market much faster. The technology combines a generic Idylla™ cartridge, which can be mass-manufactured on Biocartis' high-throughput manufacturing line at low cost, with the test-specific components that are provided in a separate vial of which the content can be added into the generic Idylla™ cartridge by the user together with the sample. The Idylla™ FLEX technology will first be deployed for tests that use FFPE, peripheral blood

mononuclear cells, bone marrow mononuclear cells, whole blood or extracted DNA as sample type. In a next step, it is intended to be deployed for tests that can use up to 4 ml of plasma as sample type.

In a next phase, the off-line customization of the Idylla™ cartridge could be deployed in the rapidly growing field of molecular surveillance, where patients are monitored with molecular tests. The Idylla™ FLEX technology is ideally suited for both tumor-informed (aka bespoke or personalized) as well as tumor-naïve panels, both of which have shown promise for molecular surveillance. Moreover, Idylla™ FLEX will be a major steppingstone to testing liquid biopsy samples, which is expected to account for the largest share within the vast market opportunity of molecular surveillance monitoring.

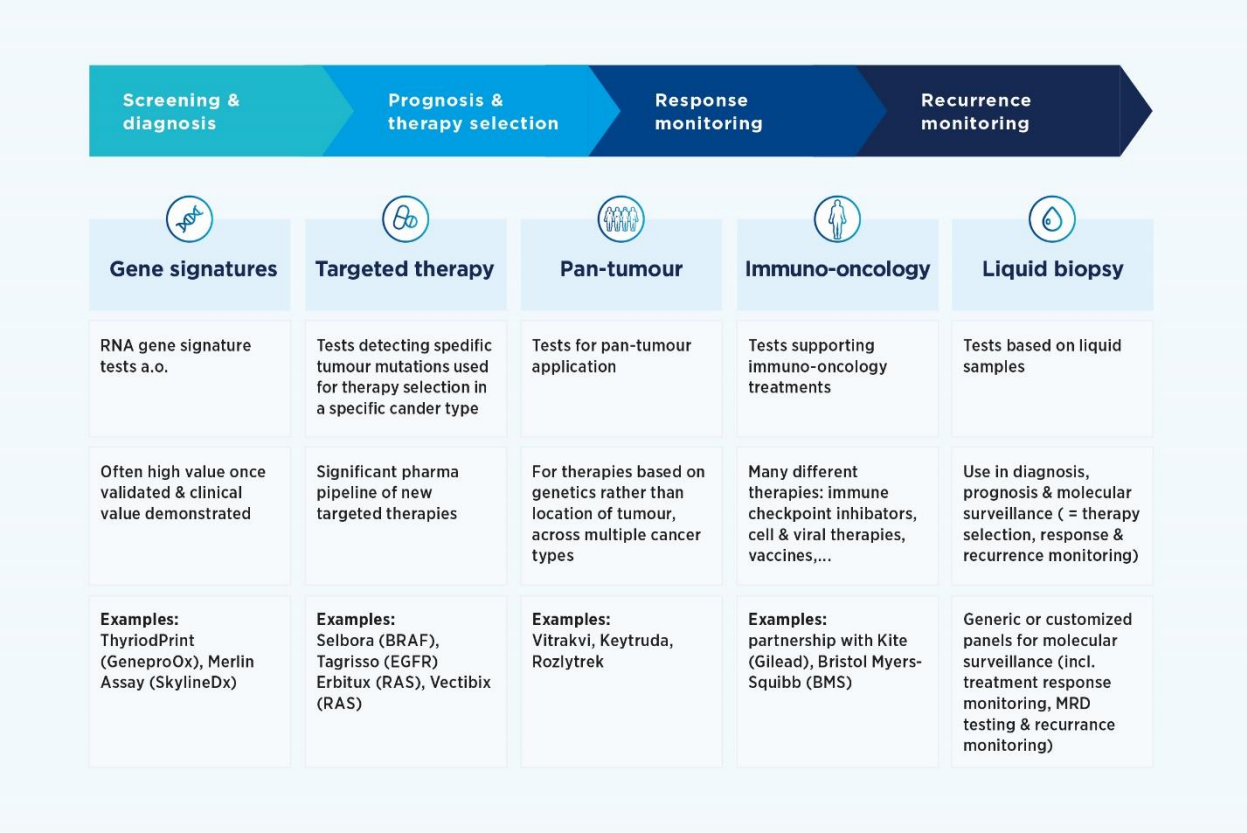
The Idylla™ IDH1-2 Mutation Assay Kit (RUO) is the first test developed using the Idylla™ FLEX technology. The assay was launched among selected customers and will be made available for partnerships with pharmaceutical companies, clinical research organizations and reference labs conducting research in the course of 2023.

Broad menu in oncology

Idylla™ solutions today include a broad menu of +10 on-market tests positioned within the entire spectrum of cancer care - from prognosis to surveillance - as well as infectious diseases, thanks to the leveraging of our network of partnerships.

Serving needs across the cancer treatment continuum

Throughout the treatment continuum, a cancer patient is confronted with cancer diagnostic testing at several points. Molecular tests are indeed used to diagnose cancer, to determine the exact stage of the disease and to select the right therapy. Later, testing occurs to amongst others measure the response to treatment, the presence of residual tumor and eventually to monitor the potential recurrence of the cancer and the need to restart therapy.



Across the cancer treatment continuum, there are five important strategic trends where Idylla™ can play a unique role:

Targeted therapies: Biocartis' current products are primarily geared at therapy selection. Especially within colorectal and lung cancer, Biocartis has built a comprehensive actionable panel of first-line tests.

Pan-tumor: An adjacent trend is the application of targeted therapies in a pan-tumor setting, where therapy selection is increasingly driven by the genetic make-up of the tumor rather than its tissue of origin within the body. This allows the use of treatments and their corresponding tests across different cancer types, which leads to a broader applicability of our Idylla™ test menu.

Gene signatures: Gene signatures have popped up as an important new class of molecular diagnostic test, offering applications beyond therapy selection, such as cancer risk or prognostics. The value of these tests is potentially high, but their development and validation is long and costly. As such, Biocartis is tackling these developments through a partnership strategy whereby validated, proprietary and high-value oncology gene signature tests are ported onto the Idylla™ platform. The growing Idylla™ installed base then facilitates the global roll-out of these high-value gene signature tests.

Immuno-oncology: This is a rapidly rising new class of cancer treatments, based on therapies that harness the immune system to fight cancer. In particular, Biocartis aims at a test menu for two major therapeutic classes: immune checkpoint inhibitors and cell-based therapy. The three primary components of this menu include (1) MSI validation for immune checkpoint inhibitor selection in colorectal cancer and later pan-cancer settings, (2) immune signatures that provide information about the immune system's activity within a tumor, and (3) tests that can predict the response or resistance of the tumor to immune therapies.

Liquid-biopsy based monitoring applications: Liquid biopsy testing continues to gain a lot of momentum. Today, it is already being used for therapy selection when insufficient tumor tissue is available. Beyond diagnosis, liquid biopsy can also be used in prognosis and therapy response. Within liquid biopsy, Biocartis will focus on key applications where Idylla™'s speed is required and thus represents a critical competitive advantage, including on-therapy monitoring and post-treatment MRD (Molecular Residual Disease) assessment for solid tumors, as well as select long-term recurrence monitoring applications in hematological cancers where guidelines already exist.

Broad oncology program and test menu

Today, Biocartis' on-market tests cover a broad range of programs including melanoma, colorectal and lung cancer, with tests in breast cancer, thyroid cancer and brain cancer/hematology in development.

- Melanoma is the deadliest form of skin cancer. Prognosis depends on disease staging. BRAF testing has become a common practice in the diagnosis of patients with advanced BRAF-mutated melanoma, for which multiple effective 1st-line treatment options exist. The Merlin Test (CE-IVD), of which an Idylla™ version is under development in collaboration with SkylineDx, reduces unnecessary lymph node surgeries and rapidly and easily identifies patients at low risk of nodal metastasis.

- Colorectal cancer is the third most frequent cancer and the fourth leading cause of cancer-deaths worldwide. RAS mutations occur in approximately 50% of colorectal cancers. Biocartis has an agreement for the registration and potential use of a CDx of the Idylla™ MSI Test in connection with immuno-oncology therapies in metastatic colorectal cancer (mCRC) of Bristol-Myers Squibb in the US and in the People's Republic of China.

- Within lung cancer and specifically within non-small cell lung cancer (NSCLC), mutations in the EGFR gene occur as the 2nd most common cancer driver mutation. Approximately 50% of NSCLC patients have tumor mutations that could inform targeted treatment, but many are not tested. A key issue is insufficient or low-quality samples, often leading to sample failure which results in high rejection rate for NGS testing, the recommended testing method for NSCLC. Today Biocartis has a partnership with AstraZeneca, lung cancer therapy leader, aimed at facilitating rapid and easy access to EGFR testing products with Idylla™. On 22 June 2022, Biocartis extended its collaboration with AstraZeneca aimed at the development and applicable pre-market notification or approval with the US FDA of a novel companion diagnostic (CDx) test on the Idylla™ platform, for use with Tagrisso® (osimertinib), AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment.

- Within thyroid cancer, approximately 1.2 million thyroid cytology evaluations are reported as indeterminate each year[23], regularly leading to unnecessary surgical intervention or removal of the thyroid. Biocartis has an ongoing partnership with GeneproDx: their proprietary ThyroidPrint® test is being ported on Idylla™. This is a quantitative RT-PCR based mRNA-expression classifier test which helps call an indeterminate cytology result as benign or malignant.

- Breast cancer is the most common cancer among women worldwide. Activating mutations in the (PI3K)/AKT/mTOR pathway are present in the majority of breast cancers and are therefore a major focus of drug development and clinical trials. Biocartis has the Idylla™ PIK3CA-AKT1 Mutation Assay under development for the molecular characterization of hormone receptor positive (HR+) HER2 negative (HER2-) metastatic breast cancer.

- Brain cancer is the biggest cancer killer of children and adults under 40 for which several targeted treatments exist. This is also one of the focus areas for the Idylla™ test menu.

- Hematologic or blood cancer is a cancer that begins in blood-forming tissue, such as the bone marrow, or in the cells of the immune system. Examples of hematologic cancer are leukemia, lymphoma, and multiple myeloma[24]. An estimated 1.24 million blood cancer cases occur annually worldwide, accounting for approximately 6% of all cancer cases[25].

- Primary liver cancer is the sixth most common and third most lethal cancer in the world, with more than 900,000 new cases per year and resulting in more than 800,000 deaths per year[26]. Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer that frequently occurs in people with chronic liver diseases, such as cirrhosis.

As per end 2022, Biocartis offered oncology tests for melanoma, colorectal, lung and liver cancer.

Metastatic colorectal cancer (mCRC)

Clinical information

RAS - Colorectal cancer (CRC) remains the third most frequent and the fourth leading cause of cancer-associated mortalities worldwide. Oncogenic mutations in the RAS gene have been identified in ~50% of CRC with activating KRAS mutations identified in 46% and NRAS mutations in 5% of CRC cases[27]. RAS mutations are important drivers of tumor resistance against anti-EGFR therapies. Therefore, testing of mutations in exons 2, 3 and 4 of KRAS and NRAS is a requirement prior to initiating treatment with anti-EGFR therapy[28].

BRAF - BRAF mutations are present in 8-15% of CRC cases[29]. The presence of a BRAF V600E mutation shows to be a poor prognostic factor in patients with mCRC[30]. BRAF V600E status can be assessed alongside RAS to guide therapeutic decision making for patients with mCRC[31].

MSI - MSI status is a critical marker for the screening of Lynch syndrome and can provide valuable information for prognosis and treatment stratification in colorectal cancers[32]. Guidelines recommend assessing the MSI status for all patients with colorectal or endometrial carcinomas for screening for Lynch syndrome as well as for prognostic stratification and potential eligibility for immunotherapy[33]. Research studies have shown that MSI-High patients respond favorably to immune checkpoint inhibitors, and checkpoint blockade therapy has recently been incorporated into clinical care for gastrointestinal cancers[34].

In vitro diagnostic tests

KRAS and NRAS-BRAF Mutation Tests - Idylla™ solid biopsy tests for mCRC provide fast, reliable information on tumor mutation status for KRAS, NRAS and BRAF reducing the clinical turnaround time significantly to 1-2 days. In an independent comparison study, the Idylla™ KRAS Mutation Test outperformed several NGS technologies as well as other PCR-based technologies with regard to sensitivity, turn-around-time and ease of use[35]. The Idylla™ mCRC solid biopsy panel includes 3 different RAS mutation tests:

- Idylla™ KRAS Mutation Test
- Idylla™ NRAS-BRAF Mutation Test

MSI Test - The fully automated Idylla™ MSI Test provides fast and accurate information on MSI status directly from 1 FFPE sample from human colorectal cancer. The Idylla™ MSI Test shows high concordance (>97%) and lower failure rates compared to standard methods[36]. The 7 novel biomarkers used for the Idylla™ MSI Test are tumor-specific eliminating the need for paired normal tissue samples leading to an improved operational efficiency. The Idylla™ MSI Test provides unbiased result reporting without the need for visual interpretation.

Lung cancer

Clinical information

Lung cancer is the most common cancer worldwide, contributing for 13% of all cancer types. 85% of lung cancers are non-small cell lung cancers (NSCLC), of which histologically adenocarcinoma is the most prevalent. EGFR mutations in exons 18-21 have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics and testing is recommended in all patients with advanced NSCLC of a non-squamous subtype[37]. Exon 19 deletion and exon 21 (L858R, L861Q), exon 18 (G719X), and exon 20 (S768I) mutations are associated with sensitivity to EGFR tyrosine kinase inhibitors (TKIs) whereas exon 20 insertion mutations may predict resistance to TKIs. EGFR T790M mutation is the main cause of acquired resistance to TKI therapy and has been reported in about 55% of patients with disease progression after initial response to 1st or 2nd generation TKIs[38]. Prevalence of EGFR mutations in NSCLC adenocarcinomas is 10-15% in Western and up to 50% in Asian patients[39].

In vitro diagnostic tests

The Idylla™ EGFR Mutation Test -The Idylla™ EGFR Mutation Test provides fast, reliable information on the EGFR tumor mutation status reducing the clinical turnaround time from sample to result report significantly. Insufficient samples are a persistent problem in lung cancer genomic profiling resulting in a high invalid/ rejection rate. Idylla™ EGFR only requires 1 tissue section (5-10 µm) per assay and shows a significant lower invalid rate compared to other methods.

GeneFusion Panel - The Idylla™ GeneFusion Panel consolidates traditional testing workflows into one streamlined, fully automated process providing reliable, objective information on ALK, ROS1, RET and METex14 skipping in about 180 minutes. The Panel provides simultaneous detection of internationally recommended biomarkers from a limited amount of sample thereby saving valuable tissue specimens and is a rapid actionable solution which can be seamlessly integrated into virtually any laboratory workflow. The Panel demonstrated high concordance results in a clinical comparison study where ALK was compared with IHC and ROS1, RET and METex14 skipping were compared with NGS[40].

Melanoma

Clinical information

BRAF - Somatic mutations in BRAF have been found in 37-50% of all malignant melanomas (mycancergenome.org). Multiple effective first-line systemic treatment options are available for patients with advanced BRAF-mutated melanoma including BRAF/MEK as well as PD-L1 inhibitors. Current guidelines recognize the importance of BRAF V600 testing for patients with metastatic disease recommending BRAF mutation status assessment[41].

In vitro diagnostic tests

BRAF Test - The Idylla™ BRAF Mutation Test provides fast, reliable information on the BRAF tumor mutation status reducing the clinical turnaround time significantly. The Idylla™ BRAF Mutation Test only requires 1 tissue section (5-10 µm) per sample and independent studies have shown that the test is able to detect mutations in samples with as low as 2% neoplastic cells. Even for challenging samples with high melanin content the Idylla™ BRAF Mutation Test ensures consistent high sensitivity and accuracy[42].

Partner test: Merlin™ Assay - On 1 September 2022, Biocartis announced the start of the commercialization in Europe of SkylineDx's innovative Merlin™ Assay as a CE-IVD marked manual kit. The test, developed by SkylineDx together with the Mayo Clinic (US), aims to predict a melanoma patient's risk of nodal metastasis and may help safely forgo an invasive surgery, which is now often performed to determine metastatic spread of the cancer for staging purposes. In approximately 80% of surgeries, the biopsy comes back negative for metastasis, where it does not further impact the patient pathway. The Merlin™ Assay provides a more personalized insight, identifying patients with a low-risk tumor that could avoid the surgery[43]. The Merlin™ Assay will be commercialized in Europe by Biocartis as a CE-IVD marked manual kit, ahead of the launch of an Idylla™ version of the test which is under development.

Liver cancer

Clinical information

Primary liver cancer is the sixth most common and third most lethal cancer in the world, with more than 900,000 new cases per year and resulting in more than 800,000 deaths per year. HCC is the most common type of primary liver cancer that frequently occurs in people with chronic liver diseases, such as cirrhosis44. Liver transplantation is the best curative treatment for HCC patients. The current criteria used to identify patients for transplantation are either too strict (by rejecting patients that could benefit from the transplant) or overestimate the benefit from a liver transplantation (by selecting patients that will relapse afterwards).

In vitro diagnostic tests

Partner test: HepatoPredict - On 10 October 2022, Biocartis announced the start of the commercialization in Europe of the HepatoPredict test as a CE-IVD marked manual kit. The test, developed by Ophiomics, is a prognostic diagnostic test that supports the decision of liver transplantation in patients with Hepatocellular Carcinoma (HCC). HepatoPredict employs a machine learning algorithm combining tumor gene expression with clinical variables to accurately identify hepatocellular carcinoma patients for liver transplantation. The test, requiring 1 to 2 FFPE tissue sections, is an IVD with a 5-hour hands-on time providing an easy-to-interpret report.

Research

Biocartis encourages the research into new and emerging uses for different biomarkers. In this regards we offer the following assays for research use only:

Idylla™ MSI Assay	Fully automated detection of mutations in 7 novel MSI loci.
Idylla™ KRAS Mutation Assay	Fully automated detection of 21 KRAS mutations directly from a single slice of FFPE tissue.
Idylla™ ctKRAS Mutation Assay	Fully automated detection of 21 KRAS mutations directly from 1mL plasma.
Idylla™ BRAF Mutation Assay	Fully automated detection of 7 BRAF mutations directly from a single slice of FFPE tissue.
Idylla™ ctBRAF Mutation Assay	Covers 7 BRAF mutations and showed a 100% concordance compared to plasma-based reference technologies.

Idylla™ EGFR Mutation Assay	Fully automated detection of 51 EGFR mutations directly from a single slice of FFPE tissue.
Idylla™ ctEGFR Mutation Assay	Covers 49 EGFR mutations and showed high concordance compared to NGS.
Idylla™ NRAS-BRAF-EGFR- S492R Mutation Assay	Fully automated detection of 18 mutations in NRAS and 5 mutations in BRAF as well as 2 EGFR mutations directly from a single slice of FFPE tissue.
Idylla™ ctNRAS-BRAF-EGFR- S492R Mutation Assay	Fully automated detection of 18 mutations in NRAS and 5 mutations in BRAF as well as 2 EGFR mutations directly from 1mL plasma.
Idylla™ GeneFusion Assay	Fully automated detection of ALK, ROS1, RET, NTRK1/2/3 rearrangements and MET exon 14 skipping in a single cartridge.
Idylla™ IDH1-2 Mutation Assay Kit	Fully automated detection of 5 mutations in IDH1 and 10 mutations in IDH2[45] directly from FFPE tissue or extracted DNA.

Infectious diseases

The pandemic context brought about a higher need for decentralized molecular diagnostic testing, which matches Biocartis' ambition to build an installed base in acute settings where rapid diagnostic information is needed most, such as in the intensive care unit (ICU).

- Idylla™ SARS-CoV-2 Test: Fully automated rRT-PCR test intended for the qualitative detection of SARS-CoV-2 RNA in nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider. Results are obtained in as soon as 90 minutes using 200 µl of viral transport media (VTM) with less than 2 minutes hands-on time.
- Idylla™ SARS-CoV-2/Flu/RSV Panel: Fully automated rRT-PCR test intended for the detection of SARS-CoV-2, Flu A, Flu B and RSV nucleic acids in nasopharyngeal swab specimens from individuals suspected of respiratory infections by their healthcare provider. Results are obtained in as soon as 90 minutes with less than 2 minutes hands-on time, using 400 µl of viral transport media (VTM).

Both tests are CE-IVD marked.

- SeptiCyte® RAPID[46]: Fully automated rapid host-response test that distinguishes sepsis from non-infectious systemic inflammation (INSI/SIRS), developed on Idylla™ in collaboration with Immunexpress. The test provides actionable results in about one hour enabling physicians to optimize their patient management decisions. The test is CE-IVD

marked and received 510(k) clearance by the US FDA in December 2021. On 23 August 2022, Immunexpress launched a new version of the SeptiCyte RAPID® EDTA (CE-IVD) blood compatible cartridges.

- Endpoint Health: Biocartis is developing a test together with Endpoint Health aimed at informing biomarker-based therapeutic decisions in patients with critical illnesses, such as sepsis.

The pandemic test menu on Idylla™ has the potential to be a steppingstone towards the development of a broader Biocartis infectious disease menu with partners, aimed at supporting the patient journey with easy and rapid Idylla™ testing in acute settings, including rapid triage and therapy selection for critically ill patients. Furthermore, Biocartis sees that Idylla™'s unique multiplexing-related platform capabilities can bring clear distinctive benefits in the area of syndromic panel testing, one of the fastest growing MDx segments.

Leveraging novel partner test content

Partnerships are essential to the continued expansion of the test menu on Idylla™. Together with development partners, we offer proprietary third-party content on the Idylla™ platform, expanding our menu with tests that appeal to a larger audience and with an attractive margin profile, while facilitating global roll-out of the test content for the partner. With leading pharmaceutical partners, we develop companion diagnostic tests that allow fast pinpointing of therapy selection for eligible patients, while Biocartis benefits from increased commercial adoption of its Idylla™ tests with higher market shares.

End of 2022, Biocartis had the following active key partnerships in place (selection, in alphabetical order):

ASTRAZENECA - Biocartis and AstraZeneca, a global science-led biopharmaceutical company (LSE/STO/Nasdaq: AZN), announced their first partnership agreement on 29 November 2018, focused on overcoming the current complexity and long turnaround time of biomarker testing for lung cancer patients. In January 2020, the collaboration expanded to a master collaboration agreement, including the large prospective lung cancer FACILITATE study with the Idylla™ ctEGFR Mutation Assay (Research Use Only). The study was presented at the renowned ESMO Virtual Congress in September 2020 (poster 1205P) and concluded that Idylla™ EGFR testing may add value in a clinical setting to generate actionable EGFR mutation results for non-small cell lung cancer (NSCLC) patients faster than routinely used methods. On 4 May 2021, Biocartis and AstraZeneca announced a new agreement aimed at providing access to rapid and easy-to-use Idylla™ EGFR testing products at selected hospital sites in Biocartis' European and global distributor markets to support the identification of patients with EGFR mutations. On 22 June 2022, Biocartis announced the extension of its collaboration with AstraZeneca aimed at the development and US FDA premarket approval of a novel companion diagnostic (CDx) test for use with Tagrisso® (osimertinib), AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment. Under the terms of the agreement, Biocartis and AstraZeneca will co-lead the development and applicable premarket approval of the Idylla™ EGFR CDx Assay intended to aid in identifying patients with non-small cell lung cancer (NSCLC) who may respond to treatment with Tagrisso®. In addition to formalin fixed, paraffin embedded (FFPE) tissue, Biocartis will seek to validate the use of less invasive cytology samples such as fine needle aspirates for use with the Idylla™ EGFR CDx Assay, to expand patient access to testing.

BRISTOL-MYERS SQUIBB (BMS) - On 12 March 2019, Biocartis announced the signing of a collaboration agreement with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company, aimed at the potential registration as a companion diagnostic and use of the Idylla™ MSI test in connection with immuno-oncology therapies. The collaboration agreement allows for joint developments and registrations of the Idylla™ MSI test for use in a variety of indications, commercial settings and geographies. The first focus under the agreement is expected to be the registration in the US of the Idylla™ MSI test as a companion diagnostic test in mCRC. On 5 March 2020, Biocartis announced to have signed a new immune-oncology project with Bristol-Myers Squibb Company aimed at the registration of the Idylla™ MSI test in the People's Republic of China.

ENDPOINT HEALTH - On 3 November 2020, Biocartis announced a partnership agreement with Endpoint Health, a Palo Alto, CA (USA) based company developing personalized care solutions and targeted therapies for critically ill patients. The partnership targets the development and commercialization of a novel companion diagnostic (CDx) test on the Idylla™ platform and will further strengthen the CDx business and infectious disease test menu on Idylla™. Under the terms of the agreement, Endpoint

Health will lead the development and registration of the Idylla™ Endpoint test in interventional trials across a range of interventions including targeted immunotherapy and coagulation therapy indications.

GENEPRODX - On 3 November 2020, Biocartis announced a license, development and commercialization agreement with GeneproDx, a molecular diagnostics company based in Santiago, Chile, for the development of GeneproDx's novel genomic test ThyroidPrint® on the Idylla™ platform. ThyroidPrint® is a quantitative RT-PCR[47] based mRNA-expression classifier[48] test that helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant[49]. A benign test result[50] allows physicians to recommend watchful waiting as an alternative to diagnostic surgery and prevents exposing patients to surgical risks and permanent thyroid hormone supplementation. Under the terms of the agreement, GeneproDx will take the lead in the development of the Idylla™ ThyroidPrint® test, whereas Biocartis will be responsible for the distribution of the ThyroidPrint® on Idylla™ through its growing commercial infrastructure of Idylla™ instruments across the globe.

IMMUNEXPRESS - Biocartis and Immunexpress Pty Ltd ('Immunexpress'), a host response molecular diagnostic company committed to improving clinical and economic outcomes for suspected sepsis patients, collaborate since 24 January 2018 on the development and commercialization of Immunexpress' SeptiCyte® test for use on the Idylla™ platform. On 26 March 2020, Biocartis announced the expansion of its Immunexpress partnership with a co-commercialization agreement for the SeptiCyte® RAPID test for use on the Idylla™ platform, in which Biocartis will lead commercialization in Europe as the exclusive distributor of the SeptiCyte® RAPID on Idylla™, while Immunexpress will lead commercialization of the SeptiCyte® RAPID on Idylla™ in the US. The SeptiCyte® RAPID on Idylla™ was released on market as a CE-marked IVD test on 6 October 2020 and Immunexpress received 510(k) clearance by the US FDA for this test on 30 November 2021. On 23 August 2022, Immunexpress launched a new version of the SeptiCyte RAPID® EDTA (CE-IVD) blood compatible cartridges.

KITE/GILEAD - On 1 June 2019, Biocartis announced a master development and commercialization agreement with Kite, a Gilead Company (a pharmaceutical company engaged in the development of innovative cancer cell therapies). The agreement aims at developing molecular-based assays on the Idylla™ platform that are supportive to Kite's therapies. The collaboration with Kite is Biocartis' second assay development partnership (next to the partnership with BMS) in the immunotherapy domain, a fast-growing market and one of the key strategic focus areas of the Idylla™ assay menu.

LABCORP - On 23 April 2019, Biocartis announced the global strategic commercialization agreement with Labcorp Drug Development (formerly Covance), which has the leading central laboratory network serving the biopharma industry, across multiple therapeutic areas, with a specific focus on precision medicine. The agreement aims at offering the Idylla™ platform and its existing Idylla™ oncology assay menu (research use only) to Covance's customer base to support global oncology trials and, when appropriate, to validate and implement companion diagnostic applications.

LIFEARC - On 7 June 2017, Biocartis announced its agreement with LifeArc, a medical research charity, for the development of selected MDx tests for Idylla™. For each selected test, LifeArc will act as a development contractor, whereas Biocartis will be responsible for the commercialization of the tests under its own label. Biocartis and LifeArc are developing the Idylla™ PIK3CA-AKT1 Mutation Assay which is positioned to target a multi-gene panel of predictive and resistance-inducing mutations based on an FFPE sample type for use in research setting (RUO). On 1 September 2020, Biocartis announced to have expanded its agreement with LifeArc. Under the new agreement, LifeArc obtained a non-exclusive license to use the Idylla™ platform for the development of Idylla™ assays in the area of infectious and immune related diseases, aimed at supporting patient stratification and treatment monitoring of patients with, amongst others, bacterial, fungal and viral infections.

MERCK KGAA (DARMSTADT, GERMANY) - Biocartis announced a partnership with Merck KGaA (Darmstadt, Germany) in January 2016 to improve access to easy, rapid and low invasive blood-based molecular diagnostic testing for mCRC patients through liquid biopsy testing. The Idylla™ ctKRAS Mutation Assay and the Idylla™ ctNRAS-BRAF Mutation Assay are used to detect RAS and BRAF mutations.

NICHIREI BIOSCIENCES - On 7 January 2019, Biocartis announced to have signed an agreement with Nichirei Biosciences for the product registrations and distribution of the Idylla™ platform in Japan. In October 2019, Nichirei Bio completed the registration of the Idylla™ Instrument and Idylla™ Console with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. With that,

Nichirei Biosciences will now be able to offer the Idylla™ platform in combination with Idylla™ RUO assays to local pathology laboratories in Japan. On 29 August 2022, Nichirei Biosciences received approval by the Japanese regulatory authorities (Ministry of Health, Labor and Welfare) for the commercialization of the Idylla™ MSI Test in Japan.

OPHIOMICS - On 8 February 2022, Biocartis and Ophiomics (a Lisbon, Portugal based biotech company developing a precision medicine portfolio focused on liver cancer) announced their partnership agreement. Under the terms of this agreement, Biocartis is leading the commercialization of the manual HepatoPredict kit in Europe, of which the start of the commercialization was announced on 10 October 2022. Depending on the successful commercial uptake of the kit, Ophiomics and Biocartis aim to initiate the development of a fully automated version of the test on Biocartis' decentralized Idylla™ platform.

SKYLINEDx - On 22 April 2021, Biocartis and SkylineDx, a Dutch (Rotterdam) and US (San Diego, California) based private biotechnology company, announced a partnership agreement which targets the development of SkylineDx' novel proprietary test, the Merlin™ Assay, on the Idylla™ platform. This assay is designed to predict a patient's risk of nodal metastasis in melanoma. Under the terms of the partnership agreement, SkylineDx will lead the development of the Merlin™ Assay on Idylla™, while Biocartis will lead the commercialization in Europe through its growing Idylla™ network. The start of the commercialization in Europe of SkylineDx's Merlin™ Test as a CE-IVD marked manual kit was announced on 1 September 2022.

WONDFO - On 3 September 2018, Biocartis announced to have established a joint venture with Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast-growing diagnostics leader in China. The joint venture Wondfo-Cartis is 50% owned by Biocartis and 50% owned by Wondfo. On 16 September 2022 the Idylla™ Instrument and Console was approved by the Chinese regulatory authorities NMPA, an important step towards the further regulatory approval and commercialization of Idylla™ assays in China. The set-up of local manufacturing capability is nearing completion.

Intellectual property

The protection of Biocartis' intellectual property rights, which form the basis of its products and technologies, is a critical factor for Biocartis' commercial success. Biocartis' intellectual property portfolio is managed by our IP department. The current patent portfolio was built through acquisitions of third-party patents, patent applications and know-how, as well as through creation of new intellectual property. Furthermore, Biocartis also has in-licensed specific third-party technologies. On 31 December 2022, Biocartis' patent portfolio consisted of 30 proprietary patent families comprising issued and pending patents worldwide with patent lives which will expire between 2026 and 2041, and 31 exclusively and non-exclusively in-licensed patent families providing additional strength to the patent portfolio. The patent portfolio covers various aspects of the Idylla™ platform technology (basic system, fluidics, ultra-sonification, thermal control, downstream analysis, signal processing and assay design technology), its associated biochemistry (test design, reagent storage, sample intake, etc.) and biomarkers. In addition to its patent portfolio, Biocartis also relies on a combination of trade secrets, know-how, trademarks, design rights, copyrights, non-disclosure agreements and other contractual provisions and technical measures.

2.3. Commercial strategy

A multi-pronged approach to adoption

Building on Idylla™'s key features of enabling faster local testing which drives quicker treatment and may lower healthcare costs, Biocartis deploys a multi-pronged approach in three key markets where Idylla™ represents exceptional benefits:

- Large hospitals, reference labs and cancer centers: Idylla™ offers fast turnaround-time and delivers directly actionable test results, as an ideal complementary first-line testing solution ahead of NGS.
- Regional hospital labs & specialized group practices: Idylla™ enables in-house MDx testing through an easy-to-use platform, with no technical skills required while retaining control of the sample.
- Community setting hospitals and medical offices: Idylla™ integrates a fully automated local, decentralized MDx testing solution in the physicians' earnings model.

Users

Oncology: pathology labs & hospitals

Oncology MDx testing today is performed by molecular pathologists who determine the molecular changes present in tumors for diagnostic, prognostic or predictive purposes. Pathologists increasingly use different MDx testing technologies, depending on the specific patient case. An easy and fully automated workflow and highly accurate, easily interpretable test results, in combination with a comprehensive test menu in oncology are key Idylla™ features for the pathologist in an increasingly complex molecular testing scene. On the other end of the spectrum, the oncologist, who is in contact with the patient, is a key user of MDx information to determine the best treatment plan for each individual patient. Obtaining fast test results for rapid treatment initiation is of the essence for the oncologist.

Firstly, Biocartis targets the central MDx testing labs and mid and large sized pathology laboratories that already perform oncology MDx testing today. One of the biggest challenges these large pathology labs face with biomarker testing is the ability to obtain samples of sufficient size and quality. With Idylla™, only a minimal amount of sample is needed. Compared with NGS and other RT-PCR testing methods, Idylla™ also eliminates the need for the use of multiple instruments, large quantities of consumable items and increased square footage of laboratory space. Everything the lab needs is provided in a single disposable cartridge, making it also fast and easy to use compared to existing molecular diagnostic workflows. Secondly, Biocartis targets the smaller sized pathology laboratories and hospitals that today do not yet perform MDx testing. The unique features and ease of use of the Idylla™ platform allows these customers to bring MDx testing in-house. Biocartis entered into multiple collaborations with various development partners aimed at developing Idylla™ versions of such partners' tests. Biocartis may commercialize of certain tests that are already available as CE-IVD marked manual kits awaiting the development of the Idylla™ version, allowing customers early access to these novel tests. In 2022, Biocartis started the commercialization of the manual CE-IVD marked kit versions of the Merlin™ Assay and of HepatoPredict from SkylineDx and Ophiomics, respectively.

Infectious diseases: microbiology labs

Infectious disease MDx testing is implemented in microbiology laboratories. Molecular diagnostic techniques are used in the microbiology lab to identify the most common infectious organisms by their DNA or RNA. The clinical microbiologist participates in decisions regarding adoption of testing platforms and training of front-line providers on appropriate use of testing methodologies. Clinical microbiologists also consult on individual patients providing advice on which microbiologic studies should be performed, the type and timing of specimens to be collected, the conditions for their transportation and storage, and interpretation of laboratory results. With the Idylla™ rapid response pandemic test menu, Biocartis aims to make a difference in

acute settings such as the hospital intensive care unit (ICU) with combined COVID-19 and sepsis testing on Idylla™ to identify patients with severe disease, as recent data indicate that sepsis is the most frequently observed complication in COVID-19.

Direct and indirect sales channels

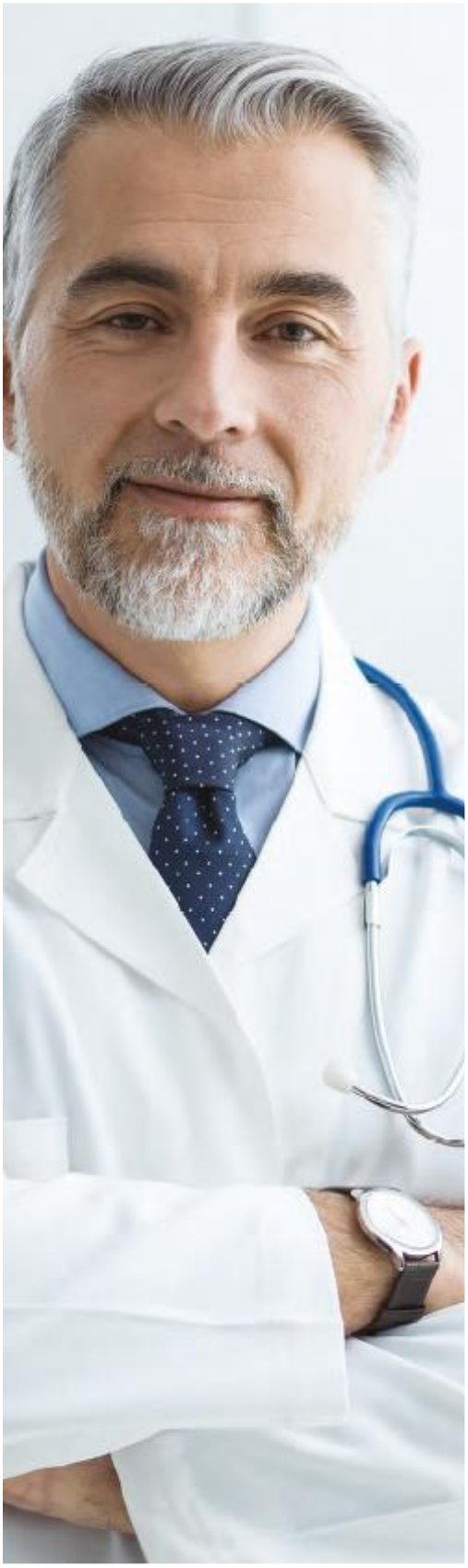
End 2022, Biocartis was active in over 70 countries through a combination of direct sales and (distribution) partners.

Direct sales strategy: In all key European countries, US and Canada, Biocartis has a go-to-market strategy based on a direct sales force. The Biocartis direct sales force is in direct contact with a vast network of pathology labs and hospitals for its oncology products, as well as an expanding network of microbiology labs for its infectious disease products.

- Distributor sales strategy in distribution markets and Japan: In distribution market countries[51], Biocartis collaborates with a vast network of distributors. Since 2017, Biocartis focuses on working with its distribution partners to support commercial market adoption of the Idylla™ platform, for oncology especially in countries where pharmaceutical oncology treatment companies could benefit from Idylla™ MDx testing. Biocartis has set up an efficient organization to manage distributor business, including quality control, logistics, registration, customer care and a dedicated team of sales employees. The sales team organizes a number of activities, including product trainings, regular distributor update meetings, access to an online marketing platform and occasional joint visits to individual key hospitals. The experience built since 2017 allows for efficient market and product updates and the fast roll out new tests.

- Joint venture: In 2018, Biocartis established WondfoCartis, a joint venture with Wondfo, a fast-growing diagnostics leader in China, aimed at the commercialization and local manufacturing of Idylla™ oncology products in mainland China.

- Pharmaceutical and diagnostic test development content partners: Biocartis also partners with a number of pharmaceutical oncology treatment companies such as with Amgen. This allows the pharmaceutical partners to benefit from an increased number of eligible patients for their targeted therapies driven by the key benefits of the Idylla™ platform, such as fast turnaround times. Partnerships with diagnostic test development content partners who port their proprietary biomarker panels to the Idylla™ platform (such as the partnership with Immunexpress for the SeptiCyte RAPID® on Idylla™) benefit from an accelerated global roll-out of their test content, cost efficiencies and faster customer adoption since no platform education is needed.



Strong validation by customers and key opinion leaders

Biocartis is in continuous dialogue with KOLs who serve as true Idylla™ ambassadors in the market. The KOLs play an important role in providing continuous feedback on the Idylla™ product offering. In 2022, oncology activities here consisted of:

Papers, abstracts and posters

During 2022, 42 new Idylla™ papers were published, bringing the total number of Idylla™ papers to 166. Some highlights:

- In May 2022, Biocartis announced the publication of a study by Memorial Sloan Kettering Cancer Center ('MSKCC', New York, US) on the use of Biocartis' Idylla™ GeneFusion Assay (RUO) highlighting the quicker turnaround and the lower tissue requirements compared to immunohistochemistry and molecular methods, while also circumventing the infrastructure dependencies associated with NGS and fluorescence in situ hybridization.

- In November 2022, Biocartis announced the publication of a large prospective study demonstrating that the Idylla™ EGFR Mutation Test (CE-IVD) leads to the significant reduction of the time-to-treatment by on average 16.8 days or 48% compared to NGS testing for EGFR positive patients.

- In the context of measuring and improving customer experience, end of 2022, Biocartis launched a first customer centricity survey among approx. 7,000 customers and prospects in Europe, US and distributor countries.

Key expert meetings

In 2022, Biocartis organized a KOL meeting in Paris, France with experts, oncologists and pathologists, to assess current trends and market opportunities in oncology MDx testing. The meeting focused on lung cancer, colorectal cancer and potential new cancer areas for Biocartis, including breast, brain and endometrial cancer as well as new targeted therapies and biomarkers in these areas. Liquid biopsy and molecular surveillance testing was also on the agenda. In lung cancer, experts endorsed the Idylla™ GeneFusion Panel and confirmed its strong positioning.

In total, 13 experts from different European countries attended and shared their insights and vision on the evolution of molecular diagnostics and therapeutics in cancer care.

2.4. Market access

Regulatory compliance

Regulatory compliance is a key condition for market access in MDx. Depending on the type of product and the geography, various regulatory processes exist subject to which certain MDx devices need to be approved or cleared by regulators. An overview of Biocartis' Idylla™ products and their label is available under the section 'Products' above or on the Biocartis website.

IVD products

EU: CE-MARK - Market clearance for Biocartis' products is achieved in the EU through CE-marking, previously via the European Directive 98/79/EC on in vitro diagnostic medical devices (the "IVD Directive") and as of 26 May 2022 via the IVD Regulation (subject to transitional measures). Under the IVD Directive, the Idylla™ platform and Idylla™ tests were CE-marked following a self-certification process conducted by Biocartis. For compliance with the IVD Regulation, Idylla™ oncology tests are classified as high-risk (class C under the IVD Regulation), thereby requiring the services of a Notified Body for their CE-marking under the IVD Regulation latest by 26 May 2026. A sub-set of Idylla™ oncology tests are classified as high-risk companion diagnostic ("CDx") assays requiring additional review by a competent authority or the European Medicine Agency ("EMA").

US: FDA MARKETING AUTHORIZATION - In the United States, IVDs are regulated by FDA as medical devices under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and may also be regulated as biological products subject to the Public Health Service Act. The US FDA is the federal agency of the United States Department of Health and Human Services, responsible for protecting and promoting public health through the control and supervision of food safety, pharmaceutical drugs and medical devices[52]. Like other medical devices, IVDs are subject to FDA's premarket and post market controls, including labeling requirements, provisions against adulteration and misbranding, good manufacturing practices, establishment registration, medical device listing, records and medical device reporting, and notification, amongst other things. IVDs are generally also subject to regulation under the Clinical Laboratory Improvement Amendments of 1988 Act (the "CLIA" Act), which establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. IVD tests are categorized into CLIA test complexity categories: (1) waived tests, (2) tests of moderate complexity, and (3) tests of high complexity.

Under the FDCA, certain medical devices require US FDA 510(k) clearance or premarket approval ("PMA") prior to marketing in the United States. CLIA categorization is determined after the FDA has cleared or approved a medical device marketing submission, or upon request for a legally marketed device. The majority of Biocartis' current and planned Idylla™ tests is expected to require US FDA 510(k) clearance or PMA approval before marketing is permissible in the United States. These tests will also be categorized under the CLIA Act.

CHINA - In China, the National Medical Products Administration (NMPA) is the administrative body responsible for the regulation of medical devices on the Chinese mainland. WondfoCartis, the joint venture with Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast-growing diagnostics leader in China, is responsible for the commercialization of the Idylla™ platform in China. On 16 September 2022, Biocartis received approval from NMPA to commercialize the Idylla™ platform in China.

JAPAN - All medical devices in Japan require registration with the Ministry of Health, Labor and Welfare via the Pharmaceuticals and Medical Devices Agency (PMDA). Biocartis' partner in Japan, Nichirei Biosciences, completed the registration of the Idylla™ Instrument and Idylla™ Console with the PMDA as a General medical device (Class I) in Japan in October 2019 and is responsible for further Idylla™ product registrations and commercialization. After successfully completing the clinical performance evaluation studies in Japan, Biocartis' partner Nichirei Biosciences submitted in Q4 2021 the registration applications of the Idylla™ MSI Test, the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test with the Japanese PMDA agency. On 29 August 2022, approval to commercialize the Idylla™ MSI Test was achieved in Japan.

DISTRIBUTION MARKETS - In many distribution markets, the IVD products with CE-marking are accepted. Various markets also have their own specific local authorization requirements, in which case additional product registration efforts are required. Every individual market is therefore assessed in terms of efforts needed to comply with these local market authorizations.

Research use only products

In addition to IVD medical devices, Biocartis also offers products for Research Use Only (RUO), meaning they may only be used in research applications, as opposed to clinical applications where patients are managed. In many of the markets in which Biocartis operates, such RUO products may be offered for sale if for example IVD products are not yet approved for sale or distribution.

Reimbursement

Although Biocartis directly invoices its customers, prices for its products are driven by the level of reimbursement to which its customers are entitled either by public payers or private insurance companies. Each national health system and private insurer considers different aspects when deciding whether or not to reimburse an IVD test, such as the cost to society or the price. Biocartis' product offering today includes both tests with biomarkers that are already included in the clinical guidelines and are as such already reimbursed by third-party payers, and tests with novel content that is not yet under reimbursement. As such, changes in reimbursement levels or methods may positively or negatively affect sales of Idylla™ products. Through its partners or directly, Biocartis therefore works with several specialized consulting companies that also have specialized skills in reimbursement and market access, or contacts with payors.

Below is an overview of the main MDx markets and their reimbursement systems.

EUROPE - In Europe, diagnostics expenses are mostly publicly funded and paid for by public health authorities usually within a third-party payer system. Each European market however has its own unique characteristics. In some countries, reimbursement decisions are made by regional authorities while in others these are made at national level[53]. Within Europe, reimbursement schemes are varying, influencing who within the healthcare system actually performs the testing. In the past years, changes have occurred regularly in the reimbursement policies in a number of European countries, sometimes favoring highly centralized testing and sometimes favoring highly decentralized testing, with many variations in between. Biocartis was able to navigate this diverse reimbursement landscape, as the use of our highly flexible Idylla™ platform can be adapted to various reimbursement scenarios and settings.

US - In the US, reimbursement is typically higher in comparison with Europe, driven by the fact that the reimbursement system is a mixed payment system where both the government, employers and individuals share the costs of healthcare. Here, private insurance is the most common form of coverage, with insurance premiums being paid by individuals or employers. In 2018, PAMA (Protecting Access to Medicare Act) came into force in the US to normalize the price between government reimbursement and that of the private sector. Under PAMA, many (but not all) clinical laboratories must report their private payer rates on a test-by-test basis along with associated test volumes[54]. Save for the Idylla™ GeneFusion test, all of Biocartis' current products are eligible for reimbursement using established codes.

CHINA - In China, every citizen is entitled to receive basic health care services which is paid for by the central government and financed by local governments. The publicly financed health insurance covers most diagnostics for some 95% of the population, including most diagnostics. IVD reimbursement is entirely done at provincial level. The reimbursement processes amongst the provinces are similar but can result in different reimbursement amounts[55]. As such, the adoption level of tests can differ per cancer type and per province.

JAPAN - Cost of services for the health care system in Japan is covered partly by patients via mandatory health care insurance and partly by the government. Medical service fees (reimbursement) are controlled by the government at a national fixed level for each molecular diagnostic test.

DISTRIBUTION MARKETS - Reimbursement in distribution countries varies per region and is dependent on the local healthcare and insurance system. In several geographies pharmaceutical companies support the local availability of MDx testing should reimbursement policies be insufficient.

2.5. Risks related to our business

The following risk factors may affect the future operating and financial performance of Biocartis and the value of an investment in the Company's securities. Examples of past experience have been included where material in aiding the understanding of the risks. If any of these risks actually occurs, Biocartis' business, results of operations, financial condition and prospects could be adversely affected. These risks and uncertainties are not the only ones Biocartis faces. Additional risks and uncertainties not presently known, or that management currently believes to be immaterial, could have the effects set forth above. If any of those risks or uncertainties occur, the price of the Company's securities may decline and subscribers for the Company's securities could lose all or part of their investment. The risk factors presented herein have been divided into five categories based on their nature (i.e., strategic and commercial risks, operational risks, legal and intellectual property related risks, regulatory risks and financial risks).

Strategic and commercial risks

Biocartis' past growth is not indicative (nor a guarantee) of future growth. Biocartis may be unable to manage its growth effectively, and may not be successful in further growing its commercialization infrastructure.

Since the Company's initial public offering and listing on Euronext Brussels in 2015, Biocartis has experienced significant growth in revenues, Idylla™ installed base and cartridge volumes, including in the areas of development (Idylla™ menu expansion and improvement of the Idylla™ platform), quality control, regulatory and clinical affairs, customer service and support, and commercialization. This growth may not continue in the future and past growth is not necessarily indicative (nor a guarantee) of future growth. To reach profitability, the Company needs to continue to grow.

To manage Biocartis' anticipated future growth, it must continue to implement and improve its managerial, operational, financial, data security and data protection systems, and continue to recruit and train additional qualified personnel. The growth of Biocartis and the execution of its strategy might require additional capabilities that may not exist yet in the organization, especially when new proprietary or partner tests are being developed, manufactured and/or commercialized. The growth of Biocartis might also require an increased number of employees and a growth in the scope of operations. An inability to access these capabilities, either by engaging additional employees or through partnerships, in a timely manner or at all, or to integrate these additional capabilities in its organization and further developing its processes while maintaining its efficiency, may limit the ability for Biocartis to growth further. Biocartis may not be able to effectively manage such expansion of its operations or recruit and train additional qualified personnel. An expansion of Biocartis' operations may lead to significant costs, while the Company may not have the required funds to finance such costs. Any inability to manage (or finance) growth could delay the execution of Biocartis' business plans or disrupt its operations.

As mentioned, Biocartis is continuing to expand its commercialization infrastructure for the Idylla™ platform and tests and the partners' tests which Biocartis has agreed to distribute. Furthermore, to commercialize the Idylla™ platform and tests, Biocartis will need to further build a maintenance and service organization in order to ensure adequate installation and servicing of its installed base. Biocartis will also need to coordinate commercialization with its partners, distributors and other third parties outside of its control. Biocartis must ensure that its commercialization infrastructure is adequately equipped and its staff is adequately trained to distribute such products.

In addition, relative to some of its competitors and partners, Biocartis is limited in size and resources. It may not be able to compete under favorable conditions when it comes to selling the Idylla™ platform in comparison with larger companies that are able to propose to customers a broader portfolio of MDx products, on potentially more favorable conditions.

Furthermore, part of Biocartis' commercial strategy is placing its diagnostic platform with clients under, among others, reagent rental or operational lease contracts. As of the end of 2021 and 2022, the installed base consisted of 1,912 and 2,085 instruments, respectively. As of the end of 2021, 46% of the installed base consisted of capital sales and 46% consisted of lease agreements.

As of the end of 2022, 50% of the installed base consisted of capital sales and 44% consisted of lease agreements. Under such operational lease contracts, the customers are entitled to return the platform to Biocartis under certain conditions, which could have an impact on Biocartis' installed base and could result in a loss in product revenues.

The Company continues to attract and onboard new customers. An increasing number of such new customers onboard the Idylla™ platform™ through a free-of-charge Idylla™ instrument evaluation program before purchasing or renting new systems. Under such program, clients can make use of the Idylla™ platform™ while only paying for the cartridge consumption. Revenues from the sale or the rental of these instruments are therefore delayed by an average of six months, subject to the satisfactory outcome of the evaluation of the Idylla™ platform.

See also risk factor "The molecular diagnostics (MDx) industry is highly competitive and characterized by rapid technological changes, and Biocartis may be unable to keep pace with its competitors." and "The commercial success of Biocartis will depend on the continued growth in market acceptance of the Idylla™ platform, the menu of Idylla™ and partner tests it offers and the relevance thereof.".

The molecular diagnostics industry is highly competitive and characterized by rapid technological changes, and biocartis may be unable to keep pace with its competitors.

The MDx industry is characterized by a rapid and continuous drive for technological innovation, new biomarker discovery, evolving market standards, changes in customer needs, reimbursement uncertainty, emerging competition and new product launches that could impact the competitive positioning of Biocartis' current and future products and the competitive positioning of proprietary products of its partners which Biocartis manufactures and/or commercializes. Biocartis may need to develop or in-license new technologies, biomarkers and solutions, or enter into new partnerships with third parties who own or have rights to proprietary biomarker content, to remain competitive, at which it may not succeed or which could come with significant investments. Current or future competitors may succeed, or may have already succeeded, in developing solutions or services that are more effective or affordable, which could render Biocartis' or its partners' present or future solutions obsolete or uneconomical. In addition, the introduction or announcement of new solutions by Biocartis, or others, could result in a delay of, or decrease in, sales of existing solutions, as Biocartis, or others, await marketing authorizations and as customers evaluate these new solutions.

Biocartis faces intense competition from a number of companies that offer solutions and technologies in its target markets, covering both oncology and infectious disease applications. Although the Idylla™ platform is the first random-access sample-to-result platform to offer a broad menu of MDx tests in the oncology field, it could be that other random-access sample-to-result platforms will be brought to the market along with a broad menu of MDx tests in the oncology field in the future or that existing random-access sample-to-result platforms that are currently deployed in other MDx markets could extend their focus to the oncology MDx market. Biocartis is extending its offering with tests that target its partners' proprietary biomarkers (either plate-based tests or tests to be performed on the Idylla™ platform), and consequently will also face competition from companies that offer tests targeting competing biomarkers to be run on a random-access MDx platform or as a plate-based test. Biocartis' primary competitors within the oncology and infectious disease MDx industry, some of which have substantially greater financial resources and larger, more established marketing, sales and service organizations than those of Biocartis, include:

- Larger and/or more established diagnostic companies with existing installed bases of plate-based MDx systems, high-throughput batch-based MDx systems and existing menus of tests
- Clinical service laboratories that provide entire MDx service solutions to customers, including tests, which they may themselves perform on commercially available instruments and test platforms or on internally developed manual test protocols, also known as 'homebrew' tests
- Companies that market and/or develop integrated random-access sample-to-result systems that may directly compete with Idylla™

- Companies that market and/or develop sequencing-, qPCR-, digital PCR-, or mass spectrometry-based detection systems for use in MDx testing; and
- Companies developing tests for the abovementioned systems
- If Biocartis is unable to compete successfully, it will not be able to achieve profitability

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- Companies that market and/or develop sequencing-, qPCR-, digital PCR-, or mass spectrometry-based detection systems for use in MDx testing; and
- Companies developing tests for the abovementioned systems.

If Biocartis is unable to compete successfully, it will not be able to achieve profitability.

Biocartis has entered into, and relies upon, a number of partnerships and alliances, including joint ventures, and the termination of such partnerships or alliances or disagreements with these partners, may have negative effects on Biocartis.

To develop, commercialize and distribute the Idylla™ platform and tests, Biocartis has entered into several commercial and strategic partnerships and alliances, including joint ventures. Biocartis has also entered into, and intends to continue to enter into, partnerships with third parties who own or have rights to proprietary biomarkers. Such partnerships and alliances could be terminated, as the case may be outside the control of Biocartis, which could lead to reputational damages, increased investments and costs to be incurred by Biocartis, as well as other commercial prejudice. Moreover, finding alternatives for such partnerships might be difficult, time-consuming and may not be successful. Furthermore, as Biocartis relies on certain partners, the development and commercialization of the Idylla™ platform and tests and the proprietary partner tests that Biocartis offers or will offer in the future, could be substantially delayed or impaired if such partners:

- Fail to comply with their regulatory obligations
- Do not successfully develop or commercialize the tests or commercialize the Idylla™ platform
- Do not conduct their collaborative activities in a timely manner
- Do not devote sufficient time and resources to the partnership
- Develop, either alone or with others, products that may compete with the Idylla™ platform or the tests offered by Biocartis
- Dispute Biocartis' respective allocations of rights to any products or technology developed during the collaboration
- Change their business strategy
- Fail to attract sufficient funding to continue to perform their obligations under the partnership
- Merge with, or are acquired by, a third party that wants to terminate the collaboration with Biocartis
- Do not properly maintain or defend Biocartis' intellectual property rights or use proprietary information in such a way as to invite litigation that could jeopardize or invalidate Biocartis' intellectual property or proprietary information or expose Biocartis to potential litigation; or
- Infringe the intellectual property rights of third parties, which may expose Biocartis to litigation and potential liability

For example, Biocartis had a collaboration with Genomic Health, Inc. (now part of Exact Sciences Corporation) which was focused on the development of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform. On 29 October 2020, however, the Company and Genomic Health, Inc. announced that they jointly agreed to terminate, with immediate effect, their collaboration due to changed market circumstances. In particular, as a result of COVID-19, the project had been suspended earlier in 2020, with the project plan and timing under evaluation. The decision to terminate the collaboration was driven by the uncertain timing of a product market release because of the pandemic and a decision by Exact Sciences to shift priorities to other initiatives. In addition, Biocartis previously had a distribution collaboration with Fisher Healthcare (part of Thermo Fisher Scientific Inc.) for the US market, pursuant to which Fisher Healthcare had exclusive distribution rights on the Idylla™ tests and non-exclusive distribution rights on the Idylla™ instruments. In September 2019, the Company and Fisher Healthcare jointly agreed to terminate their collaboration for distribution for the US market.

These and similar situations, as well as possible disagreements with partners, could lead to delays in the collaborative research, development or commercialization of the Idylla™ platform and tests or the proprietary partner tests that Biocartis offers or intends to offer in the future. Furthermore, disagreements with these partners could require or result in litigation or arbitration, which would be time-consuming, distracting and expensive.

Biocartis faces uncertainties over the reimbursement by third party payers for the products it offers and may be subject to strict price controls. Biocartis' potential customers are in part dependent on such reimbursement from third party payers, and inadequate coverage of reimbursement may compromise Biocartis' commercial success and financial results.

The commercial success of Biocartis' Idylla™ platform, the Idylla™ tests and any future Biocartis or partner products depends, in part, on the degree to which they are reimbursed by government and private payors such as health insurers, managed care organizations and others ("third party payers") in the countries in which Biocartis operates. Physicians and hospitals are unlikely to use the Idylla™ platform, the Idylla™ tests and/or any future products offered by Biocartis, at all or to a material extent, if they do not receive adequate reimbursement.

To date, in most countries where Biocartis is commercializing its Idylla™ products, these are covered by existing 'reimbursement codes'. However, it may be that in some countries reimbursement for the Idylla™ platform, the current Idylla™ tests and/or any future products offered by Biocartis will depend on obtaining a 'reimbursement code' for such product. Obtaining a reimbursement code can be a lengthy process (which can take months to years) and there is no guarantee that such a code can be obtained at satisfactory pricing levels, or at all. Following the grant of a 'reimbursement code', third party payers have to agree to provide coverage. Moreover, third party payers regularly review reimbursement levels and may decide to change the reimbursement levels or stop reimbursement altogether for such product. Failure to obtain attractive reimbursement may materially and adversely affect Biocartis' ability to achieve profitability. There is a risk that a portion of the patients that could benefit from the products offered by Biocartis will not have any form of health insurance, and that those patients will not seek treatment for their conditions, which could have a negative impact on the estimated market sizes for Biocartis.

Reimbursement procedures in most countries where Biocartis is or intends to be active are highly complex, and third party payer health plans are fragmented, which makes systematic reimbursement arrangements for new products that do not yet have an existing reimbursement difficult to establish. Consequently, Biocartis and, as the case may be, its partners could be faced with significant efforts and expenses to establish, and may never succeed in establishing, widespread or systematic reimbursement arrangements for their products.

Furthermore, reimbursement levels are set by parties outside the control of Biocartis and they may change over time. Generally, third party payers are increasingly exerting downward pressure on pricing and reviewing the cost effectiveness of medical products and services. With this global pressure on healthcare costs, third party payers are attempting to contain costs by, for example, limiting coverage and the level of reimbursement for new products. A reduction in reimbursement levels may affect the price that Biocartis is able to obtain for the products it offers and negatively impact Biocartis' financial results.

The Idylla™ platform requires sophisticated computer systems and software, which continuously need to be updated and monitored. The inability to update computer systems and software as quickly or cost efficiently as competitors and inability to monitor such computer systems and software may have a material adverse effect on operating results and financial condition of Biocartis.

Biocartis intends to continue to invest in molecular diagnostics, among others by improving the Idylla™ platform and the Idylla™ tests. The Idylla™ platform and Idylla™ tests require sophisticated computer systems and software, as well as periodic updates and risk assessments (to evaluate, predict and prevent the occurrence of potential technological failures or bugs). Some of the technologies underlying the Idylla™ platform are changing rapidly, and Biocartis must continue to adapt to these changes in a timely and effective manner at an acceptable cost. Biocartis may not be able to develop, acquire, enhance, deploy or integrate new technologies, or to do so as quickly or as cost-effectively as its competitors, and these new technologies may not meet its needs or achieve its expected goals. Significant technological change could render the Idylla™ platform obsolete. Biocartis' continued success will depend on its ability to adapt to changing technologies, manage and process ever-increasing amounts of data and information and improve the performance features of the Idylla™ platform and Idylla™ tests in response to an ever-changing patient population. Biocartis may experience difficulties that could delay or prevent the successful design, development, testing, and introduction of advanced versions of the Idylla™ platform, limiting its ability to be compatible with new tests. Any of these failures could have a material adverse effect on its operating results and financial condition. See also risk factor "A breach

of security in Biocartis' products or computer systems may compromise the integrity of Biocartis' products, harm Biocartis' reputation and create additional liability."

Operational risks

Biocartis may not be able to manufacture or outsource manufacturing of its products in sufficient quantities, in a timely manner or at a cost that is economically attractive.

Biocartis' revenues and other operating results going forward will depend, in large part, on its ability to manufacture and deliver its Idylla™ platform in sufficient quantities and quality, in a timely manner, and at a cost that is economically attractive. The Idylla™ platform currently comprises three components: the instrument, the console and the cartridge-based test. The manufacturing or assembly of the instrument and the console has been outsourced to a contract manufacturing partner ("CMO"). The manufacturing of the bill of materials for the tests, including the test's plastic parts, are also outsourced to third parties. The assembly of the cartridge is currently performed in-house at Biocartis' facilities in Mechelen (Belgium).

Due to the high level of complexity of the cartridge manufacturing process, Biocartis may not be able to continue manufacturing products in sufficient quantities, to the same standards and at an economically attractive cost compared to Biocartis' competitors, or at all. If there are any unexpected stoppages or interruptions in production caused by, among other things, mechanical breakdown, a fire or other incident at Biocartis' facilities in Mechelen or at the facilities of a CMO, or a delay in supply of components, this may lead to Biocartis failing to meet its obligations under any existing or future contracts it is a party to, customer complaints and delays in Biocartis' ability to realize revenues. For example, on 30 July 2021 a fire broke out at one of Biocartis' warehouse facilities in Mechelen, Belgium, causing the loss of finished products and raw materials as well as the temporary unavailability of the high-throughput ML2 manufacturing line. Cartridge manufacturing was suspended on the ML2 line for nearly two months, and the time needed to replenish available stocks of raw materials caused order backlogs across a variety of Idylla™ assays in the second half of 2021. This resulted in lost revenue, a write-off of EUR 3.2 million on raw materials and cartridges lost in the fire, and Biocartis submitting and collecting an insurance claim for EUR 4.6 million for damages caused by the fire, including the impact of lost revenue. Although Biocartis maintains insurance policies (such as fire insurance and business continuity insurance) at levels which management believes are in line with market practice, and such insurance policies helped Biocartis to mitigate the losses caused by the Mechelen warehouse fire in July 2021, not all damages which may occur may be fully covered by insurance policies, and the process for payment of insurance claims is often a long process with an uncertain outcome which may require significant financial and managerial resources and may limit Biocartis' ability to obtain, or increase the cost of obtaining, renewal of its insurance policies on acceptable terms.

Contracted third parties may not deliver products on time, or in compliance with the standards that are required by the relevant regulatory authorities, or they may not be able to manufacture Biocartis' products in sufficient quantities, to the same standards and at an economically attractive cost compared to Biocartis' competitors, or at all. In all these cases, the successful commercialization of Biocartis' products may be adversely affected.

Furthermore, Biocartis may need to enter into contractual relationships with other manufacturers for future increased demand of its products or to replace certain aging components of the Idylla™ platform, and it may not be able to do so on a timely basis, in sufficient quantities or on commercially reasonable terms. Accordingly, Biocartis may not be able to establish or maintain reliable, high-volume manufacturing at commercially reasonable costs, which in turn may have an adverse impact on Biocartis' manufacturing ability.

Delays in the development of tests may occur and cause a slower availability of a broad and clinically relevant menu of tests, which may result in increased costs and/or jeopardize Biocartis' ability to obtain market acceptance and/or relevant marketing authorizations in line with its strategy. Biocartis may not be able to launch new tests as quickly as it anticipates.

The availability of a broad and clinically relevant menu of tests that are approved for clinical use is an important factor in the decision to acquire and use a diagnostic platform, and management believes that offering a broader menu of such tests, including obtaining the required marketing authorizations, in combination with making such tests globally available will be a key driver of

demand for the Idylla™ platform. The continued development and commercialization of additional tests and geographical expansion are therefore a key part of Biocartis' strategy. In addition, Biocartis intends to seek marketing authorization for the Idylla™ platform and its menu of tests in a broad range of jurisdictions, which could come with significant investments and registration timelines. These products and any further products launched by Biocartis may not gain market acceptance.

Although Biocartis has a dedicated and experienced research and development team in place to develop tests, it may nevertheless not be able to launch new tests as quickly as it anticipates. Biocartis' in-house R&D team is complemented by external development partners. Additionally, Biocartis has established partnerships to develop and commercialize Idylla™ compatible tests and, in some cases, will also allow such partners to distribute the Idylla™ instrumentation. Biocartis has also entered into partnerships to commercialize proprietary plate-based tests. Biocartis intends to enter into additional (strategic) relationships with third parties for future tests. However, establishing such relationships can be difficult and time-consuming and may not be successful. To the extent Biocartis agrees to work exclusively with a party in a given diagnostic area, opportunities to collaborate with others or develop opportunities independently could be limited. Furthermore, the development and commercialization of Idylla™ compatible tests or proprietary plate-based tests via partners is outside of Biocartis' control (for further information, please see risk factor "Biocartis has entered into, and relies upon, a number of partnerships and alliances, including joint ventures, and the termination of such partnerships or alliances or disagreements with these partners, may have negative effects on Biocartis.").

Furthermore, Biocartis may experience unexpected delays or difficulties in the development and/or commercialization of tests (both on a standalone basis and together with partners), which may jeopardize and/or delay market acceptance of the Idylla™ platform. This could also jeopardize Biocartis' ability to enter into additional partnerships for the development and commercialization of tests and could consequently affect future revenue growth. A number of factors, many of which are outside the control of Biocartis, may result in delays or difficulties in the development or commercialization of tests by Biocartis and/or its partners, including:

- The launch of a competing test by a competitor with similar or better performance, which could require a new development phase for Biocartis' tests in order to meet, among others, the desired performance levels;
- Technical or performance setbacks that require additional development work to be performed in order to meet the desired test specifications;
- Biocartis' delays in, or poor performance of, verification, validation or clinical studies for any number of reasons, including a lack of sufficient numbers of testing samples, or a failure to meet the product specifications;
- Unexpected manufacturing or process flaws, which may require modifications to the test, platform or manufacturing processes (for further information, see risk factor "Biocartis may not be able to manufacture or outsource manufacturing of its products in sufficient quantities, in a timely manner or at a cost that is economically attractive.");
- A changing regulatory environment, or delays in obtaining marketing authorization (for further information, see risk factor "Biocartis' business could be significantly and negatively affected by substantial changes to government regulations, particularly in the European Union, the United Kingdom and the United States");
- Biocartis' partners may have different strategies (including due to conflicts of interest), may not exercise the same level of diligence, or may have a lower success rate than Biocartis, when developing tests for the Idylla™ platform, or may choose to stop developing tests with Biocartis altogether.

Each of these factors could result in increased costs for Biocartis and/or jeopardize Biocartis' ability to obtain market acceptance of, or relevant marketing authorizations for, the Idylla™ platform and its menu of tests in line with its strategy.

Biocartis relies on multiple suppliers to produce the individual components required for its Idylla™ platform and Idylla™ tests, some of whom are single source suppliers, and issues with suppliers may impact the

ability of Biocartis to continue supply to its customers, lead to additional costs, or require additional managerial resources.

The nature of Biocartis' products requires customized components that are currently available from a limited number of sources. For a number of components, Biocartis relies on single source suppliers. Although management believes that current capacity and required production equipment at Biocartis' suppliers are sufficient to support Biocartis' commercial supply of the Idylla™ platform and Idylla™ tests, Biocartis' suppliers may not be able or willing to continue to provide the components Biocartis needs, at suitable prices, in a timely fashion, or in sufficient quantity or quality. This could affect Biocartis' ability to continue supply to its customers which could result in financial and reputational damages.

In addition, if Biocartis needs alternative sources for key components, for any reason, these alternative components may not be available on short notice, on acceptable terms, or at all. Furthermore, alternative components may require Biocartis to modify its products which is likely to result in important re-design and approval costs and delays in supply. For instances where Biocartis relies on a single source supplier for a critical component, even if additional suppliers are available to provide a secondary source for these critical components, the addition of a new supplier to the production process generally requires extensive evaluations, testing and potentially marketing authorization, making it difficult and costly for Biocartis to diversify its exposure to single source suppliers.

If Biocartis fails to attract or retain key personnel, its ability to conduct and expand its business could be negatively affected.

The performance of Biocartis is dependent, to a certain extent, on the members of its management team and its technical and scientific personnel. Biocartis does not maintain "key man" insurance policies on the lives of these individuals or the lives of any other employees. Biocartis relies on personnel with experience in the development, registration, manufacturing and commercialization of complex MDx products. Competition for personnel with the appropriate skill set and experience is intense and may limit Biocartis' ability to hire and retain highly qualified personnel on acceptable terms, or at all. Many competitors have greater financial and other resources, different risk profiles and a longer history than Biocartis. In addition, Biocartis' anticipated growth and expansion in accordance with its strategy is expected to place greater demands on its resources, requiring the addition of new skilled personnel. Attracting, retaining and training personnel with the requisite skills could therefore be challenging. In addition, Biocartis relies on consultants who may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to Biocartis. If, at any point, Biocartis is unable to hire, train and retain a sufficient number of qualified personnel to support its growth, this could have a material adverse effect on its ability to implement its business strategy.

A breach of security in Biocartis' products or computer systems may compromise the integrity of Biocartis' products, harm Biocartis' reputation and create additional liability.

Biocartis relies heavily on IT systems for its daily operations. The risk of a security breach or disruption, particularly through cyber-attack or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. These threats include identity theft, unauthorized access, domain name system attacks, wireless network attacks, viruses and worms, advanced persistent threat, application centric attacks, peer-to-peer attacks, phishing, backdoor trojans and distributed denial of service attacks. Any of the foregoing could attack Biocartis' products and computer systems. Despite significant efforts to create security barriers to such programs and Biocartis being ISO 27001 certified for the Idylla platform™ and associated customer-facing software, it is virtually impossible to entirely eliminate this risk. Like all software products and computer systems, Biocartis' software products and computer systems are vulnerable to cyber-attacks. The impact of cyber-attacks could disrupt the proper functioning of Biocartis' software products and computer systems (including Idylla™ Connect and Idylla™ Explore), cause errors in the output of Biocartis' systems, allow unauthorized access to sensitive, proprietary or confidential information of Biocartis, its customers or the patients that Biocartis' customers serve. If any of the foregoing were to occur, Biocartis' ability to manufacture, release and ship products and its ability to access, operate or service its installed base of Idylla™ platforms may be impacted, Biocartis' reputation may suffer, customers may stop buying Biocartis' products, Biocartis could face lawsuits and potential liability.

Biocartis is exposed to potential liability related to the protection of personal data Biocartis collects.

Although the Idylla™ platform is designed to process pseudonymized personal data, in which the data cannot be attributed to a specific data subject without the use of separately kept additional information, in particular for data concerning health, genetic data, and biometric data for the purpose of uniquely identifying a natural person, Biocartis may inadvertently gain access, or be determined to have access to personal information that is subject to a number of US federal and state laws, EU laws (such as the General Data Protection Regulation (EU) 2016/679 of 27 April 2016) and other applicable foreign laws protecting the confidentiality of certain patient health or other private information, and restricting the use and disclosure of that protected information. If Biocartis would be alleged to have breached any such laws, it may be subject to substantial sanctions and irreparable harm to its reputation.

If Biocartis fails to accurately anticipate the application or interpretation of such laws when developing its products, fails to comply with their requirements (such as evolving encryption and security requirements) or becomes subject to an allegation that defects in Biocartis' products have resulted in non-compliance by Biocartis' customers, this could create material civil and criminal liability, resulting in adverse publicity and material adverse effects on Biocartis' business. Any legislation or regulation in the area of privacy and security of personal information could affect the way Biocartis operates and could harm Biocartis' business. The costs of compliance with, and the other burdens imposed by, these and other laws or regulatory actions may prevent Biocartis from selling its products, or increase the costs associated with selling its products, and may affect Biocartis' ability to invest in, or jointly develop, Biocartis' products in the United States, the European Union (the "EU") and in foreign jurisdictions. Further, Biocartis' privacy and security policies and practices may not be sufficient to protect it from liability or adverse publicity relating to the privacy and security of personal information.

Biocartis is exposed to risks associated with macroeconomic and geopolitical turbulence, including supply chain disruptions.

Biocartis' business environment can be adversely impacted by macroeconomic and geopolitical conditions in individual and global markets. There is general uncertainty with regard to macroeconomic factors, such as rapidly rising inflation, monetary and healthcare policies, regulatory change, public capital investments in healthcare ecosystems, consumer confidence and spending, pandemics, civil unrest and war amongst other things. Geopolitical tensions and protectionism have intensified generally in recent years, and in particular following the escalation of the conflict between Russia and Ukraine in February 2022. Although difficult to predict, these tensions and potential further escalation of the conflict may increasingly affect policies on trade, production, duties and taxation globally, and may also disrupt the Biocartis' supply chain and create bottleneck situations for components as well as raw materials. Higher cyber risks also cannot be ruled out.

The factors described above, or other factors which may impact conditions relevant to Biocartis' business environment, are difficult to predict. They can also make it more difficult to budget and make reliable financial forecasts or could have a negative impact on the Biocartis' access to funding. These factors may also adversely affect Biocartis' ability to secure additional financing rounds or undertake future capital market transactions.

Biocartis may continue to be exposed to risks associated with the COVID-19 pandemic, including supply chain shortages.

The COVID-19 pandemic impacted Biocartis' business in various respects. Initially, the pandemic deprioritized and disrupted cancer care globally, with patient access to hospitals significantly restricted throughout much of H1 2020, as well as resulting in a severe hampering of seeking new customers. Testing volumes started to recover and gradually normalized to pre-pandemic levels in the second half of 2020. In 2021, patient access to hospitals was more sporadically restricted in specific regions with a high surge of COVID-19 cases, which resulted in overburdened healthcare systems and resulted in delays to cancer diagnosis and treatment. In 2021, Biocartis was also affected by the worldwide reagent supply shortages caused by the growing and worldwide need for COVID-19 PCR testing, one of the most effective components in the fight against the pandemic. The shortfall in critical reagents constrained Biocartis' production capacity during H1 2021. As of today, Biocartis is no longer materially impacted by the aforementioned supply constraints.

Biocartis may not be able to run its operations without future disruptions from a potential resurgence of COVID-19, as new variants of the virus may result in increased absence of employees in manufacturing, development and other key positions. Biocartis' suppliers and partners may be exposed to similar risks, which could lead to a disruption in the supply of components in sufficient quantity and quality required to manufacture the Idylla™ platform and Idylla™ tests, result in disruptions in ongoing development and partner activities, or adversely affect Biocartis' ability to manufacture its products and deliver them to its customers. Conversely, with the progression of the response to the pandemic COVID-19 testing using the Idylla™ SARS-COV-2 assay have declined.

Legal and intellectual property related risks

Biocartis faces an inherent risk of product liability claims and may not have adequate insurance coverage.

Biocartis is exposed to potential product liability or public liability claims that are inherent in clinical testing and MDx. Biocartis faces the risk of liability for damages if there are deficiencies with any of its products, affecting among others product performance, due to component failures, manufacturing errors, design or labelling defects or other deficiencies and issues. Biocartis could also be exposed to potential litigation or liability if patients, hospitals, physicians or other parties were to improperly rely on the products for clinical decisions. Biocartis cannot be certain that it will be able to successfully defend any product liability or public liability lawsuit brought against it. Regardless of merit or eventual outcome, product liability claims may result in decreased demand, reputational damage, litigation costs and potential monetary awards.

Biocartis maintains product liability and public liability insurance at levels which management believes are in line with market practice. However, not all claims and damages may be covered fully, or at all, in case of a product liability or public liability lawsuit. As a consequence, Biocartis might have to face liabilities for a claim that may not be covered by its insurance or its liabilities could exceed the limits of its insurance. Moreover, product liability claims or public liability claims may require significant financial and managerial resources and may limit or prevent the further development or commercialization of Biocartis' products.

To date, no product liability or public liability claims have been initiated against Biocartis, however claims may be brought in the future, and Biocartis may not be able to maintain sufficient insurance coverage on commercially acceptable terms or with adequate protection against all potential risks. In addition, Biocartis' insurance policies will not protect Biocartis against any reputational harm that it may suffer if the market perceives its products to be unreliable or defective.

If Biocartis fails to obtain patent protection for the products it develops or otherwise fails to maintain and adequately protect its intellectual property rights, Biocartis' business could suffer.

Biocartis' intellectual property ("IP") rights form the basis of its products and technologies. Biocartis invests in different forms of IP right development and has set up an internal IP department that overlooks the different IP related activities. The patent portfolio of Biocartis consists of various proprietary families comprising issued and pending patents worldwide. The portfolio further includes multiple in-licensed patent families. On 31 December 2022, Biocartis' patent portfolio consisted of 30 proprietary patent families comprising issued and pending patents worldwide whose patent life will expire between 2026 and 2041, and multiple in-licensed patent families providing additional strength to the patent portfolio.

On 31 December 2022, the value of the Idylla™ platform was protected by a group of 61 patent families (30 proprietary patent families and 31 exclusively and non-exclusively in-licensed patent families), comprising issued patents and pending patent applications worldwide, covering the platform technology (basic system, fluidics, ultra-sonification, thermal control, downstream analysis, signal processing and assay design technology) and its associated biochemistry (test design, reagent storage, sample intake, etc.).

In addition to patents, Biocartis also relies on a combination of trade secrets, know-how, trademarks, design rights, copyrights, non-disclosure agreements and other contractual provisions and technical measures. Management believes that protecting the IP rights that it owns and licenses from other parties is critical to its success, but this will depend on a number of complex legal and factual questions.

- Firstly, pending patent applications (whether submitted by Biocartis or a third party licensor) may not result in granted patent rights, as the examination may lead to the conclusion that no patent will be granted. The process of obtaining patents involves filing applications in multiple jurisdictions, and may take many years. Success in one jurisdiction does not guarantee success in another jurisdiction, particularly as different jurisdictions may apply different legal principles. Therefore, there may be circumstances where an invention is patentable in one jurisdiction but a patent cannot be obtained in other jurisdictions. In responding to a patent application, a patent office may reject one or more claims of the application. This may lead to an extensive and time consuming dialogue between Biocartis and the patent office in an effort by Biocartis to reach agreement with regard to the issuance of some of its claims. Such efforts may not successfully result in issued patent claims, whether or not of any value.

- Secondly, once a patent has been granted, third parties may initiate opposition proceedings (for example, in the case of a patent granted under the European Patent Convention, third parties have until nine months after publication of the grant to oppose it), or may intervene in pending proceedings, either of which may lead to the revocation of the patent. Biocartis' patents have received a couple of non-substantial oppositions to date, all of which were unsuccessful or closed without loss of substantial patent rights. Further oppositions may occur in the future. In addition, even after the term for initiating opposition proceedings has expired, third parties may initiate court proceedings seeking the nullity of the relevant patent. Generally, the existing license agreements entered into by Biocartis with third parties do not provide for any warranty as to the validity of the licensed IP rights.

Biocartis' IP rights may be challenged, invalidated, circumvented or rendered unenforceable. Biocartis' competitors or other third parties may successfully challenge and invalidate or render unenforceable Biocartis' issued patents, including any patents that may be issued in the future. This could prevent or limit Biocartis' ability to stop competitors from marketing products that are identical or substantially equivalent to the Idylla™ platform, the Idylla™ tests and/or any future products. In addition, competitors may be able to design around Biocartis' patents or develop products that provide outcomes that are comparable to the Idylla™ platform, the Idylla™ tests and/or any future products but that are not covered by Biocartis' patents. Much of Biocartis' value is in its IP, and any challenge to Biocartis' intellectual property portfolio (whether successful or not) may impact its value.

Biocartis may initiate patent litigation against third parties to protect or enforce its patent rights, which may be expensive and divert management's attention from other business concerns. Litigation may also put its patents at risk of being invalidated or narrowly interpreted, and its patent applications at risk of not being granted. Biocartis may not prevail in any such litigation, and the damages or other remedies awarded, if any, as set off by negative publicity, if any, may not be adequate.

Biocartis decides on a case by case basis the countries in which to seek patent protection. It is not economically feasible or practical to seek patent protection in every country, and it is possible that one or more third parties may develop and market devices similar or identical to the Idylla™ platform, the Idylla™ tests and/or any future products in countries where Biocartis has not obtained patent protection. Biocartis may not be able to prevent such third party action, which may limit Biocartis' ability to pursue those markets.

Biocartis is dependent on (sub)licenses for key technologies from third parties and may require additional (sub)licenses. Biocartis may not be able to comply with its obligations under the (sub)licenses, or the (sub)licensors may not be able to maintain and adequately protect their intellectual property rights.

Biocartis relies on key technologies from third parties and has entered into (sub)license agreements with a number of (sub)licensors. Various license agreements impose on Biocartis various development obligations, payment of royalties and fees obligations, as well as other obligations. If Biocartis fails to comply with any of its obligations under these agreements, the (sub)licensor may have the right to terminate the (sub)license. In addition, if the (sub)licensor fails to comply with its license or the licensor fails to enforce its IP, the (sub)licensed rights may not be adequately maintained. The termination of any (sub)license agreements, or the failure to adequately protect the IP rights which are the subject matter of such (sub)license agreements, could prevent Biocartis from commercializing products covered by the (sub)licensed IP or have another negative impact on such commercialization.

In addition, Biocartis may require access to additional third party technologies for which an additional (sub)license, or (sub)licenses, need to be obtained in order to be able to sell certain of its products. If Biocartis is unable to sustain or enter into adequate (sub)licensing agreements to access these technologies, either on acceptable terms or at all, it may be unable to sell all, or certain of, its products, or access some geographic or industry markets.

Intellectual property infringement claims from third parties could be time-consuming and costly to defend and may result in liability for damages, or prevent Biocartis from commercializing its products.

The MDx industry is characterized by a large number of patents, claims of which appear to come close to one another or overlap in certain cases. Furthermore, certain proprietary rights of third parties may be unknown to Biocartis up until the point of enforcement. As a result, there is a degree of uncertainty regarding the extent of patent protection and infringement. Biocartis may have unknowingly infringed in the past, and may still be infringing, the proprietary rights of third parties. In addition, third parties may have pending patent applications, which are typically confidential for the first eighteen months following filing, and which may cover technologies Biocartis and/or its partners incorporate in their MDx platforms and tests. Following the publication of such patent applications, Biocartis may need to obtain additional third party licenses, but may not be able to obtain these on acceptable terms, or at all.

To date, no intellectual property infringement claims from third parties have been initiated against Biocartis. In the event that third parties accuse Biocartis of infringing their patents, Biocartis could incur substantial costs and consume substantial resources in defending against these claims. If such claims prove to be valid, this could lead to significant damages, royalty payments or an injunction preventing the sale of certain of Biocartis' products.

Certain of Biocartis' past and present employees were previously employed at Biocartis' competitors and executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although Biocartis tries to ensure that Biocartis' employees do not use the proprietary information or know-how of others in their work for Biocartis, Biocartis may be subject to claims that it, or these employees, have used or disclosed IP, including trade secrets or other proprietary information, of any such employee's former employer.

Biocartis' employees, independent contractors, investigators, consultants, commercial collaborators, service providers, distributors and other counterparties may engage in misconduct or other improper activities, including non-compliance with applicable laws and regulations, which may result in the imposition of significant fines or other sanctions.

Biocartis and its employees, independent contractors, investigators, consultants, commercial collaborators, service providers, distributors and counterparties are, or may be, subject to numerous regulations in the countries in which they operate, such as anti-bribery, anti-corruption, anti-kickback, competition, fraud, insider trading, data protection, health information privacy and security, adulteration related to quality manufacturing deficiencies, misbranding related to unlawful marketing or promotion beyond the scope of a marketing authorization, or environmental and health and safety laws. The costs of compliance with applicable regulations, requirements, guidance, or guidelines could be substantial, and failure to comply could result in sanctions, civil penalties, injunctions, criminal penalties, or disgorgement, which could significantly increase Biocartis' costs and delay the development and commercialization of its products.

Biocartis is also exposed to the risk that such persons may engage in fraudulent or other illegal activity. Acts or omissions of any of the parties Biocartis relies on could potentially cause Biocartis to incur liability under applicable laws and regulations, such as the US Foreign Corrupt Practices Act (the "FCPA"), the UK Bribery Act, the OECD Anti-Bribery Convention and other anti-bribery laws and regulations, export and import control laws in the EU, US and other jurisdictions, and sanctions programs, including those administered by the US Office of Foreign Asset Controls and the European Commission. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate laws and regulations, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, manufacturing standards, healthcare fraud and abuse and health regulatory laws, or laws that require the true, complete and accurate reporting of financial information or data.

Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, false claims, self-dealing and other abusive practices, and to promote transparency. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. For example, Biocartis' dependence on the distribution efforts of its commercialization partners creates the risk of non-compliance by these and other future distributors with local anti-corruption laws, the FCPA, and other local and international regulations. It is not always possible to identify and deter third-party misconduct, and the precautions Biocartis takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Biocartis from governmental investigations or civil or criminal liability, fines and/or prohibitions stemming from a failure to be in compliance with such laws or regulations.

Additionally, Biocartis is subject to the risk that a person or government could allege fraud or other misconduct, even if none occurred. If any such actions are instituted against Biocartis, and Biocartis is not successful in defending itself or asserting its rights, those actions could have a significant impact on Biocartis' business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in healthcare programs and tenders, reputational harm, diminished profits and future earnings, and curtailment of Biocartis' operations.

Certain technologies and patents have been developed with collaboration partners, and Biocartis may be limited by restrictions on this jointly developed intellectual property.

Biocartis has entered into collaboration agreements with a number of industrial, pharmaceutical and other companies, research institutions and academic partners. Biocartis can, in some cases individually and, in other cases, along with Biocartis' collaboration partners, file for patent protection for a number of technologies developed under these agreements and may, in the future, seek to commercialize such technologies. Under some of these agreements, certain IP developed by Biocartis and the relevant partner may be subject to joint ownership by Biocartis and the partner and Biocartis' commercial use of such IP may be restricted, or may require written consent from, or a separate agreement with, the partner. In other cases, Biocartis may not have any rights to use IP solely developed and owned by the partner. If Biocartis cannot obtain commercial use rights for such jointly-owned IP or partner-owned IP, Biocartis' product development and commercialization plans may be adversely affected.

Regulatory RISKS

Biocartis' business could be significantly and negatively affected by substantial changes to government regulations, particularly in the European Union, the United Kingdom and the United States.

Biocartis launched its Idylla™ platform and its first assay, the Idylla™ BRAF Mutation Test, for commercial sale in the European Union and countries recognizing CE-marked IVD devices in September 2014. Since that time it has launched several further tests in these countries and it intends to launch its products in other regions over the next few years. In each country in which Biocartis is currently active, or may become active in the future, Biocartis' products, including the Idylla™ platform and its menu of tests, are subject to material government regulations and review by a number of governmental authorities. Such regulations govern activities such as product development, testing, labelling, storage, premarket clearance or approval, manufacturing, advertising, promotion, sales, interaction with healthcare practitioners, permissible reimbursement, reporting of certain product failures and distribution. In many markets, the regulations applicable to IVDs are being developed or modified to align with global harmonization efforts.

In Europe, Biocartis is required to comply with the In Vitro Diagnostic Medical Devices Regulation (Regulation 2017/746) (the "IVD Regulation"). Unlike directives, which must be transposed into the national laws of the Member States, new regulations are directly applicable (i.e., without the need for adoption of Member State laws implementing them) in all Member States and are intended to eliminate current differences in the regulation of medical devices among Member States. The IVD Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for in vitro diagnostic medical devices and ensure a high level of safety and health while supporting innovation. Seeking and obtaining marketing authorization under the IVD Regulation is a new and uncertain process, and Notified Bodies (as defined below) may have limited resources and experience backlogs (see risk factor "Seeking and obtaining marketing authorization under

the IVD Regulation is a new and uncertain process, and Notified Bodies designated under the IVD Regulation may have limited resources and experience backlogs, which may delay product availability"). New devices will need to be CE-marked under the IVD Regulation after the date of application of the IVDR Regulation (i.e., 26 May 2022). This includes any device which is not CE-marked under the IVD Directive before the IVDR date of application, and hence has an impact on any new tests that Biocartis wishes to place on the market. The Idylla™ instrument, console and associated system software (which are class A non-sterile) have been CE-marked under the IVD Regulation before the date of application. However, Regulation 2022/112 amended the IVD Regulation regarding the transitional provisions, and allows most devices with CE-Mark under the IVD Directive to be placed on the market or put into service for an additional timeframe which depends on their respective risk class under the IVD Regulation, provided that there are no significant changes in the design and intended purpose of those devices.

The IVD Regulation influences the way Biocartis conducts business in Europe, and includes, among other things, the following:

- Stricter rules for placing devices on the market with increased requirements for CE-marking, as well as subsequent post-market surveillance and clinical follow-up once they are on the market
- Explicit provisions on the responsibilities of manufacturers and other supply chain actors for the follow-up of the quality, performance and safety of devices placed on the market
- Better traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number
- A central database and increased transparency requirements to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU
- Stricter rules for the assessment of certain high-risk devices, which may have to undergo additional testing (for example, on safety or efficacy) and may be subject to additional scrutiny by independent experts before they are placed on the market; and
- Re-approval requirements for medical devices currently on the market in the EEA (such as each of the currently CE-marked IVD tests) and for the organizations responsible for assessing whether manufacturers and their medical devices meet applicable regulatory requirements (the "Notified Bodies")

As set out above, market clearance for Biocartis' products is achieved in the EU through CE-marking, previously via the European Directive 98/79/EC on in vitro diagnostic medical devices (the "IVD Directive") and as of 26 May 2022 via the IVD Regulation (subject to transitional measures). Under the IVD Directive, the Idylla™ platform and Idylla™ tests were CE-marked following a self-certification process conducted by the manufacturer. For compliance with the IVD Regulation, Idylla™ oncology tests are classified as high-risk (class C under the IVD Regulation), thereby requiring the services of a Notified Body for their CE-marking under the IVD Regulation latest by 26 May 2026. A sub-set of Idylla™ oncology tests are classified as high-risk companion diagnostic ("CDx") assays requiring additional review by a competent authority or the European Medicine Agency ("EMA"), which is a new review model with related uncertainties. There are limited CDx assays that have successfully achieved the CE mark under the IVD Regulation leading to limited intelligence to leverage. The change in classification of a sub-set of Idylla™ oncology tests from a molecular diagnostic claim under IVD Directive to a CDx claim under IVD Regulation increases the level of clinical performance data required since a link with the intended use population from the drug study is required. Existing data may need to be supplemented with new studies. The required scope and size of a study may be larger than expected as the application of class C CDx regulations in the EU is evolving. Studies performed for such regulatory clearance are expensive and time-consuming. Based upon experience with markets that have similar regulations, management currently anticipates that obtaining CE-marking clearance from a Notified Body will increase the time it takes to bring a product to market in the European Union by around three to four quarters, and for tests classified as Class C CDx the additional review by the competent authorities or the EMA may add an additional 1 to 2 quarters. Any failure or material delay in obtaining such certification for a new product will delay or terminate plans of bringing new tests to the market without recovery of costs incurred while any failure or material delay in obtaining such certification for the currently CE-marked Idylla™ tests may require Biocartis to cease marketing and selling those tests until

certifications in compliance with the IVD Regulation are obtained. For further information see Risk Factor "Seeking and obtaining marketing authorization under the IVD Regulation is a new and uncertain process, and Notified Bodies designated under the IVD Regulation may have limited resources and experience backlogs, which may delay product availability".

Starting from 1 July 2024, IVDs bearing the CE-Mark under the IVD Directive or IVD Regulation will no longer be accepted in the UK. This represents a one year extension from the previously targeted implementation date of 1 July 2023. From 1 July 2024, the IVDs placed on the UK market must comply with Medical Devices Regulations 2002 (SI 2002 No 618, as amended) and bear UKCA (UK Conformity Assessed) marking. IVD manufacturers may only apply UKCA after the UK organizations responsible for assessing whether manufacturers and their medical devices meet applicable regulatory requirements in the UK certify compliance of respective IVDs (except general IVDs) with the Medical Devices Regulations 2002. General IVDs may bear UKCA following manufacturer's self-certification. Hence, Biocartis may need to ensure that the currently CE-marked Idylla™ products, or any other IVDs which Biocartis commercializes in the UK are certified under the Medical Devices Regulations 2002 before 1 July 2024. Failure or material delay in obtaining such certification for the currently CE-marked Idylla™ tests, or any other IVDs which Biocartis commercializes in the UK between now and the application date of the Medical Devices Regulations 2002, may require Biocartis to cease marketing and selling those IVDs until certifications in compliance with the Medical Devices Regulations 2002 are obtained. Any failure or material delay in obtaining certification under the Medical Devices Regulations 2002 for new products will delay or terminate plans of bringing new products to the market without recovery of costs incurred.

In the United States, IVDs are regulated by FDA as medical devices under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and may also be regulated as biological products subject to the Public Health Service Act. Like other medical devices, IVDs are subject to FDA's premarket and postmarket controls, including labeling requirements, provisions against adulteration and misbranding, good manufacturing practices, establishment registration, medical device listing, records and medical device reporting, and notification, amongst other things. IVDs are generally also subject to regulation under the Clinical Laboratory Improvement Amendments of 1988 Act (the "CLIA" Act), which establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. IVD tests are categorized into CLIA test complexity categories: (1) waived tests, (2) tests of moderate complexity, and (3) tests of high complexity.

Under the FDCA, certain medical devices require US FDA 510(k) clearance or premarket approval ("PMA") prior to marketing in the United States. CLIA categorization is determined after the FDA has cleared or approved a medical device marketing submission, or upon request for a legally marketed device. The Idylla™ Respiratory (IFV-RSV) Panel is a 510(k) cleared Class II device. The majority of Biocartis' current and planned Idylla™ tests is expected to require US FDA 510(k) clearance or PMA approval before marketing is permissible in the United States. These tests will also be categorized under the CLIA Act.

Each of the Idylla™ tests will need to undergo significant evaluation and testing to support submissions for 510(k) clearance or PMA approval. For 510(k) clearance, these requirements include an evaluation of the analytical performance characteristics of the device compared to a predicate and studies to demonstrate substantial equivalence to the predicate device. In most cases for IVDs, analytical studies using clinical samples are sufficient, but some IVDs also require clinical information if the link between analytical performance and clinical performance is not well defined. For PMA approval, the applicant will need to provide sufficiently valid scientific evidence to provide assurances that the device is safe and effective for its intended use. A PMA includes a technical section that is typically divided into non-clinical laboratory studies and clinical studies.

The required scope and size of a clinical study to support a PMA approval will need to meet regulatory requirements, and, when necessary, may be expanded to a larger cohort than anticipated. A clinical study may be expensive and time-consuming and may require significant follow-up beyond the resources of Biocartis. An evaluation or study may fail to demonstrate substantial equivalence to the safety and effectiveness of a predicate product (for 510(k) clearance), or be determined by US FDA reviewers as insufficient to demonstrate safety and effectiveness to support a PMA. FDA regulation of IVDs, and in particular companion diagnostic (CDx) products, is evolving and FDA requirements may vary depending upon the specific product and claimed indications. Recent legislation was also introduced that, if passed, would reform FDA's regulatory framework for in vitro diagnostic tests, which may create a less burdensome pathway to commercialization for certain IVDs. The passage of such legislation, and the ultimate requirements for approval set out therein, cannot be predicted.

Biocartis utilizes FDA's Pre-Submission review process to gain FDA feedback on specific questions related to product development and/or application preparation or other requirements in advance. Notably, this process is voluntary and non-binding and regulations and expectations may change during the execution of product studies, significantly changing the requirements applicable to the effort. In addition, securing FDA's feedback under the Pre-Submission process and, ultimately, obtaining the 510(k) clearance or PMA approval for Idylla™ tests may be delayed if FDA is backlogged in reviewing a large number of Pre-Submission requests.

Moreover, design controls and manufacturing that is compliant with EU regulations may not be compliant with US regulations. Marketing and promotional requirements are significantly different from those in the EU under the IVD Regulation. In addition, the commencement or completion of any study may be delayed or halted for any number of reasons. FDA 510(k) clearance or a PMA approval may not be obtained for any of Biocartis' products, on a timely basis, or at all. In addition, once a FDA 510(k) clearance or PMA approval has been obtained, any significant change or modification in design, components, method of manufacture, or intended use (which may be required due to evolving treatment protocols or standards of care), may require submission of a 510(k) for a change to an existing device or a new FDA 510(k) clearance or PMA. The change or modification may require Biocartis to cease marketing or recall the modified products until clearances or approvals are obtained.

Similarly, even if Biocartis obtains the relevant marketing authorizations in the EU or the United States, changes to regulatory requirements in other markets could prevent completion of product registrations in those markets. Biocartis may not obtain marketing authorizations elsewhere on a timely basis, if at all. Based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service (PHS) Act, to expire at the end of the day on 11 May 2023. Biocartis has relied on the Policy for Coronavirus Disease-2019 Tests, Guidance for Developers and Food and Drug Administration Staff established during the Public Health Emergency to market the Idylla™ SARS-CoV-2 Test in the US. The continued ability of Biocartis to continue to market that test when the Public Health Emergency ends will be at risk.

In addition, it is possible that the current regulatory framework could change, or additional regulations could arise, at any stage during development or marketing, which may adversely affect Biocartis' ability to obtain or maintain approval or clearance of its products, or to comply with ongoing regulations in the countries in which it operates.

Regulatory agencies such as the US Food and Drug Administration ("FDA") strictly regulate the claims that may be made about medical devices or related products placed on their market. If Biocartis is found to have made false or misleading claims about its products, or otherwise have violated promotion, advertising or distribution restrictions, Biocartis may become subject to significant fines and/or other enforcement action or liabilities, including being prohibited from importing into these markets.

In the markets in which Biocartis operates, Biocartis' promotional materials and training methods must comply with numerous applicable laws. Relevant governmental authorities may also hold Biocartis responsible for training its sales force and employees regarding these applicable laws. A relevant governmental authority may determine that an IVD's labeling violates applicable statutory requirements if the labeling is determined to be false or misleading, the labeling fails to bear adequate directions for use, there is inadequate data to substantiate the claims made, or the labeling constitutes off-label promotion (e.g., the promotion of an IVD device for a use that has not been cleared or approved by the relevant regulator or supervisory body).

If a relevant governmental authority determines that Biocartis' promotional materials, training or distribution practices violate applicable legal requirements, the relevant governmental authority could request that Biocartis modify its training or promotional materials, make other corrections or restitutions, or subject Biocartis to regulatory or enforcement actions, including the issuance of a warning or untitled letter, injunction, seizure, civil fine and criminal penalties. Other US (federal or state), EU or other applicable foreign governmental authorities might also take action if they consider Biocartis' promotion or training materials to constitute promotion of an un-cleared or unapproved use, such as laws prohibiting false claims for reimbursement, which could result in significant fines or penalties under other statutory rules and regulations. For example, in the US, off-label promotion of a medical device may subject Biocartis to Federal False Claims Act liability. The Federal False Claim Act prohibits, among other

things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government.

Violations of the applicable requirements related to promotional materials, training or distribution practices, including laws prohibiting false claims for reimbursement purposes, could result in negative publicity. This could result in potential reputational damage and subsequent impairment of product sales. Furthermore, although Biocartis trains its sales force not to promote Biocartis' products for 'off-label' uses, and Biocartis' instructions for use in all markets specify that Biocartis' products are not intended for use outside of those indicated on the label, competent governmental authorities may nevertheless hold it responsible for engaging in 'off-label' promotion or other practices if an off-label message is construed as being delivered on Biocartis' behalf, or if Biocartis is otherwise determined to have control over the messaging.

Seeking and obtaining marketing authorization under the IVD regulation is a new and uncertain process, and notified bodies designated under the IVD regulation may have limited resources and experience backlogs, which may delay product availability.

Notified Bodies are designated by the competent authority in the Member State in which they are based to assess whether manufacturers and their medical devices meet the regulatory requirements as defined in the applicable EEA regulations. Notified Bodies must submit applications for designation under the IVD Regulation to their local competent authority and the European Commission Medical Device Coordination Group (the body tasked with assisting the European Commission and Member States in ensuring a harmonized implementation of the IVD Regulation), which may be a lengthy and uncertain process. In these applications, Notified Bodies are required to demonstrate increased technical expertise in their scope of designation, as well as improved quality management systems. At present, only a minimal number of Notified Bodies have been designated under the IVD Regulation. Despite Regulation 2022/112 amending the IVD Regulation as regards the transitional provisions for certain IVD medical devices, there is still a significant risk that the number of Notified Bodies designated for the IVD Regulation will not be sufficient for the anticipated workload created by the IVD Regulation requirements. Some existing Notified Bodies may be judged unfit for designation under the IVD Regulation, or may choose not to request designation, which would decrease the overall capacity. This could lead to significant backlogs for IVD certifications as the number of Notified Bodies capable of assessing the sufficiency of medical devices under the IVD Regulation would be further diminished and the workload would need to be absorbed by the remaining Notified Bodies.

Moreover, only limited specific guidance from Notified Bodies regarding expectations for CE-marking have been published. In addition to new medical devices, devices currently on the market in the EEA (such as the Idylla™ platform and certain Idylla™ tests) will need to be evaluated and approved in accordance with the new requirements of the IVD Regulation. Biocartis has entered into contractual arrangements with a Notified Body securing the capacity of that Notified Body for IVD certification of certain Idylla™ tests. Nevertheless, a Notified Body may not provide the requisite certification for the currently CE-marked Idylla™ tests, and Biocartis' other products may require certification from a Notified Body in the future, which it may not receive on a timely basis, or at all. In the event the Idylla™ platform and tests are not approved under the IVD Regulation, on a timely basis or at all, the marketing and sale of the Idylla™ platform and tests in Member States may be temporarily or permanently prohibited.

Additionally, Biocartis' third party distributors in the Member States will also need to be compliant with the new IVD Regulation. Additional obligations of the distributors, including as regards post-market surveillance, IVD traceability and cooperation between distributors, Biocartis and the regulatory authorities need to be documented in the agreements between Biocartis and distributors, which may require substantial resources of Biocartis. If any of Biocartis' third party distributors in Member States fail to meet the requirements of the IVD Regulation and additional national legislation (including any national registration requirements for distributors), on a timely basis or at all, the marketing and sale of the Idylla™ platform and tests in those Member States by the affected distributor or distributors may be temporarily or permanently prohibited.

Performance of obligations concerning post-market surveillance and post-market performance follow up under the IVD regulation and applicable laws in other jurisdictions require significant resources. Failure to comply with such obligations may result in sanctions and prohibition of the marketing and sale of Biocartis' IVDs.

The IVD Regulation imposed additional obligations on IVD manufacturers to systematically and proactively collect and review experience gained from the IVDs they place on the market. To that end, IVD manufacturers must establish, maintain and update a post-market surveillance system based on a post-market surveillance plan for gathering data on the quality, performance and safety of an IVD throughout its entire lifetime. The post-market surveillance plan must address the collection and analysis of information concerning incidents, undesirable side-effects, relevant specialist or technical literature, complaints and publicly-available information about similar IVDs. The manufacturer must also proactively collect and evaluate performance and relevant scientific data from the use of an IVD placed on the market to confirm the safety, performance and scientific validity throughout the expected lifetime of the IVD, ensure the continued acceptability of the benefit-risk ratio and detect emerging risks on the basis of factual evidence. The results of the post-market surveillance activities must be documented in reports to be drawn by the IVD manufacturer. IVD manufacturers may also need to update technical documentation and take corrective and preventive measures.

The obligations concerning post-market surveillance apply from 26 May 2022 with respect to new IVDs that are placed on the market and with respect to IVDs that were CE-marked under the IVD Directive and that benefit from the transitional application of the IVD Regulation. Performance of such obligations, and any similar obligations under applicable laws in other jurisdictions, on an ongoing basis requires significant time, and managerial and financial resources. Failure to comply with such obligations may result in sanctions and prohibition of the marketing and sale of Biocartis' IVDs.

Data generated from post market surveillance and follow up may lead to a technical review of the IVDs, restriction or loss of market access or changes in IVDs across markets, which in turn may negatively impact Biocartis' revenue and/or cost basis.

If Biocartis' products are defective, or otherwise pose safety risks, the relevant governmental authorities could require their recall, or Biocartis may initiate a recall of Biocartis' products voluntarily.

The relevant governmental authorities may require the recall of commercialized products in the event of material deficiencies, or defects in design or manufacture, or in the event that a product poses an unacceptable risk to health. Manufacturers, on their own initiative, may recall a product if any material deficiency in a device is found. A government mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labelling defects or other deficiencies and issues. Recalls of any of Biocartis' products would divert managerial and financial resources and may result in irreparable harm to Biocartis' reputation. Any product recall could impair Biocartis' ability to produce Biocartis' products in a cost-effective and timely manner in order to meet Biocartis' customers' demands. Biocartis may also be required to bear other costs, or take other actions that may have a negative impact on Biocartis' future revenue and Biocartis' ability to generate profits. Biocartis may initiate voluntary recalls involving Biocartis' products in the future that Biocartis determines does not require notification of the relevant regulatory body. If a governmental agency disagrees with Biocartis' determination, it could require Biocartis to report such actions as recalls. In addition, the relevant authority could take enforcement action for failing to report the recalls when they were conducted.

If Biocartis' products cause or contribute to a death or a serious injury, or malfunction in certain ways, Biocartis will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. Any corrective action, whether voluntary or involuntary, as well as defending Biocartis in a lawsuit, would require the dedication of Biocartis' time and capital, distract management from operating Biocartis' business, and may materially harm Biocartis' reputation.

Healthcare policy changes, including legislation to reform the US healthcare system, could have a material adverse effect on Biocartis' business.

From time to time, legislation is enacted that could significantly change the statutory provisions governing the clearance or approval, manufacture or marketing of Biocartis' products. In addition, regulations and guidance are often revised or reinterpreted in ways that may significantly affect Biocartis' products (e.g. healthcare systems related legislation). It is impossible to predict whether legislative changes will be enacted or regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Biocartis cannot predict what healthcare programs and regulations will be ultimately implemented at the US federal or state level, or at the EU level, or within the implementing legislation of the individual EU Member States, or the effect of any future legislation or regulation. However, these types of provisions, as adopted, could materially change the way in which healthcare is delivered and financed, and may materially impact numerous aspects of Biocartis' business. In particular, changes may lower reimbursements (for further information, see risk factor "Biocartis faces uncertainties over the reimbursement by third party payers for the products it offers and may be subject to strict price controls. Biocartis' potential customers are in part dependent on such reimbursement from third party payers, and inadequate coverage of reimbursement may compromise Biocartis' commercial success and financial results.") or impose increased regulatory requirements for Biocartis' products.

In addition, in the future there may continue to be additional proposals relating to the reform of the healthcare systems of the US, the EU, any individual Member State or any other jurisdiction where Biocartis may operate in the future. Certain of these proposals could limit the prices Biocartis is able to charge for its products, or the amounts of reimbursement available for its products, and could limit the acceptance and availability of its products.

Biocartis is subject to laws prohibiting healthcare fraud and abuse and other laws applicable to Biocartis' business activities. If Biocartis is unable to comply with such laws, it could face substantial penalties.

Biocartis' and its partners' operations are subject to various fraud and abuse laws. Such laws include anti-kickback laws, physician payment transparency laws and false claims laws. These laws may impact, among other things, Biocartis and its partners' proposed sales and marketing and education programs and require them to implement additional internal systems for tracking certain marketing expenditures and to report to governmental authorities. In addition, Biocartis and its partners may be subject to patient privacy and security regulations in the countries in which Biocartis conducts its business. The laws that may affect Biocartis' or its partners' ability to operate include, inter alia:

- laws which prohibit, among other things, persons or entities from knowingly or wilfully soliciting, receiving, offering or paying any remuneration, overtly or covertly, directly or indirectly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order, arrange for, or recommendation of, any good, facility, item or services for which payment may be made, in whole or in part, under certain healthcare programs

- false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from or approval by a governmental payer program that are false or fraudulent

- laws which establish crimes for, among other things, knowingly and wilfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, wilfully obstructing a criminal investigation of a healthcare offense, concealing a material fact, or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services

- laws that require manufacturers to provide reports to governments on pricing and marketing information. Several jurisdictions have enacted legislation requiring healthcare and medical devices companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, and to prohibit or limit certain other sales and marketing practices; and

- "Sunshine" laws, which require certain manufacturers of drugs, devices, biologicals, and medical supplies to report annually to certain agencies and centers information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. This is for example the case in the United States, France and Belgium

For example, in the EU, the provision of benefits or advantages of any kind to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is generally prohibited. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States.

If Biocartis' or its partners' operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to them, they may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of Biocartis' or its partners operations, the exclusion from participation in government healthcare programs and individual imprisonment.

Patients, hospitals, physicians or other parties may try to hold Biocartis responsible for all, or part, of the medical decisions underlying the treatment of patients, which could lead to litigation or governmental action against Biocartis.

The existing Idylla™ products on the market are designed to detect the presence or levels of certain specific biomarkers. These products are not designed to specify the treatment necessary for each patient, which remains the responsibility of relevant medical personnel. Although Biocartis indicates in its marketing materials and in the labelling of its products (which indicates, among other things, the relevant test's accuracy rate) that its products are not designed to specify the course of treatment for patients and although Biocartis has not yet encountered such actions to date, patients, hospitals, physicians or other parties may nevertheless try to hold Biocartis responsible for all or a part of the medical decisions underlying the treatment of patients, exposing Biocartis to potential litigation or civil or criminal liability. Such actions or liability could lead governmental agencies to conclude that Biocartis' products or services are no longer to be used or used improperly, all of which could significantly damage Biocartis' reputation and could materially impair the continued adoption of Biocartis' product offering in the market.

Financial risks

Biocartis has incurred operating losses, negative operating cash flow and an accumulated deficit since inception and may never become profitable.

Biocartis has incurred operating losses and negative operating cash flow in each period since it was founded. Operating loss for the year ended 31 December 2022 was EUR 47 million (rounded). As of 31 December 2022, Biocartis had an accumulated deficit of EUR 443 million (rounded). These losses have resulted principally from costs incurred in the design, industrialization and commercialization of the Idylla™ platform, the development and commercialization of tests, the establishment of its manufacturing facilities, as well as from general and administrative costs associated with Biocartis' operations. Biocartis intends to continue to develop MDx tests, and to conduct regulatory activities and sales and marketing activities that, together with anticipated further investments in manufacturing capabilities and general and administrative expenses, will likely result in Biocartis incurring further losses for at least the next few years. In addition, macroeconomic factors, including a continued recessionary and/or inflationary environment, combined with austerity measures by certain European governments, and restrictive monetary policies, may further negatively impact Biocartis' operating results. In particular, the rising inflation leads to significant higher costs (in particular for raw materials and labor), which cannot be passed on to the Company's customers through price increases; which in turn has an impact on the Company's profitability.

Biocartis may never achieve profitability, which could impair its ability to sustain operations or obtain any required additional funding. If Biocartis does achieve profitability in the future, it may not be able to sustain profitability in subsequent periods, and it may suffer net losses and/or negative operating cash flows in subsequent periods.

It is possible that Biocartis will experience fluctuating revenues, operating results and cash flows. In that case, as a result, period-to-period comparisons of financial results are not necessarily meaningful, and results of operations in prior periods should not be relied upon as an indication of future performance.

Biocartis might require substantial additional funding to respond to business challenges, take advantage of new business opportunities or repay or refinance its outstanding convertible bonds, which may not be available on acceptable terms, or at all.

Biocartis intends to continue to make appropriate investments to support the execution of its business plan and its growth. Existing sources of financing and any funds generated from operations may not provide Biocartis with sufficient capital. Biocartis may require additional equity or debt funding from time to time to meet funding needs; to repay or refinance both its old and its new outstanding convertible bonds and its credit facilities; to respond to business challenges; or to take advantage of new business opportunities. Equity and debt financing, however, might not be available when needed or, if available, might not be available on acceptable terms. In addition, to the extent that additional capital is raised through the issuance of equity or convertible debt securities, the issuance of these securities could result in the dilution of the interests of Biocartis' existing shareholders and may provide for rights, preferences or privileges senior to those of holders of common stock. In addition, these securities may be sold at a discount from the market price of Biocartis' common stock. If additional funds are raised by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of shareholders, and the terms of the debt securities issued could impose significant restrictions on Biocartis' operations. If Biocartis is unable to obtain adequate financing as a result of increasing interest rates in many jurisdictions, including the Eurozone, or otherwise, its ability to continue to support its business growth and to respond to business challenges could be significantly limited. Moreover, the Company's loan and credit agreements are linked to floating Euribor rates and consequently any increase in interest rates will result in an additional interest cost. Existing sources of cash and any funds generated from operations may not provide Biocartis with sufficient capital and may result in delays in its operations that could affect its operational and financial performance.

Biocartis' finance agreements contain restrictive covenants that may limit its ability to respond to changes in market conditions or pursue business opportunities.

Biocartis and its material subsidiaries are currently subject to restrictive covenants, including a financial covenant linked to a minimum liquidity amount equal to at least EUR 10,000,000, as well as certain general undertakings including a limit on the ability to do any of the following, subject to exceptions:

- create or permit to subsist any security over any of its assets or sell, transfer or otherwise dispose of any of its assets or receivables on recourse terms
- whether voluntary or involuntary, sell, lease, transfer, grant, lease or license out, lend or otherwise dispose of all or any part of its respective assets, except in the ordinary course of business
- make any acquisition of, or participate in, any company, business, or undertaking, incorporate a company, or invest in any joint venture (other than the Company's existing joint venture Wondfo-Cartis)
- incur, create or permit to subsist or have outstanding certain additional financial indebtedness, subject to material exceptions
- make any loans, grant any credit or provide any other financial accommodation to or for the benefit of any person, including any of its shareholders
- grant, incur or allow to remain outstanding any guarantee, surety or indemnity (including by way of letters of comfort) or other similar assurance in respect of obligations of any other person which could result in a payment claim by the beneficiary against the grantor thereof
- declare, make or pay any dividend (save where such dividend is capitalized) or similar distribution (or interest on any unpaid dividend or similar distribution whether in cash or in kind) on or in respect of its issued share capital (or any

class of its share capital) save where the same is made or paid to another member of the group; (b) repay or distribute any dividend or share premium reserve, or make any other payment to its shareholders; (c) redeem, repurchase, retire or repay any of its share capital or resolve to do so; or (d) redeem, repurchase, retire or repay prior to its stated maturity date, or make any other payment of any of its convertible bonds, or resolve to do so

- issue any shares or grant any conditional or unconditional option, warrant or other right to call for the issue or allotment of, subscribe for, purchase or otherwise any share of any member of the group or alter any right attaching to any share capital of any member of the group, except in the framework of a broad set of agreed permitted share issues, including share issuances by the Company that do not result in a change of control

- make any substantial change to the general nature of the business of the group as a whole from that which is carried on at the date the relevant covenant was agreed upon; and

- enter into any treasury transaction other than spot and forward delivery foreign exchange contracts or contracts against fluctuation of any interest rate, in each case entered into in the ordinary course of business and not for speculative purposes

These limitations are subject to a number of important qualifications and exceptions. Complying with the restrictions may materially and adversely affect Biocartis' ability to react to changes in market conditions, take advantage of business opportunities it believes to be desirable, obtain future financing, fund needed capital expenditures, or withstand a continuing or future downturn in its business.

Biocartis' operating results could be materially and adversely affected by unanticipated changes in tax laws and regulations, adjustments to its tax provisions and its allocation of income, exposure to additional tax liabilities, or forfeiture of its tax assets.

The determination of Biocartis' provision for income taxes and other tax liabilities requires significant judgment, including the adoption of certain accounting policies and Biocartis' determination of whether its deferred tax assets are, and will remain, tax effective. Although management believes its determinations, its estimates and its judgment are reasonable, they remain subject to review by the relevant tax authorities. Biocartis' interpretations, determinations, estimates and judgment may be questioned by the relevant tax authorities, positions taken by the relevant tax authorities in different jurisdictions may not be consistent, and the relevant tax laws and regulations, and the interpretation thereof by the relevant tax authorities across all jurisdictions where Biocartis is active or may be subject to tax, is subject to change, including changes that may have a retroactive effect. Any adverse outcome of such a review may lead to adjustments in the amounts recorded in Biocartis' financial statements, and could have a materially adverse effect on Biocartis' operating results and financial condition.

Biocartis is subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing, custom duties, sales taxes and tax regulations for the compensation of personnel and third parties. Biocartis' tax structure involves a number of transfers and transfer price determinations between the parent company and its subsidiaries or other affiliates.

Biocartis' effective tax rates could be adversely affected by changes in tax laws, treaties, guidelines and regulations, both internationally and domestically, including possible changes to the patent income deduction regime, the innovation deduction regime, the tax credit for R&D investments and wage withholding tax incentive for qualified research and development personnel in Belgium and other tax incentives, or the way they proportionally impact Biocartis' effective tax rate.

In addition, Biocartis may not be able to use, or changes in tax regulations may affect the use of, certain tax assets or credits that it has built over the years. For instance, some of Biocartis' entities have significant tax loss carry forwards. Some of these tax loss carry forwards may be forfeited in whole, or in part in, as a result of transactions, or their utilization may be restricted by statutory law in the relevant jurisdiction. Any corporate reorganization within the group or relating to Biocartis' shareholding structure may result in partial or complete forfeiture of tax loss carry forwards. The tax burden would increase if profits could not be set off against tax loss carry forwards.

Furthermore, Biocartis' increasing international business may make it subject to income tax, custom duties, sales taxes and other direct or indirect taxes in countries where it was previously not the case.

Changes in currency exchange rates could have a material negative impact on the profitability of Biocartis.

Biocartis records its transactions, prepares its financial statements and incurs substantially all of its costs in euros and enters into certain sale and purchase transactions in US dollars and other currencies. In addition, in view of Biocartis' global commercialization strategy and the range of markets in which it intends to operate, more and more transactions entered into by Biocartis may be in foreign currencies. The relationships between different currencies may be volatile and vary based on a number of interrelated factors, including the supply and demand for each currency, political, economic, legal, financial, accounting and tax matters and other actions that Biocartis cannot control. If the currencies in which Biocartis earns its revenues and/or holds its cash balances weaken against the currencies in which it incurs costs and expenses, this could lead to Biocartis suffering exchange rate losses, and declines in such currencies against the euro would negatively impact Biocartis' results when translated into euro for reporting purposes. Biocartis has a subsidiary in the United States and the conversion of its financial statements for purposes of preparing Biocartis' consolidated financial statements is subject to fluctuations of the US dollar against the euro. Any of the foregoing could have a materially adverse effect on Biocartis' financial condition and results of operations.

Biocartis may face risks associated with previous or future acquisitions and disposals of companies, assets, solutions and technologies, and its business could be harmed if Biocartis is unable to address these risks.

Since its incorporation, Biocartis has grown through licensing and asset acquisition transactions with third parties. If, in the future, Biocartis is presented with appropriate opportunities, it may acquire or make other investments in complementary companies, solutions or technologies. Biocartis may not be able to realize the anticipated benefits of the assets it secured, or may fail to secure or assess, through its past or future licensing transactions or acquisitions, the actual value of the assets or technology (which could result in impairments), or may fail to further use and develop or integrate these assets or technology into its existing business or may face claims from third parties. Moreover, Biocartis may have to incur debt or issue further equity to pay for any additional future acquisitions or investments, the issuance of which could dilute the interests of its existing shareholders. Biocartis has also made disposals of assets that it deemed no longer core, and may decide to do so in the future with other assets. When disposing of assets, Biocartis may not be able to complete the disposal at terms deemed acceptable, may be required to give guarantees, and may expose itself to claims from purchasers, as well as creditors of the transferred business.

The processes by which Biocartis acquires or disposes of businesses, licenses assets or technologies may be lengthy and complex and may result in a diversion of management's attention from other business concerns. All of the foregoing could have a material adverse effect on Biocartis' financial condition and results of operations.

3.1. Approach to sustainability

As a molecular diagnostics company, our Idylla™ products focus on providing more, better and faster molecular diagnostics solutions to patients across the globe to support optimal treatment decisions. This has the potential to positively impact the overall healthcare cost for society.

"One Idylla™ test can bring one patient one step closer towards getting the right treatment, with the best possible health outcome."

Herman Verrelst, CEO Biocartis

Sustainability governance

Sustainability is integrated in the governance of our organization, under the responsibility of our board and executive management. At management level, the Chief Operations Officer holds an oversight role in all social and environmental related matters. He is supported by a team of operational managers including the Head of Facilities for environmental matters, the Head of HR for employee matters and the Head of Supply Chain for supply chain matters.

Sustainability strategy and management

In 2022 Biocartis took further steps in its sustainability approach through the set-up of a sustainability ambassadors' team and the implementation of a sustainability materiality review that led to the development of a materiality matrix.

Sustainability: roadmap/journey towards materiality

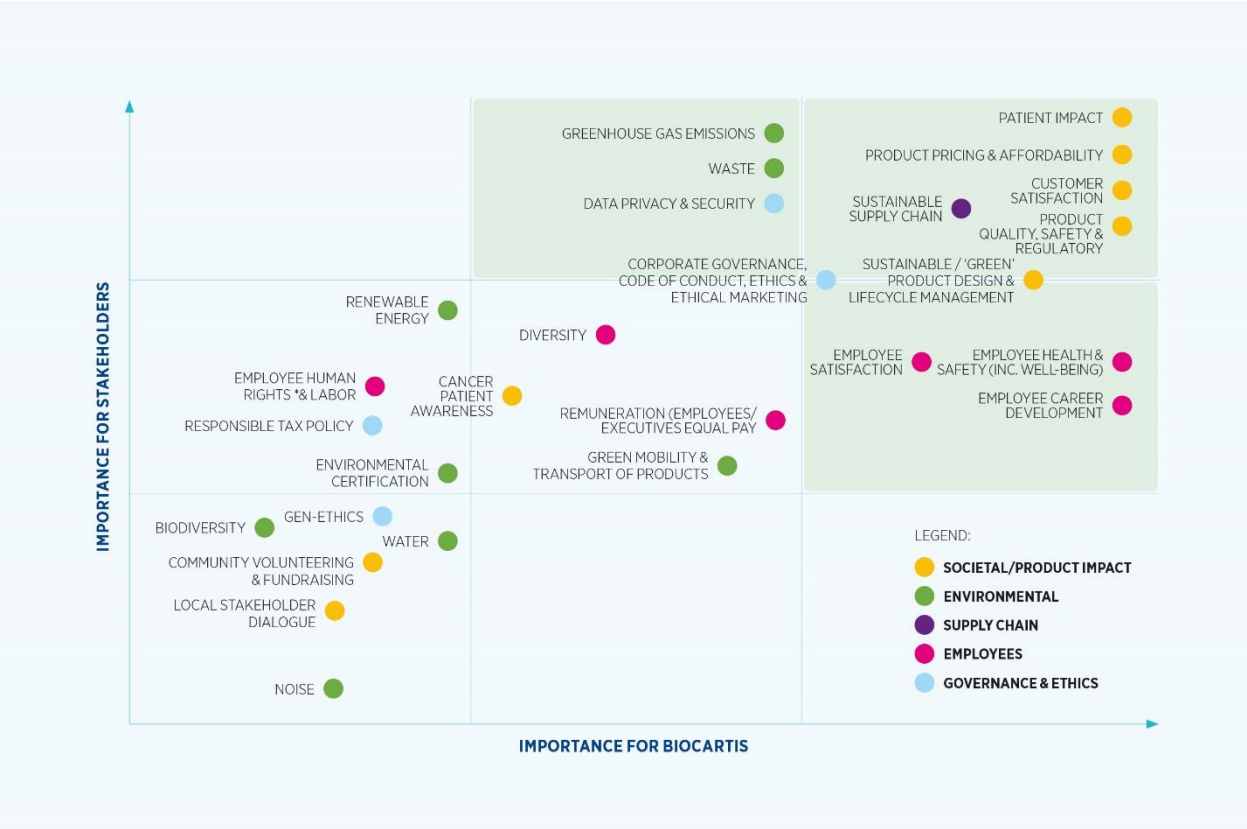
The main objective in 2022 for Biocartis was to establish a management process to support the implementation of the Biocartis sustainability projects. By means of the Sustatool, developed by the University of Antwerp, sponsored by the Belgium Government, and based on academic research and management literature, an AS-IS analysis of the Biocartis management processes was initiated.

The Sustatool is a 5-stage management process and consists of a fully customized dashboard of 15 sustainability and optimization themes across 3 organizational levels:

- Product & Service Excellence
- Operational Excellence
- Organizational Excellence

This AS-IS analysis resulted into 31 sustainability topics that were prioritized with a focus on Biocartis' contribution to sustainable development, taking into consideration the various categories found in the international sustainability standards such as the Sustainability Development Goals (SDGs) and the GRI (Global Reporting Initiative) and SASB (Sustainability Accounting Standards Board) standards.

In a next step the prioritized sustainability topics were used as input to the materiality matrix. The matrix visualizes Biocartis priority topics as shown below:



The priority topics in the right upper corner of the materiality matrix were then translated into the 3 core and 3 supporting topics:

In the first half of 2023, Biocartis will further translate these materiality topics in a multi-year sustainability action plan; focusing on 9 of the 17 Sustainability Development Goals (SDGs).

A key element of this action plan will address Biocartis approach to baselining, measurement, action planning, reduction, and reporting of Scope 1, 2 and 3 Greenhouse Gas Emissions, in line with the Greenhouse Gas (GHG) Protocol.

The current sustainability approach focuses on 6 Sustainability Development Goals (SDGs) with progress reported on each of these SDG's as summarized below:

SDG 3: Ensure healthy lives and promote well-being for all at all ages

Enabling personalized medicine for patients worldwide through rapid, easy & highly accurate MDx testing.
In 2022:

- Installed base of 2,085 Idylla™ instruments
- Instrument Registration in China in September
- Commercial cartridge volume of 321k cartridges
- SkylineDx Launch in September
- HepatoPredict launch in October
- MSI CDx approval Japan in October

Investing in the health and well-being of all staff members
In 2022:

- Globetrotter Challenge resulting in 248 trees planted in collaboration with BOS+
- Lunch boxes made from sustainable materials
- Healthy Habits for operators related to 'sleep' – 'positive mindset' – 'rest/recuperation'
- After two years of COVID related absence, the Fruit@Work initiative has been relaunched
- Boost my lifestyle – AG Health
- Sponsoring this year's Music for Life initiative against poverty

SDG 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all

Promoting lifelong learning of its employees
In 2022:

- 18,630 training hours amongst others through an integrated Quality Management System
- On average 46 training hours per employee

SDG 5: Achieve gender equality and empower all women and girls

A balanced gender diversity
In 2022:

- 420 employees across more than 30 nationalities
- 53% women – 47% men balanced gender diversity

SDG 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation

Delivering growth
In 2022:

- Revenue from product sales and Idylla™ system services amounted to EUR 42.2m, a year-over-year increase of 27%
- + 40% Idylla™ cartridge volume or 323k cartridges sold
- + 331 Idylla™ instruments added to the installed base

SDG 13: Take urgent action to combat climate change and its impacts

Reducing our environmental impact
In 2022:

- Yield improvement ML2, transfer of products from ML1 to ML2 such that ML1 can be discontinued in 2023
- Energy efficiency audit conducted, and plan defined to implement recommendations
- More detailed measuring tools implemented to better understand consumption and actions defined to impact / reduce consumption
- Increased awareness within the organization to measure carbon footprint scope 1, 2 & 3. External party defined to support Biocartis in this exercise

SDG 17: Strengthen the means of implementation and revitalize the global partnership for sustainable development

Building a global Idylla™ ecosystem with partners
In 2022:

8 events were announced:

- Feb - Ophiomics new deal
- Apr - Merlin study published
- Apr - IXP publications ECCMID
- June – Astra Zeneca agreement
- Sep – Idylla Instrument registration China
- Sep - SkylineDx launch,
- Oct - MSI CDx approval Japan
- Oct - HepatoPredict launch

3.2. Code of conduct

With activities in over 70 countries worldwide, in 2018 Biocartis established a Code of Conduct to assist its employees in making ethical decisions which comply with applicable laws, regulations and codes when conducting Biocartis' business and when interacting with stakeholders (including colleagues, business partners, suppliers or other third parties).

Principles

Conduct at Biocartis is based on several principles, including:

- Non-Discrimination, respect, diversity and inclusiveness: Biocartis does not tolerate any form of harassment, or any form of discrimination based on, among others, race, sex, age, nationality, ethnic background, skin color, political persuasion, sexual orientation, religious conviction, social background or disability. Biocartis values the diversity of its workforce and encourages professional behavior where people treat each other with dignity, fairness and mutual respect.

- Respect for human rights: Biocartis strives to ensure that the activities within its sphere of influence do not negatively impact fundamental human rights, as set out in among others the core conventions of the international labor organization (ILO), both directly and through the Biocartis business relations. This includes but is not limited to the principles set out in the ILO conventions regarding the freedom of association and protection of the right to organize, the abolition of forced labor, minimum age, equal remuneration and non-discrimination.

- Freedom of opinion, speech and association: Biocartis respects the right of employees to choose to join a union, provided that applicable law is complied with. Biocartis engages in constructive dialogue with its employees and their representatives and recognizes that every employee is entitled to freedom of opinion, expression and speech.

- Financial and scientific integrity: Biocartis requires that its employees uphold the highest degree of integrity, reliability and accuracy when drafting financial statements, performing research activities or developing products.

- No bribery or fraud: Biocartis does not permit any employee to commit any form of bribery or participate in any form of fraud or money laundering or induce another employee or third party to do so.

- Ethical marketing practices: Biocartis strives to market and sell its products in compliance with all applicable rules and regulations, and in line with high ethical standards. In this respect, Biocartis also adopted a Code of IVD Compliance which provides guidance for all employees with regards to all types of interactions with healthcare professionals and with the outside world.

Compliance with the code & whistleblowing procedure

Every employee is provided with a copy of the Code of Conduct at the start of his or her contractual relationship with Biocartis and every time the code is revised thereafter (and at least every two years), and employees receive training on it. All employees are required to review the code and sign an acknowledgement with respect thereto.

A whistleblowing procedure exists within Biocartis as every employee is strongly encouraged to report any actual or potential breaches of the Code of Conduct or any applicable laws, regulations, policies, guidelines or procedures, and no retaliation against such employee will be taken by Biocartis merely because of the whistleblowing. The employee can report such breach with its manager, the Compliance Officer (being the Biocartis CFO) or the Chairman of the Audit Committee, depending on the circumstances. Reports can be made anonymously and upon receipt of a report an investigation of the report is initiated to resolve the matter as quickly as possible. All reports and/or related actions and status is reported in an internal whistleblowing register which is presented to the Audit Committee or Board of Directors for discussion and resolution.

In 2020, 2021 and 2022, no reports were filed in accordance with the whistleblowing policy. Biocartis did not have any legal proceedings associated with bribery or corruption. An update of the Code of Conduct and the whistleblowing procedure is planned early 2023.

Business continuity - Biocartis has established several business continuity workstreams that aim at establishing appropriate processes and procedures to ensure business can continue, even in adverse circumstances, and which enable us to respond to unexpected events. This includes risk assessments with regards to incident management within the domains of IT, manufacturing and supply chain. In 2022, particular attention was given to elimination of a limited amount of upstream supply risks associated with the Ukraine crisis.

3.3. Product responsibility

Ethical marketing

Both in its Code of Conduct and in its Code of IVD Compliance, Biocartis included the principle of ethical marketing in which it states to strive to market and sell its products in compliance with all applicable rules and regulations, in accordance with high ethical standards. The Biocartis Code of IVD Compliance provides guidance for all employees with regard to all types of interactions with Healthcare Professionals and with the outside world and with regard to legal use of human biological material. This includes the granting of research grants, educational grants, charitable donations, the provision of training and/or demonstration or evaluation of products, the offering of gifts and entertainment to Healthcare Professionals, the organization of sales and promotional meetings, the visits to Healthcare Professionals by sales representatives, the diffusion of scientific or advertising material, the invitation of Healthcare Professionals to Biocartis organized scientific events (internal events) and to third party organized scientific events (external events), the vigilance requirements and the incident reporting obligations and the collecting and handling of human biological samples. The key principle is that offering or granting any gift or advantage to Healthcare Professionals to encourage the purchase, prescription or use of medical devices is prohibited and that the use of human biological samples is subject to specific legal requirements.

Biocartis Biobank - The Biobank of Biocartis manages the acquisition and use of Human Biospecimen necessary for all research and development activities within Biocartis. The biobank is notified to the Federal Agency for Medicine and Health products of Belgium (FAMHP) and safeguards all aspects required in the management of Human Biospecimen in accordance with the Belgian biobank legislation and international standards of ethics and protection of privacy and personal data and the General Data Protection Regulation (GDPR). In 2022, the biobank registered more than 14,000 samples (clinical and reference materials) and shipped more than 3,000 samples worldwide. Finally, in 2022, process improvements were implemented with respect to the qualification of suppliers of Human Biospecimen as well as to the more accurate identification and selection of Human Biospecimen for use in development projects. Several agreements were reached with the Ethics committee of the AFMHP enabling adherence to the increasingly stringent application of applicable laws.

Furthermore, the Biocartis Code of IVD Compliance also describes the prohibition of any form of promotion of use of IVD products which may deviate from the intended purpose described in the Instructions for Use (IFU's) or promotion of RUO products for clinical use. When advertising its products, Biocartis commits to not mislead the audience as to the intended purpose of its products. Adherence to the Biocartis Code of IVD Compliance is monitored by the Biocartis Regulatory Affairs and Legal Department and by the Compliance Officer. Training is provided at a minimum every two years to all employees with roles in which they interact with doctors and hospitals for any reason.

As Member of Medtech Europe, Biocartis also closely follows the 'Medtech Europe Code of Ethical Business Practice Guidelines' and the reporting obligations. The overview of the reporting is as follows:

2020	2021	2022
EUR 0*	GBP 2000	**

* Reporting for 2020 was EUR 0 due to government shutdown related to the COVID-19 pandemic

**Reporting for 2022 will be uploaded in August 2023. An overview of payments made in line with the Medtech Europe reporting can be found on the website of the Transparency Medtech *here*

Furthermore, since 2017, Biocartis complies with the legal obligation to disclose premiums and benefits granted to Healthcare Professionals, Healthcare Organizations and/or Patient Organizations according to the Belgian beMedtech reporting requirements.

2019	2020	2021	2022
EUR 11,035.25	EUR 3,206,6	EUR 4,870	*

*Reporting for 2022 will be completed in 2023. An overview of payments made in line with the Belgian beMedtech reporting can be found on the website of the Belgian Transparency Register *here*.

In France, Biocartis complies with the transparency obligations required by the French Public Health Code. Biocartis has reported the following payments starting from 2017:

2017	2018	2019	2020	2021	2022
EUR 12,000	EUR 36,919	EUR 19,598	EUR 10,700	EUR 2,575	EUR 3,654

An overview of payments made in line with the French Public Health Code can be found *here*

In the US, Biocartis has taken the necessary actions since 2018 to ensure transparency on certain payments or other transfers of value provided to US physicians or teaching hospitals and other research entities in accordance with the US Sunshine Act. An overview of payments made in the US can be found below:

2019	2020	2021	2022
USD 986.99	USD 0*	USD 521.31	**

* Reporting for 2020 was EUR 0 due to government shutdown related to the COVID-19 pandemic

**Reporting for 2022 will be completed in 2023. An overview of payments made in line with the US Sunshine Act can be found on the website of the US Federal Government 'Open Payments Data' *here*.

Biocartis has never been subject to any legal proceedings associated with misleading or inaccurate marketing claims.

Quality and product safety

Quality

Quality plays a crucial role in Biocartis' ambition to enhance the healthcare outcome for patients through the use of its unique Idylla™ products.

- We have established a Quality Management System (QMS) which provides a framework to consistently develop, manufacture and deliver safe, effective and compliant products (i.e. product quality)
- Key processes for the management of product quality are defined in a Quality Manual, described in procedures and work instructions and deployed throughout the organization.
- The CEO has ultimate responsibility for Quality. He has delegated the daily management to the Head of Quality, who also oversees that all employees understand their own responsibilities within their work areas to help ensure that Quality is embedded within the entire company
- Biocartis complies with the following international standards and regulations:
- Regulation (EU) 2017/746 of the European Parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices (IVDR) and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (IVDR)
- Full set of MDSAP regulations (Australia, Brazil, Canada, Japan, USA FDA 21 CFR part 820)
- ISO 13485:2016 (Medical devices—Quality management systems—Requirements for regulatory purposes)
- EN ISO 14971:2019 (Medical devices—Application of risk management to medical devices)

- EN IEC 62304:2006 (Medical device software—Software life cycle processes)
- EN IEC 62366:2015 (Medical devices—Application of usability engineering to medical devices)

In 2022, we achieved recertification of the Biocartis QMS against the IVDR requirements. We also successfully passed surveillance on our certification against the ISO 13485:2016 standard and full set of MDSAP regulations (Australia, Brazil, Canada, Japan, USA).

Product safety

In line with the abovementioned international standards and regulations, safety, effectiveness and compliance of our products is fully embedded in our product realization processes. The expectations from a safety, customer and regulatory point of view are defined at the onset of product development and serve as input for product design. Product performance in relation to these needs and requirements is subsequently verified and validated, and corresponding performance specifications and residual risks are disclosed to the customer. Production, purchasing and service controls further safeguard that each manufacturing lot up to delivery to the customers is safe and effective.

We are committed to continuous improvement. The Quality management system includes key processes for measuring and improving performance of our products and processes and to leverage customer feedback for continuous improvement.

- Biocartis has established an Internal Audit Program to verify compliance with the QMS, the planned arrangements for product realization, the requirements from relevant standards and regulations and internal processes
- A Post Market Surveillance process is in place to measure and evaluate on-market performance of our products
- Every employee at Biocartis is obliged to report potential issues related to the safety or effectiveness of our products and any deviation from our processes
- When a customer reports an event, we immediately register the event and assess patient safety in relation to the known safety profile of the product. In case of an adverse event, product recall processes are initiated, including relevant reports to the regulatory authorities as per country-specific regulations

All feedback loops within Biocartis' process model for measurement, analysis and improvement have been set up to interface with the determination of corrective and preventive actions to eliminate the cause of potential nonconformities and feed the continuous improvement process.

The suitability and effectiveness of our Quality Management System to ensure safe and effective products is reflected by our solid on- market product performance: 1 product recall in 2022, 0 product recalls in 2021, 1 in 2020. For none of these cases, patient harm was confirmed.

To ensure that every Idylla™ product is both effective and safe, we have established a systematic process designed to optimize safety throughout the lifecycle of an Idylla™ product. Clinical trials provide important information on the clinical value of a diagnostic test during the clinical management of a patient. They are essential to determine whether diagnostics are safe and effective when used.

- We conduct each trial according to a comprehensive plan or protocol and Good Clinical Practice (GCP) guidelines that regulators require in order to protect patient safety. The plan outlines the patient population to be tested, the type(s) of specimens to be evaluated and the endpoint used to determine acceptable performance of the diagnostic test when compared to other state of the art devices.
- After rigorous testing and data analysis by Biocartis biostatisticians, clinical, medical and regulatory professionals, the information is shared with regulatory authorities, such as the US Food and Drug Administration, Competent Authorities in the EU and local agencies from other countries to obtain marketing approval.

Cybersecurity

In an increasingly digitized world, Biocartis' management is committed to keep information secure and private, specifically when dealing with sensitive patient information entrusted to Biocartis by its customers. Personal data accessible to Biocartis employees is highly pseudonymized, meaning re-identification is virtually impossible. Moreover, Biocartis can only act by means of documented instructions, meaning that the customer will always be in charge of determining the purposes and the means of processing patient information.

To enhance the protection of personal data, Biocartis installed a wide range of technical and organizational measures and implemented an Information Security Management System (ISMS) according to the ISO 27001 certification standard. The main goal of the ISMS is to protect Biocartis' information assets against all internal, external, deliberate, or accidental threats.

The ISMS aims to:

- Foster a company culture with a high level of information security awareness and maturity
- Assure and maintain a high level of compliance with business, legal, and contractual requirements, and data protection regulations
- Receive from customers a high level of confidence and trust in Biocartis information security management practices

Our commitment to information security warrants that:

- Technical and organizational measures shall be put in place and appropriately kept up to date to protect information assets, driven by business needs, in accordance with the reference controls as stated in the ISO 27001 standard applicable to Biocartis
- Data protection requirements shall be captured and serve as input requirements to the design stage of each product.
- Information security awareness training shall be provided to employees and all relevant controls, policies, and procedures shall be regularly communicated through team meetings and briefing documents
- Procedures shall be put into place to correct and prevent any deviations and information security incidents

Biocartis strives for a high standard in data protection by continually monitoring and improving the effectiveness and efficiency of the ISMS. To this purpose, the following has been put in place:

- Risk assessments, risk treatment plans and the associated mitigating information security controls are reviewed on a regular basis
- Information security objectives and related KPIs are defined and monitored regularly as part of management reviews
- Ideas for continuous improvement are proactively obtained and reviewed for implementation as part of management reviews
- Employee awareness and training initiatives were set up including employee awareness campaigns such as the sending of 'mystery' phishing emails and information security classroom trainings
- A disaster recovery procedure has been put in place
- In terms of third-party vulnerability analysis including simulated hacker attacks, Biocartis has performed several penetration tests on the Idylla™ Console device and Idylla™ Explore web application. These activities have been

initiated in the context of a continuous effort to improve the cyber security and vulnerability status of Biocartis' products and added value services

- Biocartis has worldwide insurance coverage for information security breaches or other cybersecurity incidents

From a governance point of view, Biocartis' Information Security Officer manages the set-up and management of the ISMS and reports to the Head of IT who reports directly to the Chief Operations Officer. In 2022, Biocartis obtained the ISO 27001 certification for the design, development, maintenance, service provision and support of the Idylla™ platform and associated customer-facing software.. The scope includes Biocartis' Belgian and US offices and relates to its commercial products, services and support, covering both Biocartis' cloud production environments used by customers and partners ('primary assets') as well as Biocartis' office infrastructure such as its network, systems, devices and applications ('supporting assets').

	2020	2021	2022
Total number of personal data breaches	1	0	0
Total number of customers and employees affected by company's personal data breach	No third-party impact	N/A	N/A

In 2022, Biocartis continued the further fine-tuning of its information security processes, including monitoring, reporting and awareness raising around the topic.

3.4. Employees

"In this new post-pandemic world of remote and hybrid working regimes, we continued to pivot our people strategy to meet new challenges and keep our employees thriving."

Susy Spruyt, Head of People & Organization Biocartis

People strategy

Operating at the intersection of technology and molecular diagnostics, attracting, developing and retaining a diverse, global team of highly skilled employees is what makes Biocartis grow and thrive. Therefore, Biocartis encourages a work environment that empowers all of its employees. The Biocartis HR strategy is supported by five pillars:

1. A competency-based approach that supports our strategic objectives. Core behavioral competencies, cross-functional teamwork, accountable and a result-driven approach while striving for innovation and continuous improvement, using the right quality mindset and focus on the customer
2. A management structure where employees are accountable and empowered to take decisions at the right level, with fast escalation for issue resolution when needed
3. A focus on project execution skills including competences in clinical validity, regulatory compliance, and quality
4. A succession planning and talent acquisition program
5. A learning & development framework that challenges employees to grow every day

In 2022, we further progressed our HR strategy with key developments in:

- Initiatives to propagate the company strategy and to embed it in day-to-day practices across the entire organization
- Adoption of the hybrid way of working within our organizational matrix structure
- Further developing our Learning & Development program with new competencies and skills
- Improving our workforce and succession planning
- Adoption of a hybrid way of working within our organizational matrix structure
- Anchoring various wellbeing initiatives into our people strategy
- Streamlining the organizational structure to withstand the impact of the current economic environment

Diversity

With 420 employees of over 30 different nationalities across more than 20 countries at the end of 2022, Biocartis displays an inclusive company culture where every employee is valued, heard and empowered as an individual belonging to a community that is passionate about bringing rapid and easy molecular diagnostic solutions to patients across the world. Biocartis does not

tolerate any form of harassment or discrimination based on, among others, race, sex, age, nationality, ethnic background, skin color, political persuasion, sexual orientation, religious conviction, social background or disability. Biocartis values the diversity of its workforce as it brings diverse perspectives and strong teamwork to deliver better solutions to our customers across the globe.

In 2022, the gender split across Biocartis remained relatively stable with 47% men and 53% women. In management positions we counted 38% women, a slight increase from 37% in 2021.

Biocartis has several programs ongoing that promote flexible working regimes including parental leave, different (full or part time) working regimes and increased flexible working measures. Since the pandemic, Biocartis accelerated its transition to a hybrid way of working, providing more flexible work options for our employees.

Gender wage gap

Although the gender pay gap measures a broader concept than pay discrimination alone, and is also connected to e.g., the industry or overrepresentation of women in relatively low-paying sectors, it is important for companies to monitor and improve their gender balance.

In the development of its Compensation policy, Biocartis makes use of a compensation structure that combines pay grades with benchmarking methods, independent of gender or other diversity characteristics.

Corporate citizenship

Every year, Biocartis employees join forces in November and December to fund-raise for a good cause. In 2022, the Biocartis employee volunteering teams got together to serve soup, desserts, or Tajine lunches on site in Mechelen for the benefit of 'the Warmest Week', a non-profit project organized in Flanders, Belgium. Some of the sportier colleagues also gathered to run a locally organized 'Warmathon' on 22 December 2022.

Training & development

Biocartis cultivates learning and career development not only as an integral part of the employee experience but also as a fundamental building block of our continuous growth. Learning & development activities include:

- For new employees: welcome days are often organized in a hybrid way, physical and virtual. 17 sessions were set up in 2022
- For existing employees:
  - In collaboration with a reputable business school, several initiatives were taken to enhance strategy formulation and planning for execution at managerial level
  - Through the Biocartis Academy, the company's core learning & development program, we continued to offer training programs with a focus on business & financial acumen, process ownership, leadership development and communication skills. These programs are rolled out across different functions within Biocartis
  - Biocartis also offers open learning through a.o. Learn & Grow sessions, and ad hoc expert speaker events led by key opinions leaders
  - On an individual level, employees can define a personal learning & development path together with their manager, which is based on goals, competence, and career development
  - Leadership development: Since 2020, Biocartis has an active Leadership development program addressing talented employees to support them in their career growth. In 2022, 30 employees followed a Leadership training including modules on leadership styles, connecting & feedback, and dealing with change
  - In 2020, Biocartis implemented an online tool to facilitate regular employee engagement meetings and create a forum for giving and receiving feedback across functions. In 2021, a Learning Management System (LMS) module was added, making trainings, tutorials, webinars, etc. accessible for employees. In 2022, more than 300 employees attended a variety of facilitator-led and e-learning trainings via the LMS platform

Employee wellbeing

At Biocartis, we promote wellbeing and recognize the importance of a positive physical and mental health environment in the workplace to enable our people to thrive. Being active in a rapidly changing environment which requires agility and resilience, Biocartis has increasingly focused on the wellbeing of its employees in the past years. By empowering our employees to be the best version of themselves, especially in pandemic times, we help everyone to work safely and effectively.

Looking ahead at how work will continue to change, we further progressed the initiatives to support employee wellbeing based on the pillars: My Body, My Mind, My Connections, My Environment.

Through the wellbeing program 'My Health Partner' we continued to offer a series of educational programs and workshops focused on social, physical, and mental health, and covering specific topics such as nutrition, stress management, burnout, sleep and professional development. In 2022 we participated to the Globetrotter Challenge, a well-rounded virtual experience, putting the four pillars of My Body, My Mind, My Connections, My Environment at work for the good cause of planting trees with BOS+.

Biocartis also received the certificate of Pioneering Employer 2023 ("Baanbrekende Werkgever 2023") through the completion in 2022 of a learning path that was focused on hybrid working and sustainable mobility.

Flex income plan

In 2022, Biocartis continued to add new options to the Flex Income Plan (FIP) that was launched in 2021. By offering a Flex Income Plan, employees have the possibility to tailor a part of their salary package to their personal healthcare and hybrid working needs. Benefits added are primarily related to alternative mobility, multimedia and educational programs related to wellbeing.

Health & safety

Biocartis is committed to invest in a safe, healthy workplace, while operating in an environmentally responsible manner through several tools & activities:

- The Biocartis Health Safety and Environmental (HS&E) Policy aims at compliance with HS&E regulatory requirements and to be able to demonstrate our compliance at any time.
- Through a dynamic risk assessment, Biocartis strives to continuously reduce health and safety risks.
- Biocartis fosters an HS&E culture by following up and analyzing key HS&E performance indicators, such as accidents and unsafe conditions.
- Biocartis welcomes ideas from employees on how to improve safety and implements these where found appropriate
- Biocartis also commits to train and inform all its employees, contractors, visitors and partners worldwide to ensure safe working is possible through the understanding and respecting of safety rules, through the preventing of safety risks in every business initiative, and through the active tackling of unsafe conditions towards continuous improvement
- A cross-functional HS&E leadership team has the governance over this HS&E Policy

In 2022:

- Biocartis invested into an internal HSE team consisting of 2 FTEs: one senior HSE Manager and one Safety Advisor. Besides this, there is still support of external specialists in case a specific expertise is not available within the HSE team, such as a company doctor, psychologist, environmental specialist, biosafety expert.
- A detailed review against Belgian safety law was performed. No major legal HS&E regulation breaches were found, nor were any breaches reported during 2022.
- Biocartis employees followed several virtual H&S trainings, including basic rescue trainings, first-aid refreshment trainings, fire safety & spill training and machine & electrical safety.

Four occupational accidents with minor injuries occurred in 2022. There were no lethal accidents or working accidents causing disability. This translates into a severity rate of 0, which is a decrease versus 2021 and below average of our industry. A continued effort during the monthly 'walks & talks' (Gemba walks) resulted in a significant increase of reporting on unsafe situations. Findings are closely followed up to continuously improve safety.

KPIS

Workforce

Status as per 31 Dec	2020	2021	2022
Total number of employees (FTE)	**366.3**	**407.1**	**420.2**
Biocartis Group NV	21.0	23.5	23,9
Biocartis NV	300.9	341.8	347,2
Biocartis US, Inc.	44.4	39.2	46
Biocartis Italy srl	0	2.6	3,1
Total number of employees (FTE) by gender	**366.3**	**407.1**	**420.2**
Male	182.4 (50%)	201.9 (50%)	199.1 (47%)
Female	183.9 (50%)	205.2 (50%)	221.1 (53%)
Total number of employees (FTE) by level[56]	**383.8**	**427**	**414.3**
Management positions[57]	64.3	69.1	77.4
Other employees	319.5	357.9	336.9
Total share of women in management positions	**43%**	**37%**	**38%**
Total number of employees (FTE) by age group	**366.3**	**407.1**	**420.2**
Under 30	31.2	48	47
30-50	249.2	275.6	289.2
Over 50	85.9	83.5	84
Average age workforce	**42.3**	**41.3**	**41.7**
Average age in management positions	**44.4**	**44.3**	**45.4**
Total number of employees (FTE) by work regime	**383.8**	**427**	**414.3**
Full time	355 (92%)	389 (91%)	381 (91%)
Part time	28.8 (8%)	38 (9%)	33.3 (8%)
Total number of new fixed employee hires	**94**	**106**	**67**
Total number of fixed employee departures	**56**	**58**	**77**

Training

	2020	2021	2022
Total training hours followed by employees	(*)	15,842	18,630
Share of employees who benefited from a training during the financial year (training ratio all employees)	(*)	95%	96%
Average number of training hours per employee	(*)	32	46
Share of employees who had an individual engagement conversation	(*)	88%	90%

(*) No data available for 2019 and 2020 due to change in the reporting scope (reporting scope 2019-2020 only included employees on the Belgian payroll)

Health & safety

	2020	2021	2022
Absenteeism rate (in % as nr of absenteeism days versus total working days)	4.25%	4.24%	4.63%
Accident frequency rate (Number of lost time accidents x 1,000,000 / number of hours worked, for fixed employees)	2.07	17.0	3.65
Accident severity rate (Number of days lost to accidents or occupational diseases x 1000 / number of hours worked, for fixed employees)	0.09	0.19	0

3.5. Climate change and environment

Climate change causes extreme natural events, deviations in temperatures and precipitation patterns, and rising sea levels. Biocartis acknowledges it has a role to play in the reduction of its environmental footprint. The ongoing transition to a lower carbon economy is also presenting Biocartis with opportunities while expanding its business of decentralized molecular diagnostics solutions.

Climate change & environmental governance

At executive management level, climate change is under the leadership of our Chief Operations Officer who holds a management oversight role in all environmental related matters and reports to the board when questions on climate change or environmental related matters arise.

Climate change & environmental strategy and management

Biocartis' aim is to provide a safe and healthy work environment for its employees by systematically identifying and managing health, safety and environmental risks in its activities and proactively fostering and encouraging a culture of safe behavior. Biocartis strives to make efficient use of natural resources and to minimize the environmental impact of its activities. This is achieved through Biocartis' climate change & environmental strategy which is currently focused on compliance with a set of European, national and regional regulations covering the environmental impact of our products and their waste. In this respect, Biocartis' Environmental Management System ensures environmental compliance and keeps track of all activities reducing our environmental footprint. Operational activities are led by Biocartis' Head of HS&E and Facilities, supported by an external environmental coordinator, who is responsible to stay up-to-date with all legislative changes, actions and results.

As a medical device company producing Idylla™ instruments and cartridges, Biocartis complies with the following environmental directives addressing the environmental impact of its products and their waste:

- The RoHS[58] directive regarding the Restriction of Hazardous Substances in electrical and electronic equipment
- The WEEE directive[59] to improve the environmental management of electrical and electronic waste, contribute to a circular economy and enhance resource efficiency
- The Battery directive to protect, preserve and improve the quality of the environment by minimizing the negative impact of batteries and accumulators and waste batteries and accumulators
- The Packaging and packaging waste directive to improve recovery and recycling of packaging waste
- The REACH regulation which restricts the use of chemical substances that could have an impact on human health and the environment[60]
- The Contained Use Directive aimed at limiting contact of the environment with genetically modified and infectious microorganisms
- The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) aimed at a sustainable management of biocides and reduce the risk and impact of it on the environment and human and animal health
- The Waste Directive aimed at improving the recovery and recycling of waste
- The Energy Efficiency Directive aimed at a more efficient use of energy at all stages of the energy chain, from production to final consumption

Biocartis performed detailed review against REACH and CLP Regulation. REACH Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals) aims to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. The CLP Regulation requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately, providing relevant safety information, before placing them on the market. No major non-compliances were found.

In 2022, Biocartis successfully adjusted its environmental permit for the rebuilt of the warehouse according to 'VLAREM II - Order of the Flemish Government of 1 June 1995 concerning General and Sectoral provisions relating to Environmental Safety'.

In 2022, no significant changes in the environmental legislation occurred that had an impact on Biocartis' activities.

Operational management of climate change & environmental matters

Biocartis' largest environmental impact results from (a) the use of energy and greenhouse gas emissions (GHG) caused by cartridge manufacturing, and office occupancy, (b) waste associated with the production of cartridges, and (c) the use of water.

Energy

Scope: Biocartis NV, consisting of the company's headquarters and the cartridge manufacturing activities in Mechelen, Belgium (97% of total scope).

Description:

- Biocartis uses energy both for its cartridge production as well as its office activities.
- Due to the lack of individual energy meters in the different Biocartis buildings of the Mechelen campus, which are often shared with other companies, a detailed split registration of energy use is not possible.

Actions and results in 2022:

- Energy use: Today, Biocartis' electricity comes from 39% green and 61% grey energy sources.
- Measurement energy consumption: In August 2022, individual energy meters were installed in different Biocartis buildings of the Mechelen campus. This will give us better understanding of consumption by enabling the measurement of the effectiveness of implemented improvements, and by having a detailed understanding of the consumption including the shared buildings.
- Energy efficiency: In 2022 Biocartis completed an energy efficiency audit on site in Mechelen. Suggested improvements will be implemented during 2023.

Waste

Scope: Biocartis NV, consisting of the company's headquarters and the cartridge manufacturing activities in Mechelen, Belgium (97% of total scope)

Description:

- Biocartis' waste streams come from its cartridge production, R&D labs as well as from its office activities.
- All waste is sorted into hazardous and non-hazardous waste:

- Hazardous waste comes from its cartridge production and R&D activities and consists of individual units of, or cartridges filled with chemicals, medical waste and chemicals (solvents, acids, bases). Different types of Idylla™ cartridges use a different mix of raw materials. All on-site hazardous waste is collected by certified, external waste collectors.
- Non-hazardous waste consists of plastics, paper and carton, both from production activities (mainly packaging from raw materials for cartridges) as well as office waste.

Actions and results in 2022:

In tons	2020	2021	2022
Hazardous waste	**24.3**	**33.5**	**37.6**
Non-hazardous waste	**86.5**	**119.2**	**96.9**

The year-on-year increase in waste is directly related to growing commercial activities and the resulting increased cartridge production. The increase in hazardous and non-hazardous waste was particularly strong in 2021 because of the fire in the warehouse facilities in the summer of 2021, and increased packaging waste related to the redesign and refurbishment of the office space following the implementation of a hybrid way of working. The amount of 2022 is more in line with 2019 and 2020 years taking the increased production into account.

Water

Scope: Biocartis NV, consisting of the company's headquarters and the cartridge manufacturing activities in Mechelen, Belgium (97% of total scope)

Description:

- Biocartis' main water use comes from office occupancy. Our cartridge production does not have any wet processes and water is only used for cooling and air moisturizing of our manufacturing clean rooms. All water used is therefore municipal water. This wastewater stream is transported through a separate sewer system to the Mechelen Noord wastewater treatment plant.
- Other wastewater originating from production or R&D is collected and sent for further treatment to certified professionals. The volumes are part of waste fraction reported in the waste section.

Actions and results in 2022:

m^3/year	2020	2021	2022
Water use	**1,611**	**1,620**	**1,297**

Greenhouse Gas Emissions (GHG)

Scope: Biocartis NV, consisting of the company's headquarters and the cartridge manufacturing activities in Mechelen, Belgium (97% of total scope). No information is available on emissions from US locations.

Description:

- Biocartis' main GHG emissions come from its use of gas and electricity.
- GHG emissions include emissions both from cartridge production as well as from office occupancy.

Actions and results in 2022:

In tons CO_2	2020	2021	2022
GHG emissions from production and office activities	**137.9**	**144.2**	**111**
GHG emissions from employee business travel - flights	**256**	**171**	**560**

After a decrease of GHG emissions in 2020 because of the pandemic, they slightly increased again in 2021 since more employees came back to the office and cartridge production increased. Furthermore, employee travel decreased strongly in 2020 and in 2021 due to pandemic related travel restriction. In 2022 there was a shift in production from manufacturing line ML1 to the more efficient manufacturing line ML2, leading to a reduction in shifts and thus less on-site occupancy.

Electric mobility

In 2021, Biocartis launched its electric mobility project with a first focus on electric bicycle leasing and the expansion of the offering of reimbursement of kilometers travelled by (electric) bicycle, now also for employees that have a company car. This resulted in a significant increase of 77,990 kilometers travelled by bicycle in 2022, or 190,706km compared to 112,716 km in 2021. Biocartis aims at gradually greening the Biocartis employee car fleet towards a 100% green fleet. The goal is to have a zero emission for cars that are ordered from 1 January 2026. The following table provides the evolution of maximal allowed emissions, according to WLTP norm, when ordering a new car in a specific year.

Year	Max CO_2 emission (WLTP norm)
2022	**100**
2023	**60**
2024	**40**
2025	**25**
2026	**0**

3.6. Supply chain

Our suppliers are critical to delivering on our mission. Biocartis' global supply chain consists of approximately 30 suppliers of various materials, our manufacturing site in Mechelen (Belgium) as well several service providers and sub-contractors.

- Most of Biocartis' direct suppliers are based in Europe, including its subcontractor who manufactures the Idylla™ instruments and console.
- In 2022, Biocartis had 1 direct supplier based in China. Additionally, our joint venture WondfoCartis is based in China.

Biocartis is working closely with its direct suppliers to ensure that they meet Biocartis' requirements in terms of quality, safety and environmental compliance. Business Continuity remains a key area of focus and continuous improvement to minimize the risk of disrupted supply and to ensure the continuity in the manufacturing and sale of Idylla™ instruments and cartridges.

Post the pandemic, Biocartis' successful efforts to overcome the impact of globally disrupted supply and to ensure the continued supply of Idylla™ products to its customers included:

- Strengthening the governance around the internal sales and operations (S&OP) planning focusing on close alignment of demand and supply
- Re-establishing inventory levels of raw materials and finished goods to ensure consistent supply to partners and customers
- Installation of a supply chain monitoring system (OTIF, on time in full) to measure performance of supply to customers
- Working closely with main suppliers to further improve our ability to respond quickly to changing demand

Supplier risk assessments, evaluation and approval process

In accordance with quality requirements, Biocartis installed a rigorous Supplier Approval Process for its direct suppliers since the start of Biocartis' commercial activities. As part of the approval process of suppliers, Biocartis applies a risk-based approach to screen on several criteria, with a high focus on quality, including the verification of ISO certificates, safety and compliance with environmental legislation such as ROHS3 on the Restriction of Hazardous Substances or REACH legislation on the restriction of chemicals and the European Directive on Waste Electrical and Electronical Equipment (WEEE). An evaluation of suppliers is performed and reviewed together with the supplier.

Biocartis today has not set specific social or environmental targets with its suppliers but considers it business-critical to work with suppliers who share our commitment to integrity. In 2023, Biocartis intends to extend its Supplier Approval Process and include additional ethical and environmental criteria. Similarly, the Code of Conduct will be updated to a higher ethical standard, such as the Modern Slavery Act.

Supplier audits, business reviews and dialogue

Our direct supplier approach is underpinned by the implementation of supplier audits. Every year, an audit plan is established, and several supplier audits are executed to ensure all materials meet expectations for technical specifications and quality. Biocartis' key direct suppliers are submitted to an annual Supplier Business Review. Furthermore, Biocartis actively monitors the performance of its direct suppliers on various topics and is continuously in dialogue to ensure they meet the required performance, such as product specification documents and audit action plans.

An average of 10 audits/year are conducted on-site or remotely. No critical observations were made during the past years.

Further key manufacturing & supply chain focus areas in 2022 included:

- Downscaling of the older manufacturing line ML1 in favor of the more efficient and automated high-throughput cartridge manufacturing line ML2
- Securing the supply of one component of our Idylla™ system affected by the war in Ukraine
- Re-establishing the on time in full (OTIF) supply performance to our customers after the fire incident that occurred in 2021 and disrupted the manufacturing of cartridges for 2 months
- Establishing a cold chain kit distribution process for certain collaboration partners

4.1. Introduction

During 2022, the Company applied the Belgian Code on Corporate Governance 2020 (the 'Corporate Governance Code 2020'), which can be consulted on the website of the Belgian Corporate Governance Committee. In accordance with the Corporate Governance Code 2020, the Company has adopted a corporate governance charter which describes the main aspects of the corporate governance of the Company, including its governance structure, the terms of reference of the board of directors and its committees and other important governance topics. The Company's corporate governance charter was last updated at the meeting of the board of directors held on 31 March 2020 to bring the corporate governance charter in line with the provisions of the Corporate Governance Code 2020. The corporate governance charter must be read together with the articles of association of the Company. The articles of association and the corporate governance charter are available on the Company's investor website.

The Company strived to comply with the rules of the Corporate Governance Code 2020 as much as possible. Nonetheless, the board of directors is of the opinion that a deviation from the provisions of the Corporate Governance Code 2020 is justified with respect to the granting of shares of the Company to non-executive directors as part of their remuneration as the Company does not own treasury shares and is currently legally not in a position to acquire treasury shares. This deviation is described below in the Remuneration Report.

4.2. Board of directors

Composition

The table below gives an overview of the members of the Company's board of directors.

Name	Position	Start of mandate	End of term
Christian Reinaudo	**Chairman, independent director**	**2018**	**2024**
Herman Verrelst(1)	**Chief executive officer, executive director**	**2017**	**2025**
Luc Gijsens(2)	**Non-executive, independent director**	**2018**	**2024**
Ann-Christine Sundell	**Non-executive, independent director**	**2018**	**2024**
Christine Kuslich	**Non-executive, independent director**	**2020**	**2024**
Bryan Dechairo(3)	**Non-executive, independent director**	**2023**	**2024**

(1) Permanently representing South Bay Ventures (SBV) BV; (2) Permanently representing Luc Gijsens BV; (3) Mr. Dechairo was appointed by the board of directors with effect as of 21 February 2023, replacing Mr. Roald Borré who resigned as director with effect as of the same date. Mr. Dechairo's appointment will be submitted for confirmation by the annual shareholders' meeting which is to be held in May 2023. The annual shareholders' meeting will resolve on the duration of Mr. Dechairo's mandate, upon proposal by the board of directors.

Christian Reinaudo joined the Company's board of directors as independent chairman in May 2018. Mr. Reinaudo started his career with Alcatel in 1978 at the research center at Marcoussis, France. In 1984, he joined Alcatel's cable activities where he became responsible for research associated with fiber optics and cable for undersea applications. In 1997, he became president of Alcatel's Submarine Networks Division. From 1999 to 2003, he was president of the Alcatel Optics Group, which comprises all activities in terrestrial and submarine transmission networking and optoelectronic components. In 2003, he was appointed president of Alcatel Asia Pacific and moved to Shanghai (China), where he stayed until 2006, also serving as vice chairman of the board of directors of Alcatel Shanghai Bell, the Chinese joint venture between Alcatel and the Chinese government. In his latest position at Alcatel, he was president Europe & North for Alcatel-Lucent and was responsible for the integration and transition process during the merger of Alcatel with Lucent Technologies. Mr. Reinaudo joined Agfa-Gevaert, a leading e-health & digital imaging solutions provider, as president of the Agfa HealthCare business group and member of the executive committee, on 1 January 2008. In 2010, Mr. Reinaudo was appointed CEO of Agfa-Gevaert (a position he held until January 2020) and became a member of the board. Mr. Reinaudo is also member of the supervisory board of Domo Chemicals Holding NV.

Herman Verrelst was appointed as chief executive officer of the Company effective as of 31 August 2017. He is a seasoned executive and technology entrepreneur with a proven international commercial track-record in molecular diagnostics. Prior to joining Biocartis, Herman Verrelst held the position of vice president and general manager of the genomics and clinical applications division of Agilent Technologies, a global leader in life sciences, diagnostics and applied chemical markets. Mr. Verrelst joined Agilent following Agilent's acquisition of Cartagenia, a spin-off of Katholieke Universiteit Leuven (Belgium) focused on software solutions for clinical genetics and molecular oncology, of which Herman Verrelst was CEO and founder. Prior to that, Herman Verrelst was CEO of Medicim, a medical imaging company acquired by Nobel Biocare, now part of Danaher, as well as founder and CEO of DATA4s, a financial services software company acquired by Norkom Technologies, now part of BAE Systems.

Luc Gijsens is a highly experienced international executive with deep knowledge in a wide range of areas in finance and capital markets, asset management, corporate and investment banking in Belgium and abroad. He served KBC Group, a leading bank & insurance group in Belgium and Central Europe for 40 years in a wide range of responsibilities. Mr. Gijsens retired from KBC Group in 2017 as CEO of the business unit International Markets and executive director of KBC Bank & Insurance, responsible for the market activities of KBC Group. He acted as chairman of the board of KBC Securities and KBC Asset Management and as chairman of the board of the banking and insurance subsidiaries in Ireland, the Slovak Republic, Hungary and Bulgaria. Prior to that, Mr. Gijsens served as senior general manager of KBC Bank, responsible for corporate banking in Belgium, Western Europe, Asia Pacific and the US.

Ann-Christine Sundell has more than 30 years of experience in the diagnostics and life science sector, where she held various global senior positions. For 10 years she served as president for the Genetic Screening (diagnostics) strategic business unit within PerkinElmer, one of the world's leading life science companies. Mrs. Sundell has deep strategic and operational experience from building, developing and managing global growth businesses. She serves on several boards and board committees, and holds an MSc in biochemistry from Åbo Akademi, Turku, Finland.

Christine Kuslich, PhD, is an in vitro diagnostic senior executive and strategic leader with a particular focus on advancing clinical diagnostics, novel assay and device development as well as quality executive leadership. As a passionate inventor with more than 40 pending and issued patents, Dr. Kuslich has a proven track record of identifying and developing new technologies with the greatest market potential with particular focus on the oncology diagnostics and therapeutic spaces. Dr. Kuslich held several positions as Chief Scientific Officer developing breakthrough diagnostics at companies including Hologic, GE Healthcare and Caris Life Sciences. Her areas of expertise include medical device development & commercialization, companion diagnostics, molecular profiling in oncology and circulating tumor detection and sequencing technologies. Dr. Kuslich holds a Ph.D. degree in Genetics from the University of Hawaii John A. Burns School of Medicine and a B.S. degree in Microbiology from Arizona State University.

Bryan Dechairo is the chief executive officer of Sherlock Biosciences, and also serves on its board of directors. He has more than 25 years of experience developing and commercializing revenue generating clinical innovations that improve patient lives. Prior to joining Sherlock Biosciences, Mr. Dechairo served as executive vice president of clinical development at Myriad Genetics, where he oversaw the development portfolio, delivering business-critical evidentiary data for value-based reimbursement and market acceptance of commercial and novel diagnostic products across six business units globally. Before joining Myriad Genetics, he was chief medical officer, chief scientific officer and senior vice president of research and development at Assurex Health, which was acquired by Myriad in 2016. During his extensive career, Mr. Dechairo held roles of increasing responsibility at Medco, Pfizer, Oxagen, Sequana and Roche, where he established a proven track record of funding and scaling businesses from venture backed start-ups to profitable fortune 50 public companies. He also authored more than 50 academic and research-based publications, and earned a Ph.D. in Common Complex Human Genetics from the Institute of Child Health at University College London and a B.A. in Integrative Biology from the University of California, Berkeley.

The business address of each of the directors for the purpose of their mandate is Generaal de Wittelaan 11B, 2800 Mechelen, Belgium.

Procedure for the appointment of directors

The directors are appointed for a term of maximum four years by the general shareholders' meeting. They may be re-elected for a new term. When a legal entity is appointed as director, it must appoint a permanent representative charged with the performance of the mandate in the name and for the account of the legal entity-director. This permanent representative must be a natural person. In the event the office of a director becomes vacant, the remaining directors can appoint a successor temporarily filling the vacancy until the next general shareholders' meeting. The general shareholders' meeting can in principle dismiss the directors at any time.

Changes to the composition of the board of directors

The annual shareholders' meeting held on 13 May 2022 reappointed Ann-Christine Sundell, Christine Kuslich, and Luc Gijsens BV, permanently represented by Luc Gijsens, as independent directors, and reappointed Roald Borré as non-executive director, for a term of two years, up to and including the closing of the annual shareholders' meeting to be held in 2024 which will have decided upon the financial statements for the financial year ended on 31 December 2023. The shareholders' meeting also confirmed the appointment of South Bay Ventures (SBV) BV, permanently represented by Herman Verrelst, as executive director for a term of three years up to and including the closing of the annual shareholders' meeting to be held in 2025 which will have decided upon the financial statements for the financial year ended on 31 December 2024.

Diversity

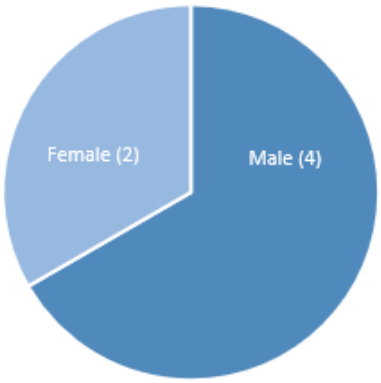
The board of directors must be composed in a manner compliant with the diversity principles applicable to listed companies. Moreover, the board aims to be composed in a manner that allows it to support in all relevant material aspects the success of Biocartis as a commercial-stage innovative molecular diagnostics company that operates internationally. Four main diversity criteria have been identified by the board of directors: functional background and expertise, gender, age and nationality/international experience. The board will reassess these criteria as often as required.

Name	Functional background and expertise	Gender	Age	Nationality
Christian Reinaudo	**E-health & digital imaging solutions Managing companies International business**	**Male**	**68**	**France**
Herman Verrelst(1)	**Molecular diagnostics Software solutions Entrepreneurship**	**Male**	**49**	**Belgium**
Luc Gijsens(2)	**Finance Capital markets Corporate and investment banking**	**Male**	**69**	**Belgium**
Ann-Christine Sundell	**Life sciences Diagnostics Strategy and operations**	**Female**	**58**	**Finland**
Christine Kuslich	**Molecular diagnostics Oncology & Infectious disease Strategy & investment**	**Female**	**55**	**USA**
Bryan Dechairo(3)	**Business and R&D strategy Molecular Diagnostics Market Access and Reimbursement**	**Male**	**50**	**USA**

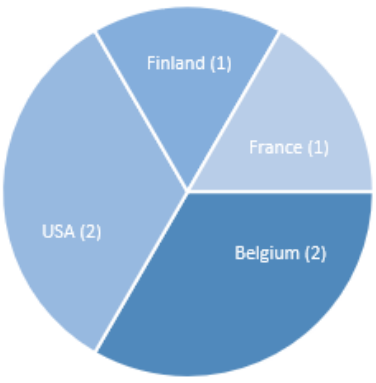
(1) Permanently representing South Bay Ventures (SBV) BV; (2) Permanently representing Luc Gijsens BV.

Belgian company law requires at least one third of the directors of a listed company to be of a different gender than the other directors. Currently, the Company has two female directors on its board of directors on a total of six directors. The board is of the opinion that there is currently sufficient diversity in terms of age. It however believes that in terms of 'functional background and expertise' it could benefit from additional profiles with relevant industry background and expertise in other go-to-market models, partnering and/or diagnostic service models, digitalization and/or AI.

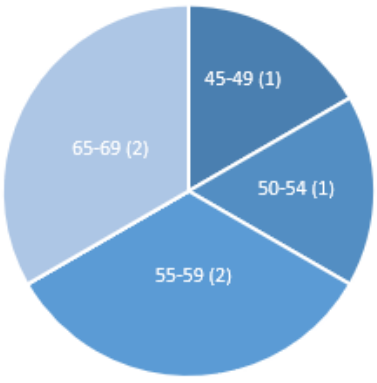
Gender



Nationality



Age



Activity report

In 2022, the board of directors held twelve meetings. The attendance rate (i.e. the attending of board meetings in person or by written proxy to a fellow director) for the board members in function as at 31 December 2022 was 100%, save for Roald Borré who was excused during one board meeting (illness).

During the meetings of the board of directors, the board among others discussed Biocartis' financing strategy and the comprehensive refinancing transactions which were announced on 1 September 2022. The board also reviewed Biocartis' strategy, operations, commercial performance and ongoing proprietary and partner menu development. It discussed business development and strategic opportunities and the status of ongoing collaborations, as well as regular updates on the quality plan and manufacturing strategy. The board also discussed various corporate governance, as well as nomination and remuneration matters, such as board evaluation, the establishment of the company goals and objectives and executive remuneration, and the proposal to the shareholders' meeting to reappoint certain directors. Moreover, the board discussed the regular updates of the financial performance and the budget for financial year 2023, as well as the Company's long-term financial plan. The board also discussed and approved the full year and half year financial statements and reports, and the Q1 and Q3 business updates and related communication.

Other board mandates

Apart from their mandate within Biocartis, the directors of the Company held the following board mandates (directly or via a management company) on 31 December 2022:

Christian Reinaudo	**Agfa Gevaert NV** **Domo Chemicals Holding NV**
Herman Verrelst(1)	**South Bay Ventures (SBV) BV** **Opdorp Finance BV(1)** **Heran Partners BV** **Icometrix NV(2)** **Medvia VZW**
Luc Gijsens(2)	**Luc Gijsens BV** **Arvesta BV** **PMV NV** **KMDA VZW** **KMDA NV** **Global Rental Properties NV**
Ann-Christine Sundell	**Raisio Oyj** **Medix Biochemica Group Oy** **Revenio Oyj** **Actim Oy** **Acmer Ab Oy** **ÅU Media Ab** **SynthticMR AB**
Christine Kuslich	**N/A**
Bryan Dechairo	**Sherlock Biosciences Inc.**

(1) Representing SBV NV, (2) Representing Heran Partners BV.

Conflicts of interest

Directors are expected to arrange their personal and business affairs so as to avoid any conflicts with the interests of the Company. Any director with a financial interest that is conflicting with the interests of the Company based on a decision or a transaction that belongs to the authority of the board of directors must, in accordance with Article 7:96 of the Belgian Code of Companies and Associations, inform his or her fellow directors and the statutory auditor thereof and may not take part in the deliberations or voting related to such matter.

The conflict of interest procedure pursuant to Article 7:96 of the Belgian Code of Companies and Associations was applied once in 2022 during the meeting held on 22 February 2022. The extract of the minutes of this meeting is as follows:

"Following the recommendations of the Remuneration and Nomination Committee, the Board discussed the goals for the CEO relating to performance year 2021 (consisting for 50% of the 1-year targets defined in the beginning of 2021, for 25% of the 2-year target taking the form of phantom stock, and for 25% of the 3-year targets defined in 2019), and assessed the degree to which these goals were achieved. The Board resolved that overall 63.9% of the 1-year targets was achieved (corresponding to a pay-out of EUR 59,906), and 38% of the 3-year targets was achieved (corresponding to a pay-out of EUR 17,813). The Board further resolved that the 2-year target taking the form of phantom stock resulted in a pay-out of EUR 42,337.

Subsequently, and following the recommendations of the Remuneration and Nomination Committee, the Board discussed the KPIs relating to the vesting of maximum 167,500 performance-based share options under the share option plan 2017 for the CEO for performance year 2021. The Board considered that overall ***63.9% of the KPIs were achieved. Therefore, after discussion, the Board resolved to approve that 107,033 performance-based share options under the share option plan 2017 relating to the performance year 2021 have vested.***

Following the recommendations of the Remuneration and Nomination Committee, the Board of Directors discussed and deliberated on the variable remuneration for the CEO for performance year 2022. For the 1-year target (for 2022), the proposal is to use the below KPIs categories, each time consisting of the specific KPIs as proposed by the Remuneration and Nomination Committee:

- 'Realize a strong financial performance' as KPI category (consisting of KPIs relating to growth of product revenue, gross margin improvement on product sales and capping the operating cash burn) having a total weight of 40% (10%-10%-20%).
- For growth of product revenue, a minimum threshold of 85% must be achieved. In case of achievement of this KPI of 85%, 85% of the percentage of the variable remuneration will be payable, while every incremental percentage of achievement will result in 1% extra being payable, provided that the maximum amount payable shall be equal to 125%. In case of an achievement of less than 85% of this KPI, no variable remuneration to which such KPI relates shall be payable.
- For gross margin improvement on product sales, a minimum threshold of 73% must be achieved. In case of achievement of this KPI of 73%, 73% of the percentage of the variable remuneration will be payable, while every incremental percentage of achievement will result in 1% extra being payable, provided that the maximum amount payable shall be equal to 125%. In case of an achievement of less than 73% of this KPI, no variable remuneration to which such KPI relates shall be payable.
- For capping of the operating cash burn, a minimum threshold of 122% of the target must be achieved (taking into account that the operating cash burn target is a negative number). In case the operating cash burn is 122% of the target amount, 100% of the percentage of the variable remuneration will be payable, with 1% extra being payable for every 1% that the operating cash burn is lower than 122% of the target. The maximum amount payable shall be equal to 147% of the target variable remuneration relating to this KPI, namely if the operating cash burn equals 75% of the target operating cash burn.

- 'Achieve commercial success' as KPI category (consisting of KPIs relating to commercial cartridge volume growth and generating a positive financial contribution to operational burn rate from the partner business) having a total weight of 20%. For the KPI relating to commercial cartridge volume growth, a minimum threshold of 90% must be achieved. In case of achievement of this KPI of 90%, 90% of the percentage of the variable remuneration will be payable, while every incremental percentage of achievement will result in 1% extra being payable, provided that for achievement above 100% every incremental percentage of achievement will result in 10% extra being payable, and provided that the maximum amount payable shall be equal to 200%. In case of an achievement of less than 90% of this KPI, no variable remuneration to which such KPI relates shall be payable.
- 'Execution and delivery on projects in support of financial and commercial growth and business expansion and customer satisfaction' as KPI category having a total weight of 12.5%. The variable remuneration payable for project-based KPIs can be between 0% and 150% depending on (timing of) project delivery.
- 'Developing and running a highly performing manufacturing and supply capability' as KPI category having a total weight of 12.5%.
- **'**Advancement of organizational capabilities' as KPI category having a total weight of 15%.

The Board considered the proposed variable remuneration mechanism and the KPIs that will be used to measure and determine the variable remuneration for the CEO to be fully in line with the Company's interests. Therefore, after discussion, the Board resolved to approve the variable remuneration mechanism for the CEO as discussed."

More information on the remuneration of Herman Verrelst in 2022 can be found in the Remuneration Report below.

The procedure pursuant to Article 7:97 of the Belgian Code of Companies and Associations was not applied in 2022.

4.3. Committees of the board of directors

The board of directors has established two board committees: an audit committee and a remuneration and nomination committee. The terms of reference of these board committees are set out in the Company's corporate governance charter.

Audit committee

Composition

According to Belgian company law, the audit committee consists of non-executive directors only, at least one member of the audit committee must be an independent director, the members of the audit committee must have a collective expertise relating to the activities of the Company, and at least one member of the audit committee must have the necessary competence in accounting and auditing. The following three directors are members of the audit committee: Luc Gijsens BV, permanently represented by Luc Gijsens (chairman), Christian Reinaudo and Bryan Dechairo (who replaced Mr. Roald Borré as of 21 February 2023). The members of the audit committee have adequate expertise in financial matters to discharge their functions and have a collective expertise relating to the activities of the Company. The members of the audit committee are competent in accounting and auditing as evidenced by their previous and current roles.

Activity report

In 2022, the audit committee held six meetings which were attended by all members, except for one meeting during which Mr. Borré was excused (illness). During its meetings, the audit committee among others reviewed and discussed the financial reporting process, the internal control processes and the privacy program management. The audit committee assessed the declarations regarding internal control and risk management in the annual report 2021. It also discussed the cooperation with the external auditor of the Company, Deloitte Bedrijfsrevisoren BV, represented by Nico Houthaeve. The audit committee approved certain non-audit services which were provided by the external auditor, among others relating to the comprehensive refinancing transactions which were announced on 1 September 2022. The external auditor attended the meetings of the audit committee that reviewed the full year and half year results and reports. It also presented the audit plan 2022 during the last meeting of the audit committee held in 2022. The audit committee reported systematically to the board of directors and ensured the co-operation of the executive management and the finance department of the Company where required.

Remuneration and nomination committee

Composition

According to Belgian company law, the remuneration and nomination committee consists of non-executive directors only, of which a majority must be independent directors. The committee has the required expertise in terms of remuneration policy. The remuneration and nomination committee consists of three directors: Christian Reinaudo (chairman), Ann-Christine Sundell and Christine Kuslich. All members of the remuneration and nomination committee are independent directors. The chief executive officer participates to the meetings of the remuneration and nomination committee in an advisory capacity each time the remuneration of another member of the executive management is discussed.

Activity report

In 2022, the remuneration and nomination committee held five meetings which were attended by all members, resulting in a 100% attendance rate for the remuneration and nomination committee meetings. The remuneration and nomination committee discussed the composition of the board of directors and executive management, lead the search for open senior leadership positions, discussed board composition, discussed and approved the achievement of the 2021 company goals and related variable remuneration of the executive management, and set the 2022 company goals and objectives (the progress of which was reviewed by the committee throughout the year). It discussed the HR and operational strategy of the Company, as well as succession

planning, wellbeing of the workforce and health and safety at work. Moreover, it supported a board evaluation exercise, and reviewed and discussed the remuneration policy and the individual remuneration of the members of board, the board committees and the executive management. It approved the remuneration report included in the 2021 annual report. The remuneration and nomination committee reported systematically to the board of directors and ensured the co-operation of the executive management and the HR department of the Company where required.

4.4. Executive management

Composition

The executive management is composed of the CEO, CFO and COO.

Name	Age	Function
Herman Verrelst(1)	49	Chief executive officer (CEO)
Jean-Marc Roelandt(2)	58	Chief financial officer (CFO)
Piet Houwen(3)	55	Chief operating officer (COO)

(1) Permanently representing South Bay Ventures (SBV) BV; Permanently representing Marcofin BV; (2) Permanently representing Scmiles BV.

Herman Verrelst is the chief executive officer (CEO) of the Company. See his biography under 'board of directors'.

Jean-Marc Roelandt is a senior executive with an established track record of more than 25 years as Chief Financial Officer in globally active publicly listed companies. With a focus on M&A, capital market transactions and the implementation of adequate financial management infrastructure in dynamic and fast-growing companies, he built up a solid expertise in various industries. Prior to joining Biocartis, he was Chief Financial Officer of MDxHealth, a multinational healthcare company that provides actionable genomic information to personalize the diagnosis and treatment of cancer. Mr. Roelandt holds a master's Degree in Applied Economics from the University of Ghent (Belgium).

Piet Houwen is the chief operating officer (COO). He has more than 29 years of experience in various operational and general management roles. Piet Houwen has a strong track record in manufacturing, process engineering, project and people management. Mr. Houwen has gained broad operational experience in dynamic international environments, including in fast moving consumer goods, food manufacturing, biopharmaceuticals and consulting. Prior to joining Biocartis, Piet Houwen was chief operations officer at Ablynx and prior to that, he held global roles for Sanofi/Genzyme and Janssen Pharmaceutica (part of Johnson & Johnson family of companies) where he was active in pharmaceutical manufacturing of large and small molecules, stent coating and medical devices. Piet Houwen holds a Master's Degree in Mechanical Engineering from the Delft University of Technology (The Netherlands).

The business address of each of the members of the executive management for the purpose of their mandate is Generaal de Wittelaan 11B, 2800 Mechelen, Belgium.

Diversity

End 2022, the executive management consisted of the CEO, CFO and COO. The board values diversity as a key business driver and focuses on a diverse set of skills and inclusive leadership throughout the Company when composing the executive management. There were no changes in 2022 as compared to 2021 in this respect. The executive management is surrounded by a diverse senior and middle management team. More information on this can be found under Part 3, sustainability, section 3.4.

4.5. Remuneration report

Introduction

This remuneration report provides an overview of the key aspects of the remuneration of Biocartis' directors and members of the executive management in 2022. Following a clear positive vote by Biocartis' shareholders on the remuneration report of 2021 and the Biocartis remuneration policy, the changes to the remuneration of the directors and members of the executive management in 2022 as compared to 2021 have been kept to a minimum. This remuneration report must be read together with Biocartis' remuneration policy which can be found on its website, as well as with the performance of Biocartis in 2022 as set out in detail in this annual report. In 2022, there were no deviations from the remuneration policy.

The remuneration of the directors and members of the executive management, and in particular the goals and objectives of the members of the executive management determined to evaluate their variable remuneration, as explained in more detail below, have been established in order to support the Company's long-term performance as it focuses on the key metrics to achieve such long-term performance.

Remuneration of the directors

Principles

The remuneration of the non-executive directors is composed of a fixed fee and an attendance fee. The amount of such fees was set by the annual shareholders' meeting. The CEO, who is also a director of the Company, is remunerated for his executive management mandate only, and not for his director mandate.

Annual fixed fees:

- Chairperson of the board: EUR 36,000
- Chairperson of the audit committee: EUR 18,000
- Chairperson of the remuneration and nomination committee: EUR 14,000
- Other non-executive directors: EUR 12,000

Attendance fees: In addition to the annual fixed fees mentioned above, each non-executive director receives an attendance fee of EUR 3,000 per regular meeting of the board of directors or EUR 1,500 per ad hoc board meeting with a more limited agenda (to be increased, as the case may be, with a fee for travel time of EUR 1,500 for Ann-Christine Sundell and EUR 2,500 for Christine Kuslich per meeting of the board attended in person), EUR 1,000 per meeting of the audit committee attended by the director who is a member of such committee, and EUR 500 per meeting of the remuneration and nomination committee attended by the director who is a member of such committee.

No share-based awards: As from 1 January 2020, the Company no longer grants share options to non-executive directors. However, certain directors do hold share options (taking the form of subscription rights, formerly called warrants) granted to them under the 2018 Plan (see below).

The board of directors, upon recommendation of the remuneration and nomination committee, decided to deviate from provision 7.6 of the Belgian Code on Corporate Governance 2020, which provides that shares of the Company should be granted to non-executive directors as part of their remuneration. The reason for this deviation is that the Company currently does not own treasury shares, and is currently legally not in a position to acquire treasury shares.

The Company also reimburses the directors for reasonable out of pocket expenses (including travel expenses) incurred while performing their mandate.

Remuneration of the members of the board of directors in 2022

Based on what is set out above, the remuneration of the directors for the performance of their director mandate in 2022 is as follows(1):

Name of Director	Fixed remuneration			Variable remuneration		Extra-ordinary items	Total remune-ration	Proportion of fixed and variable remuneration
	Fixed fees (2)	Attendance fees (3)	Fringe benefits	One-year variable	Multi-year variable			
Christian Reinaudo	50,000	34,000	0	0	0	0	84,000	Fixed: 100% Variable: 0%
Luc Gijsens BV, repr. by Luc Gijsens	18,000	31,500	0	0	0	0	49,500	Fixed: 100% Variable: 0%
Ann-Christine Sundell	12,000	35,500	0	0	0	0	47,500	Fixed: 100% Variable: 0%
Christine Kuslich	12,000	35,500	0	0	0	0	47,500	Fixed: 100% Variable: 0%
Roald Borré(4)	12,000	30,500	0	0	0	0	42,500	Fixed: 100% Variable: 0%

(1) Amounts mentioned are gross amounts in Euro.

(2) Amounts mentioned in this column relate to the directors' annual fixed fees.

(3) Amounts mentioned in this column relate to the attendance fees of the members of the board and its committees.

(4) Mr. Borré renounced his remuneration as director and member of the audit committee of the Company, and indicated that these amounts are to be paid to charity. Mr. Borré resigned from the board with effect as of 21 February 2023, and was replaced by Mr. Dechairo with effect as of the same date.

The table below provides an overview of the number of share options (taking the form of subscription rights, formerly called warrants) of the directors on 31 December 2022:

Name of Director	The main conditions of share option plans						Information regarding the reported financial year			
							Opening balance	During the year (2)		Closing balance
	Specification of plan	Award date	Vesting date (1)	End of holding period	Exercise period	Strike price	Share options held (of which vested)	Share options awarded	Share options vested	Share options held (of which vested)
Christian Reinaudo	2018 Plan	10/09/2018	1/3rd in each of 2019, 2020 and 2021	N/A	1/1/2022 – 9/9/2025	EUR 11.93	15,000 (15,000)	0	0	15,000 (15,000)
Luc Gijsens BV, repr. by Luc Gijsens	2018 Plan	10/09/2018	1/2nd in each of 2019 and 2020	N/A	1/1/2022 - 9/9/2025	EUR 11.93	10,000 (10,000)	0	0	10,000 (10,000)
Ann-Christine Sundell	2018 Plan	10/09/2018	1/2nd in each of 2019 and 2020	N/A	1/1/2022 - 9/9/2025	EUR 11.93	10,000 (10,000)	0	0	10,000 (10,000)

Christine Kuslich	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0
Roald Borré	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0

(1) Pursuant to the 2018 Plan, the share options of the directors vest in X equal instalments on each anniversary date of the date of his or her appointment as director of the Company, whereby X shall be equal to the duration of his or her director's mandate expressed in years.

(2) During 2022, no share options were exercised or became null and void for any reason.

Remuneration of the members of the executive management

Principles

The remuneration of the members of the executive management consists of the following remuneration components:

- Annual fixed cash remuneration
- Non-deferred short-term variable remuneration (cash bonus)
- Deferred short-term variable remuneration (since 2020 in the form of phantom stock)
- Long-term variable remuneration (share options)
- Certain other components

The Company's remuneration policy provides that as from 31 December 2024 the members of the executive management must hold a number of shares in the Company which is equivalent to at least one year fixed remuneration for the CEO, and 50% of one year fixed remuneration for the CFO and COO. The value of the shares held is calculated based on the average closing price of the Company's share on Euronext Brussels during the 30-day period prior to 31 December of the previous calendar year (i.e., 2022). As of 31 December 2022, Mr. Verrelst held 100,000 shares in the Company with a value of approximately 57,000 euro.

Remuneration of the members of the executive management in 2022

Total Remuneration: The total remuneration of the members of the executive management in 2022 is as follows[(1)]:

Name of Executive	Fixed remuneration			Variable remuneration		Extraordinary items	Pension expense	Total remuneration	Proportion of fixed and variable remuneration
	Base salary	Fees	Fringe benefits	One-year variable (2)	Multi-year variable (3)				
SBV BV, repr. by Herman Verrelst (CEO)	375,000	0	0	61,781	0	0	0	436,781	Fixed: 85.9% Variable: 14.1%
Other executives (CFO and COO)	678,775	0	0	124,904	0	0	0	803,679	Fixed: 84.5% Variable: 15.5%

(1) Amounts mentioned are gross amounts in Euro.

(2) Amounts mentioned in this column relate to the non-deferred short-term variable remuneration (cash bonus).

(3) Amounts mentioned in this column relate to the deferred short-term variable remuneration. The deferred variable remuneration of the executive management is structured by way of phantom stock under the phantom stock plan which was created in 2020. The value of any share options vested in 2022 have not been taken into account. See the table below for more information on the share options of the executive management as per 31 December 2022.

The remuneration of the members of the executive management is in line with the Company's remuneration policy. By creating a balanced mix between fixed and variable remuneration, as well as between short-term and long-term remuneration, the Company strives to create a focus not only on short-term operational performance but also on the long-term objective of creating

sustainable value. The goals and objectives of the members of the executive management determined to evaluate their variable remuneration have been established in order to support the Company's long-term performance as they focus on the key metrics to achieve such long-term performance.

Non-Deferred and Deferred Short-Term Variable Remuneration

The short-term variable remuneration for the CEO can be maximum 50% of his annual fixed remuneration of the year for which the variable remuneration is awarded. The short-term variable remuneration for the other members of the executive management can be maximum 30% of their respective annual fixed remuneration of the year for which the variable remuneration is awarded.

In accordance with applicable law, 50% of the short-term variable remuneration of the members of the executive management is linked to performance criteria measured over one performance year. Such non-deferred short-term variable remuneration is settled in cash. For the remaining 50% of the short-term variable remuneration, 25% is linked to performance criteria measured over two performance years and another 25% is linked to performance criteria measured over three performance years. It is to be noted that in the course of 2020, the Company decided to structure the deferred short-term variable remuneration for the members of the executive management by way of a grant of phantom stock. For more information on the phantom stock mechanism, please see the Company's remuneration policy.

The table below provides an overview of the total non-deferred short-term variable remuneration for performance year 2022[(1)].

Name of Executive	Description of the performance criteria	Relative weighting of the performance criteria	Information on Performance Targets Minimum threshold performance	Maximum performance	Measured (weighted) performance and total remuneration
SBV BV, repr. by Herman Verrelst (CEO)	Financial performance (consisting of KPIs relating to growth of product revenue, gross margin improvement on product sales and capping the operating cash burn)	40% (10%-10%-20% respectively)	For growth of product revenue: 85%. For gross margin improvement on product sales: 73% For capping the operating cash burn (taking into account that this is a negative number): 122%.	For growth of product revenue and gross margin improvement on product sales: 125%. For capping the operating cash burn (taking into account that this is a negative number): 147% (i.e., if amount equals 75% of target operating cash burn).	28.1%
	Commercial success (consisting of KPIs relating to commercial cartridge volume growth, as well as generating a positive financial contribution to operational burn rate from the partner business)	20%	For commercial cartridge volume growth: 90% For positive financial contribution to operational burn rate from the partner business: N/A	For commercial cartridge volume growth: 200% For positive financial contribution to operational burn rate from the partner business: N/A	0%
	Execution and delivery on projects in support of financial and commercial growth and business expansion and customer satisfaction	12.5%	N/A	150%	11.3%
	Development and running a highly performing manufacturing capability	12.5%	N/A	100%	13.7%

	Advancement of organizational capabilities	15%	N/A	100%	12.8%
					Total weighted performance: 65.9% %, corresponding to EUR 61,781
Other executives (CFO and COO)	Company goals account for 80% of the non-deferred short-term variable remuneration of these executives, for which the same mechanism as for the CEO (see above) applies. The other 20% of the non-deferred short-term variable remuneration of these executives is linked to individual goals of the relevant executives.				EUR 72,929

(1) Amounts mentioned are gross amounts in Euro.

The table below provides an overview of the total deferred short-term variable remuneration for 2022(1).

Name of executive	Description of the performance criteria	Relative weighting of the performance criteria	Information on Performance Targets Minimum threshold performance	Maximum performance	Measured performance and total remuneration
SBV BV, repr. by Herman Verrelst (CEO)	2-year KPIs (set in 2021) in the form of phantom stock	N/A	50%	150%	Total pay-out: 0%, corresponding to EUR 0
	3-year KPIs (set in 2020) in the form of phantom stock	N/A	50%	150%	Total pay-out 0%, corresponding to EUR 0
					Total weighted pay-out: 0%, corresponding to EUR 0
Other executive management (CFO and COO)	2-year KPIs (set in 2021) in the form of phantom stock	N/A	50%	150%	Total payout: 0%, corresponding to EUR 0
	3-year KPIs (set in 2020) in the form of phantom stock	N/A	50%	150%	Total pay-out 0%, corresponding to EUR 0
					Total weighted pay-out: 0%, corresponding to EUR 0

(1) Amounts mentioned are gross amounts in Euro.

Long-Term Variable Remuneration (share options)

The table below provides an overview of the number of share options (taking the form of subscription rights, formerly called warrants) of the members of the executive management on 31 December 2022:

Name of Executive	The main conditions of share option plans						Information regarding the reported financial year			
							Opening balance	During the year [1][2]		Closing balance
	Specification of plan	Award date	Vesting date	End of holding period	Exercise period	Strike price	Share options held (of which vested) [3]	Share options awarded	Share options vested	Share options held (of which vested)
SBV BV, repr. by Herman Verrelst	2017 Plan	11-09-2017	2018-2021	N/A	1/1/2021 – 11/9/2022	EUR 9.92	1,151,898 (1,151,898)	0	0	0
	2020B Plan	30/4/2020	1/1/2024	N/A	1/1/2024 - 29/4/2027	EUR 4.18	300,000 (0)	0	0	300,000 (0)
	2020B Plan	27/4/2021	1/1/2025	N/A	1/1/2025 – 26/4/2028	EUR 4.45	60,000 (0)	0	0	60,000 (0)
Marcofin BV, repr. by Jean-Marc Roelandt	2020B Plan	30/4/2020	1/1/2024	N/A	1/1/2024 - 29/4/2027	EUR 4.18	100,000 (0)	0	0	100,000 (0)
	2020B Plan	27/4/2021	1/1/2025	N/A	1/1/2025 – 26/4/2028	EUR 4.45	30,000 (0)	0	0	30,000 (0)
Scmiles BV, repr. by Piet Houwen	2018 Plan	9/5/2019	2020-2023 (4)	N/A	1/1/2023 – 8/5/2026	EUR 11.93	65,000 (44,687)	0	16,250 (EUR 38,025)	65,000 (60,937)
	2020B Plan	30/4/2020	1/1/2024	N/A	1/1/2024 – 29/4/2027	EUR 4.18	50,000 (0)	0	0	50,000 (0)

(1) The valuation method used is the fair value method following IFRS 2 guidance (Black & Scholes) as of the relevant offer date of the share options. It is to be noted however that the exercise price of certain share options held by the members of the executive management is above the current share price of the Company (see column 7 of the table).

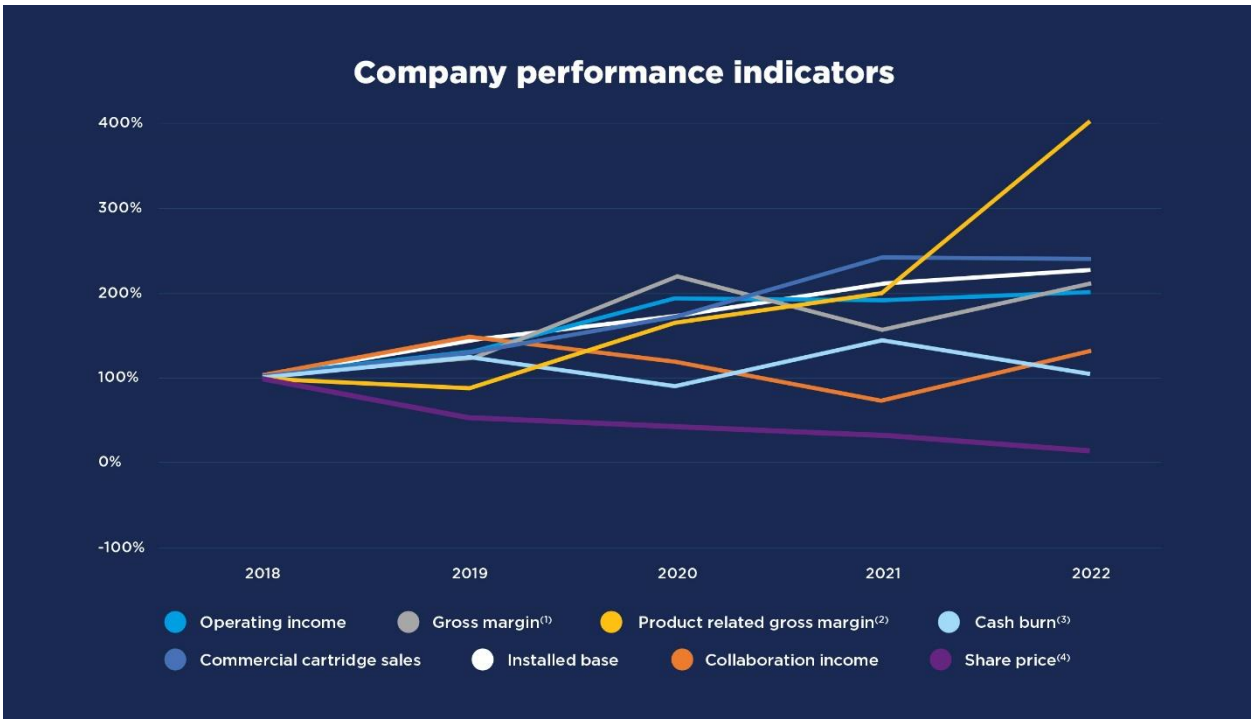
(2) During 2022, no share options were exercised by any members of the executive management. All share options held by Mr. Verrelst under the 2017 plan expired and became null and void.

(3) The amount of share options mentioned in this column relates to the total amount initially awarded minus any share options which were already exercised or became null and void before 1 January 2022.

(4) These share options awarded under the 2018 Plan vest as follows: 25% of the share options vest on March 30 of the year following the year in which the award occurred, and 6.25% of the share options vest at the end of each subsequent calendar quarter.

Yearly changes in remuneration and performance of Biocartis

The chart below shows the evolution in the performance of Biocartis over the past five years, expressed by way of key performance indicators which were used in the relevant period for determining the variable remuneration of the executive management.



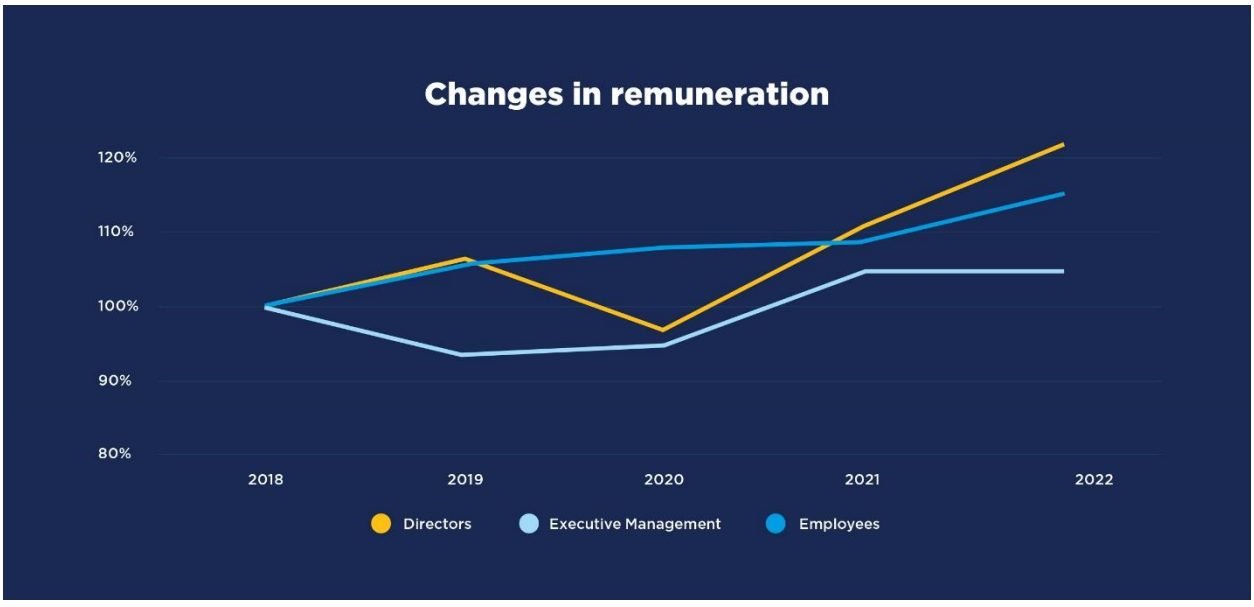
(1) Gross margin is defined as total operating income less cost of sales.

(2) Product related gross margin is defined as product sales and system service income less cost of sales.

(3) Cash burn is defined as operating and investing cash flow.

(4) Share price is calculated as the average of the share price of the Company in the period between 1 December and 30 December of the relevant year (in line with the relevant share price calculation under the phantom stock plan).

The chart below shows the changes in the remuneration of the directors and the members of the executive management and the changes in the average remuneration of the employees of Biocartis over the past five years.



The average remuneration of the employees (for the avoidance of doubt, excluding directors and members of the executive management) is calculated based on the total remuneration as of 31 December of the relevant year for the employees of Biocartis

Group NV, Biocartis NV and Biocartis US Inc. The total remuneration of the employees includes base remuneration, short term variable remuneration (bonus plan) and benefits (such as pension plan, company car, commuting allowances, disability insurance and health insurance).

It is to be noted that over the past five years the composition of the workforce (e.g., relative weight of the number of manual workers versus cognitive workers, establishment of a US workforce) and the changes in the composition of the executive management had an impact on the average remuneration evolution as shown in the above. For consistency of the calculations over the years, only the members of the executive management as it was composed in 2021 (i.e., CEO, CFO and COO) have been taken into account, it being understood that the role of COO was only created in April 2019. Share options are excluded from the calculations. The increase in director remuneration can be explained by the decision of the annual shareholders' meeting of 2021 in the framework of the COVID-19 pandemic to set the attendance fee for the regular Board meetings (irrespective of whether such meetings are held physically or virtually) to EUR 3,000, whereas before that shareholder decision a distinction was made between the attendance fees payable for physical and virtual Board meetings. Certain directors also receive a fee for travel time, as approved by the Company's shareholders' meeting. As more directors are travelling from outside of Belgium, fees are increasing. For more detailed information on the remuneration of the directors and the members of the executive management over the past five years, reference is made to the remuneration reports as included in the Company's annual reports over the past five years.

Pay ratio

The ratio between the highest remuneration of the members of executive management and the lowest remuneration (in full-time equivalent) of Biocartis' employees amounts to 10 to 1. Share options are excluded from the calculations.

Severance payments for departing members of the executive Management

No members of the executive management have left Biocartis in 2022.

4.6. Share capital and shares

Issue of shares by the company in 2022

On 1 January 2022, the share capital of the Company amounted to EUR 575,456.63, represented by 57,545,663 shares. In the course of 2022, shares were issued at the following occasions:

- On 6 September 2022, 810,734 new shares were issued to certain funds and accounts managed or advised by Highbridge Capital Management LL and to certain funds managed or advised by Whitebox Advisors LLC (together the "Lenders") to settle the fee payable by the Company to Lenders for certain backstop commitments provided by them in connection with the recapitalization transactions which were announced by the Company on 1 September 2022;
- On 27 October 2022 and 4 November 2022, a certain portion of the receivables due by the Company to the Lenders under the senior secured convertible term loan entered into with the Lenders on 1 September 2022 was contributed in kind against issuance of, in the aggregate, 228,234 shares;
- On 2 December 2022, the Company issued 33,476,932 shares following the successful completion of a capital increase through the offering of new shares with extra-legal preferential rights for existing shareholders of the Company;
- On 16 December 2022, 928,136 new shares were issued as a result of the completion of the mandatory conversion of 10% of the principal amount outstanding under the Company's 4.00% convertible bonds due 2027 and the Company's 4.50% second lien secured convertible bonds due 2026.

On 14 November 2022, the extraordinary shareholders' meeting of the Company resolved to increase the capital of the Company in an amount of EUR 43,974,595.37 without issuance of new shares by incorporating a part of the issuance premium into the capital of the Company, and immediately thereafter to decrease the capital of the Company in the same amount by way of incorporation of a part of the losses incurred.

Consequently, on 31 December 2022, the share capital of the Company amounted to EUR 929,896.99, represented by 92,989,699 shares.

An overview of the major shareholders of the Company on 31 December 2022 based on the transparency notifications received until that date can be found in the section 'Major Shareholders' under the chapter 'Share and share capital. The Company is not aware of any shareholders' agreements with respect to the Company.

Number and form of shares of the company

Of the 92,989,699 shares of the Company outstanding at 31 December 2022, 47,931 were registered shares and 92,941,768 were dematerialized shares. All shares belong to the same class and are freely transferable. All shares are issued and fully paid-up.

Rights attached to shares of the company

Each share in the Company (i) entitles its holder to one vote at the general shareholders' meetings, (ii) represents an identical fraction of the Company's share capital and has the same rights and obligations, and shares equally in the profits and losses of, the Company, and (iii) gives its holder a preferential subscription right to subscribe for new shares, convertible bonds or subscription rights in proportion to the part of the share capital represented by the shares already held. The preferential subscription right can be restricted or cancelled by a resolution approved by the general shareholders' meeting, or by the board of directors subject to an authorization of the general shareholders' meeting, in accordance with the provisions of Belgian company law and the Company's articles of association. Pursuant to Article 11 of the articles of association, the exercise of the

voting rights of all shares owned by the relevant shareholder are suspended if and as long as the board of directors calls for the payment of shares which are not fully paid-up and such calls have not been performed by such shareholder. However, all shares in the Company are currently fully paid-up. Pursuant to Article 12 of the articles of association, the Company may suspend all rights attached to a security when such security is held by more than one person, until such time as one sole person has been identified to the Company as the holder of the security.

Subject to certain exceptions, no shareholder may cast a greater number of votes at a general shareholders' meeting of the Company than those voting rights that such shareholder has notified to the Company and the Belgian Financial Services and Markets Authority ('FSMA'), in accordance with the applicable rules laid down in the Belgian Law of 2 May 2007 on the disclosure of major shareholdings, at least 20 calendar days prior to the date of the general shareholders' meeting. In general, pursuant to the aforementioned Law of 2 May 2007 and the Company's articles of association, a notification to the Company and the FSMA is required by all natural and legal persons in each case where the percentage of voting rights in the Company held by such persons reaches, exceeds or falls below the threshold of 3%, 5%, 10%, and every subsequent multiple of 5%, of the total number of voting rights in the Company. Furthermore, in certain instances, voting rights can be suspended by a competent court or by the FSMA.

Right of the board of directors to increase the share capital of the company

On 4 June 2021, the general shareholders' meeting renewed the authorization to the board of directors to increase the share capital of the Company within the framework of the authorized capital. Such authorization was granted with a maximum of 75% of the share capital at the time of the convening of the shareholders' meeting granting such authorization (i.e., EUR 431,592.47).

The general shareholders' meeting further decided that the board of directors, when exercising its powers under the authorized capital, is authorized to restrict or cancel the statutory preferential subscription rights of the shareholders (within the meaning of Belgian company law). This authorization includes the restriction or cancellation of the preferential subscription rights for the benefit of one or more specific persons (whether or not employees of the Company or its subsidiaries). The authorization is valid for a term of five years as from the date of the publication of the authorization in the Annexes to the Belgian State Gazette (Belgisch Staatsblad), i.e., until 22 June 2026. The board used its authorization with respect to 1,038,968 shares in 2022, resulting in a remaining authorization for the board to issue 42,120,279 shares.

Modifications to the articles of association and share capital

Amendments to the articles of association, other than certain specific amendments such as an amendment of the Company's purpose, require the presence or representation of at least 50% of the share capital of the Company at an extraordinary shareholders' meeting to be held before a notary public, and a majority of at least 75% of the votes cast at such meeting. An amendment of the Company's corporate purpose requires the approval of at least 80% of the votes cast at an extraordinary shareholders' meeting to be held before a notary public, which can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required attendance quorum is not present or represented at the first meeting, a second meeting needs to be convened. The second general shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special majority requirements, however, remain applicable.

The above also applies to any changes of the Company's share capital as such changes amount to an amendment of the Company's articles of association. There are no conditions imposed by the Company's articles of association that are more stringent than those required by law. Within the framework of the powers granted to it under the authorized capital, the board of directors may also increase the Company's share capital as specified in the articles of association.

Purchase and sale of treasury shares

The Company may purchase, subject to the provisions of the Belgian company law, its own shares if authorized by a prior decision of an extraordinary shareholders' meeting approved by a majority of 75% of the votes cast, at a meeting where at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required attendance quorum is not present or represented at the first meeting, a second meeting needs to be convened. The second general shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special majority requirements, however, remain applicable. The aforementioned rules are also applicable to the acquisition of shares of the Company by its subsidiaries. The sale of treasury shares is also subject to the provisions of the Belgian Code of Companies and Associations. The board of directors is currently not authorized by an extraordinary shareholders' meeting to purchase or sell its own shares. On 31 December 2022, neither the Company nor any subsidiary of the Company held any shares in the Company.

Public takeover bids

Public takeover bids for the Company's shares and other securities giving access to voting rights (such as subscription rights and convertible bonds) are subject to supervision by the FSMA. Any public takeover bid must be extended to all of the Company's voting securities, as well as all other securities giving access to voting rights. Prior to making a bid, a bidder must publish a prospectus which has been approved by the FSMA prior to publication.

The Belgian Law on public takeover bids of 1 April 2007 provides that a mandatory bid must be launched if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting for their account, directly or indirectly holds more than 30% of the voting securities in a company having its registered office in Belgium and of which at least part of the voting securities are admitted to trading on a regulated market or on a multilateral trading facility designated by the Belgian Royal Decree of 27 April 2007 on public takeover bids. The mere fact of exceeding the relevant threshold through the acquisition of shares will give rise to a mandatory bid, irrespective of whether the price paid in the relevant transaction exceeds the then current market price. The duty to launch a mandatory bid does not apply in certain cases set out in the aforementioned Belgian Royal Decree of 27 April 2007 such as (i) in case of an acquisition if it can be shown that a third-party exercises control over the Company or that such party holds a larger stake than the person holding 30% of the voting securities or (ii) in case of a capital increase with preferential subscription rights decided by the Company's general shareholders' meeting.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose significant shareholdings and merger control, which may apply to the Company and which may create hurdles to an unsolicited tender offer, merger, change in management or other change in control. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of the Company's shares. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their shares at a premium.

Pursuant to Belgian company law, the board of directors of Belgian companies may in certain circumstances, and subject to prior authorization by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (pursuant to the authorized capital) or through share buy-backs (i.e. purchase of own shares). In principle, the authorization of the board of directors to increase the share capital of the Company through contributions in kind or in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the securities of the Company. The general shareholders' meeting can, however, under certain conditions, expressly authorize the board of directors to increase the capital of the Company in such case by issuing shares in an amount of not more than 10% of the existing shares of the Company at the time of such public takeover bid. Such authorization has not been granted to the board of directors of the Company.

The Company's articles of association do not provide for any specific protective mechanisms against public takeover bids.

The Company is a party to the following significant agreements which take effect, alter or terminate upon a change of control over the Company following a takeover bid:

- The EUR 16.9m credit contract as last amended on 11 August 2022 entered into between KBC Bank NV, the Company and Biocartis NV, which provides that KBC Bank NV is entitled, without the need to have prior recourse to the courts or to give prior notice, to terminate or suspend both the utilized and the unutilized portion of the credit facility and its forms of utilization in whole or in part with immediate effect from the date the letter advising such termination or suspension is sent upon a substantial change in the shareholder structure of the borrowers that could affect the composition of the management bodies or the overall risk assessment by the bank.

- The terms and conditions of the amended 4.00% convertible bonds due 2027, which provide that if a change of control shall occur and the full outstanding principal amount of all indebtedness secured by any assets of the Company and its subsidiaries has not yet been and will not be paid in full, the principal amount outstanding of such convertible bonds (including any capitalised interest) and any accrued and uncapitalized interest will be automatically and unconditionally deemed to be zero.

- The terms of the senior secured convertible term loan entered into among others with the Lenders dated 1 September 2022 which provide that a change of control would result in an event of default under such agreement.

- The terms and conditions of the 4.50% convertible bonds due 2026, whereby bondholders will have the right to require the Company to redeem their convertible bonds at their principal amount together with accrued and unpaid interest following the occurrence of a change of control of the Company.

In addition, the Company's share option plans provide for an accelerated vesting of the share options in case of a change of control event.

4.7. External and internal control

External control

In 2022, the Company's statutory auditor was Deloitte Bedrijfsrevisoren BV, represented by Nico Houthaeve. The statutory auditor performs the external audit of the consolidated and statutory accounts of the Company and of its Belgian subsidiary (Biocartis NV), and audits specified account balances of Biocartis US Inc. For 2022, the audit fee amounted to EUR 118,240, and the fees for audit related services performed by the statutory auditor amounted to EUR 213,555 (mainly with respect to the comprehensive recapitalization transactions announced by the Company on 1 September 2022).

Internal control

Biocartis has taken different steps to identify the most important risks that it is exposed to and to keep these risks at an acceptable level. The different risks have been identified in this annual report under the section 'risks related to our business'. The control activities of Biocartis include the measures taken by it to ensure that the most important risks which were identified are controlled or mitigated. Biocartis manages some of these risks by entering into insurance contracts covering such risks.

As indicated in this annual report, the board of directors has set up an audit committee that gives guidance and controls the financial reporting of the Group. It ensures the presence of sufficient internal control mechanisms and, in co-operation with the statutory auditor of the Group, investigates questions in relation to accounting and valuation rules. The audit committee more specifically reviews the financial accounts of the Company, the management reporting and budgets and gives its recommendation with regard to these documents to the board of directors. Given the current size and complexity of the Company's business, as well as the policies and internal processes it has in place, no independent internal audit function has been established. The need for this function has been reviewed in 2022 and will continue to be reviewed annually.

Biocartis has set up control policies and risk management systems to ensure that the main business risks are properly identified, managed and disclosed. The objectives of the Biocartis internal control framework are achieving effectiveness and efficiency of operations, reliability of financial reporting, compliance with applicable laws and regulations and the safeguarding of assets. To this end, Biocartis has established a number of instruments that are discussed on a regular basis in the audit committee and are presented to the board of directors:

- Long term financial planning and annual budgets: at least once per year, the management of Biocartis prepares the annual budget. This is an important instrument to control activities of the Group and combines strategy, risk, business plans and intended results. The budget is also used as a basis to define the most important company goals for the financial year. The performance against the budget and Company goals is monitored monthly by the finance and business team and discussed on a monthly basis in the executive management meetings. Quarterly business reviews are conducted with all relevant stakeholders for more in depth analysis and for forecast updates. It is also presented to the audit committee and the board of directors. In addition, the management and board of directors prepare and update a longer term financial plan to crystalize the longer term strategy of Biocartis.

- Monthly management information reports and financial accounts to monitor (actual) performance versus (budget) objectives: every month management prepares a detailed management information report ('MIR') covering all activities of the Group (commercial, development, production, strategic, IP, HR, etc.). The MIR also maps the Company's ongoing progress against the yearly budget and longer term strategic and R&D development goals.

- Time registration on projects and activities to monitor staff resource allocation as compared to planning.

- Statutory financial and tax reporting per legal entity and IFRS financial accounts on a consolidated level: management prepares and presents to the audit committee and the board of directors these accounts at least every six months.

In order to ensure the quality and reliability of the financial information, Biocartis has established and is continuously improving and further automating its key standardized information flow processes, consistent throughout the organization. The most important financial processes are designed to ensure data consistency and comparability, as well as to detect potential anomalies. These processes include amongst others expenditure, revenue, inventory, fixed assets, financial closing and treasury processes. Management defines the values as well as the skills and job descriptions needed for all functions and tasks within the organization.

In addition, Biocartis has developed a vast set of procedures and workflows on key business cycles that are all documented through a unique IT system. The system is designed to help meet the quality levels required for Biocartis' products and is one of the elements used by the quality department to ensure product and process compliance with the regulatory framework. Further details on the quality management system are provided under Part 3, Sustainability.

Before commercializing its products, Biocartis performs the necessary tests to reach the level of quality acceptance. In order to try to assure the best possible quality standards during production, Biocartis has installed an in-house quality team that is present in the different stages of product development and manufacturing.

RESPONSIBILITY STATEMENT

The undersigned hereby declare that to the best of their knowledge:

- the annual accounts, which have been drawn up in accordance with the applicable accounting standards, give a true and fair view of the net equity, financial position and results of the Company and the companies included in the consolidation, and
- the annual report gives a true and fair view of the development and results of the business and the position of the Company and the companies included in the consolidation, as well as a description of the main risks and uncertainties they are confronted with.

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Herman Verrelst
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Herman Verrelst
CHIEF EXECUTIVE OFFICER

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Christian Reinaudo
CHAIRMAN OF THE BOARD OF DIRECTORS

5. CONSOLIDATED ANNUAL ACCOUNTS 2022

5.1. Consolidated financial statements as of and for the years ended 31 December 2022 and 2021

5.1.1. Consolidated income statement

		Years ended 31 December,	
In EUR 000	Notes	2022	2021
Collaboration revenue	5.2.4	11,068	6,053
Product sales revenue	5.2.4	45,036	40,486
Service revenue	5.2.4	1,377	1,730
Total revenue		**57,481**	**48,269**
Other operating income			
Grants and other income	5.2.5	495	6,629
Total operating income		**57,976**	**54,898**
Cost of sales	5.2.6	-29,799	-33,922
Research and development expenses	5.2.7	-38,393	-48,054
Sales and marketing expenses	5.2.8	-20,595	-16,763
General and administrative expenses	5.2.9	-16,236	-15,560
Other expenses	5.2.9		-3,244
Total operating expenses		**-105,023**	**-117,543**
Operating loss for the year		**-47,047**	**-62,645**
Financial expense	5.2.11	-21,179	-9,488
Other financial results	5.2.11	3,489	1,077
Financial result, net		**-17,690**	**-8,411**
Share in the result of joint venture		-884	-659
Loss for the year before taxes		**-65,621**	**-71,715**
Income taxes	5.2.28	240	243
Loss for the year after taxes		**-65,381**	**-71,472**
Attributable to owners of the Group		-65,381	-71,472
Earnings per share			
Basic and diluted loss per share	5.2.12	-1.08	-1.24

5.1.2. Consolidated statement of comprehensive income

In EUR 000	Notes	Years ended 31 December, 2022	2021
Loss for the year		**-65,381**	**-71,472**
Other comprehensive income (loss), not to be reclassified to profit or loss:			
Re-measurement gains and losses on defined benefit plan	5.2.24	-385	-595
Income taxes on items of other comprehensive income		114	176
Other comprehensive income (loss), that may be reclassified to profit and loss:			
Exchange differences on translation of foreign operations		378	410
Total comprehensive loss for the year		**-65,274**	**-71,481**
Attributable to owners of the Group		-65,274	-71,481

5.1.3. Consolidated statement of financial position

In EUR 000	Notes	As of 31 December, 2022	2021
Assets			
Non-current assets			
Intangible assets	5.2.13	4,770	5,067
Property, plant and equipment	5.2.14	31,527	37,192
Financial assets	5.2.15	3,640	1,140
Investment in joint ventures	5.2.16	2,538	2,344
Other non-current assets	5.2.24	204	16
Deferred tax assets and R&D Investment tax credit	5.2.17	1,664	1,595
		44,343	47,354
Current assets			
Inventories	5.2.18	18,905	16,106
Trade receivables	5.2.19	16,697	16,206
Other receivables	5.2.19	2,236	6,556
Other current assets	5.2.20	5,971	2,736
Cash and cash equivalents*	5.2.21	26,125	53,522
		69,934	95,126
Total assets		**114,277**	**142,480**
Equity and liabilities			
Capital and reserves			
Share capital	5.2.22	-220,302	-220,657
Share premium	5.2.22	631,722	711,874
Share based payment reserve	5.2.22	7,502	6,862
Accumulated deficit	5.2.22	-443,363	-526,405
Other comprehensive income	5.2.22	-5,843	-5,571
Total equity attributable to owners of the Group		**-30,284**	**-33,897**
Non-current liabilities			
Provisions	5.2.24	204	75
Borrowings and lease liabilities	5.2.25	25,824	14,133
Convertible debt	5.2.25	75,935	128,151
Deferred income	5.2.27	149	313
		102,112	142,672
Current liabilities			
Borrowings and lease liabilities	5.2.25	20,597	11,878
Trade payables	5.2.26	11,747	11,560
Deferred income	5.2.27	1,195	1,822
Other current liabilities	5.2.26	8,910	8,445
		42,449	33,705
Total equity and liabilities		**114,277**	**142,480**

*Cash and cash equivalents for 31 December 2021 and 2022 include EUR 1.2 million restricted cash related to KBC Lease financing

5.1.4. Consolidated cash flow statement

In EUR 000	Notes	Years ended 31 December, 2022	2021
Operating activities			
Loss for the year		-65,381	-71,472
Adjustments for			
Depreciation and amortization	5.2.13/5.2.14	10,481	9,845
Impairment losses	5.2.7/5.2.14	1,178	1,362
Income taxes in profit and loss	5.2.29	-240	-243
Financial result, net	5.2.11	17,690	8,411
Unrealized exchange gains/ losses			1,134
Net movement in defined benefit obligation	5.2.24	-143	69
Share of net profit of associate and joint venture	5.2.16	884	659
Share based payment expense	5.2.23	640	760
Other		-78	-162
Changes in working capital			
Net movement in inventories**	5.2.18	-5,297	-2,737
Net movement in trade and other receivables and other current assets	5.2.19/5.2.17	1,579	-5,916
Net movement in trade payables & other current liabilities	5.2.26	652	-1,489
Net movement in deferred income	5.2.27	-791	494
Cash flow from operating activities before interest and taxes paid		-38,826	-59,285
Interest paid		-6,027	-6,429
Taxes paid	5.2.29	-2	-2
Cash flow used in operating activities		**-44,855**	**-65,716**
Investing activities			
Interest received		6	7
Acquisition of property, plant & equipment**	5.2.14	-1,569	-3,686
Acquisition of intangible assets	5.2.13	-368	-69
Investment in joint venture	5.2.16	-1,000	0
Investment convertible note	5.2.15	-2,500	
Cash flow used in investing activities		**-5,431**	**-3,748**
Financing activities			
Proceeds from borrowings	5.2.25	15,000	6,000
Refinancing convertible bond and convertible term loan	5.2.25	10,782	
Net proceeds from the issue of common shares, net of transaction costs	5.2.25	23,055	
Repayment of borrowings	5.2.25	-26,301	-7,089
Bank charges		-73	-115
Cash flow used in financing activities		**22,463**	**-1,204**
Net decrease in cash and cash equivalents		**-27,823**	**-70,668**
Cash and cash equivalents at the beginning of the period		53,522	123,668
Effects of exchange rate changes on the balance of cash held in foreign currencies		426	522
Cash and cash equivalents at the end of the period*		**26,125**	**53,522**

* Including EUR 1.2 million restricted cash related to KBC Lease financing

** Including Idylla instruments placed under reagent rental agreements that were held in inventory on 31 December 2021

5.1.5. Consolidated statement of changes in equity

In EUR 000	Notes	Share capital	Share premium	Share based payment reserve	Other comprehensive income	Accumulated deficit	Total equity attributable to the owners of the Group	Total equity
Balance as at 1 January 2021		**-220,657**	**711,874**	**6,102**	**-5,153**	**-455,343**	**36,824**	**36,824**
Loss for the period						-71,472	-71,472	-71,472
Re-measurement gains and losses on defined benefit plan	5.2.24				-419		-419	-419
Consolidation translation difference						410	410	410
Total comprehensive income					**-419**	**-71,062**	**-71,481**	**-71,481**
Share-based payment expense	5.2.23			760			760	760
Balance as at 31 December 2021		**-220,657**	**711,874**	**6,862**	**-5,572**	**-526,405**	**-33,897**	**-33,897**
Balance as at 1 January 2022		**-220,657**	**711,874**	**6,862**	**-5,572**	**-526,405**	**-33,897**	**-33,897**
Loss for the period						-65,381	-65,381	-65,381
Re-measurement gains and losses on defined benefit plan	5.2.24				-271		-271	-271
Consolidation translation difference						378	378	378
Total comprehensive income					**-271**	**-65,003**	**-65,274**	**-65,274**
Share-based payment expense	5.2.23			640			640	640
Convertible bond conversion old bond	5.2.21		11				11	11
Convertible bond issue new bond	5.2.21		33,121				33,121	33,121
Capital increase by contribution in kind	5.2.21		-104,071			104,071	0	0
Share issue - contribution in kind 6 September 2022	5.2.21	8	992				1,000	1,000
Capital decrease by incorporation of accumulated losses 14 November 2022	5.2.21		-43,975			43,975	0	0
Share issue - rights offering 2 December 2022	5.2.21	336	24,773				25,108	25,108
Costs related to rights offering	5.2.21		-2,053				-2,053	-2,053
Share issue - conversion convertible term loan	5.2.21	2	240				242	242
Share issue - mandatory conversion convertible bond 16 December 2022	5.2.21	9	10,810				10,819	10,819
Balance as at 31 December 2022		**-220,302**	**631,722**	**7,502**	**-5,843**	**-443,363**	**-30,284**	**-30,284**

5.2. Notes to the consolidated financial statements

5.2.1. General information

Biocartis Group NV, a company incorporated in Belgium with registered address at Generaal de Wittelaan 11 B, 2800 Mechelen, Belgium (the 'Company') and its subsidiaries (together, the 'Group') commercialize an innovative and proprietary molecular diagnostics ('MDx') platform that offers accurate, highly-reliable molecular information from virtually any biological sample, enabling fast and effective diagnostics treatment selection and treatment progress monitoring.

The Group's mission is to become a global, fully integrated provider of novel molecular diagnostics solutions with industry-leading, high clinical value tests within the field of oncology. The Company has established subsidiaries in Mechelen (Belgium), New Jersey (US), Milan (Italy) and a joint venture in Hong Kong (China).

The consolidated financial statements have been authorized for issue on 29 March 2023 by the board of directors of the Company (the 'board of directors').

5.2.2. Summary of significant accounting policies

5.2.2.1. STATEMENT OF COMPLIANCE

The consolidated financial statements of the Group for the year ended 31 December 2022 have been prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and as adopted by the European Union.

5.2.2.2. BASIS OF PREPARATION

The consolidated financial statements have been prepared on the historical cost basis except for financial instruments at fair value and non-cash distribution (e.g. issuance of equity) that are measured at fair value at the end of each reporting period as further explained in the accounting policies. The acquired assets and assumed liabilities in a business combination are also measured initially at fair value at the date of acquisition.

Historical cost is generally based on the fair value of the consideration given in exchange for assets.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

The consolidated financial statements are presented in Euro (EUR) and all values are rounded to the nearest thousand (EUR000), except when otherwise indicated.

The Group has adopted the following new and revised standards and interpretations issued by the IASB that are relevant to its operations and effective for accounting periods beginning on 1 January 2022:

- Amendment to IFRS 16 Leases: COVID-19-Related Rent Concessions beyond 30 June 2021 (applicable for annual periods beginning on or after 1 April 2021)
- Amendments to IAS 16 Property, Plant and Equipment: Proceeds before Intended Use (applicable for annual periods beginning on or after 1 January 2022)
- Amendments to IAS 37 Provisions, Contingent Liabilities and Contingent Assets: Onerous Contracts — Cost of Fulfilling a Contract (applicable for annual periods beginning on or after 1 January 2022)
- Amendments to IFRS 3 Business Combinations: Reference to the Conceptual Framework (applicable for annual periods beginning on or after 1 January 2022)
- Annual Improvements to IFRS Standards 2018–2020 (applicable for annual periods beginning on or after 1 January 2022)

The above application of new standards did not have a significant impact on the financial position and the results of the Group. Standards and interpretations published, but not yet applicable for the annual period beginning on 1 January 2022, are listed in note 5.2.34.

5.2.2.3. CONSOLIDATION PRINCIPLES

The consolidated financial statements comprise the financial statements of the Company and entities controlled by the Company as at 31 December 2022.

Control is achieved when the Company is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee.

Specifically, the Group controls an investee if, and only if, the Company has:

- Power over the investee (i.e., existing rights that give it the current ability to direct the relevant activities of the investee)
- Exposure, or rights, to variable returns from its involvement with the investee
- The ability to use its power over the investee to affect its returns

The results of subsidiaries acquired or disposed of during the year are included in the consolidated income statement from the effective date of acquisition and up to the effective date of disposal.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction. If the Group loses control over a subsidiary, it derecognizes the related assets (including goodwill), liabilities, non-controlling interest and other components of equity while any resulting gain or loss is recognized in profit or loss. Any investment retained is recognized at fair value.

All transactions between Group companies have been eliminated upon consolidation.

5.2.2.4. FOREIGN CURRENCY TRANSLATION

The items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which each entity operates ('Functional Currency'). The consolidated financial statements are presented in Euro, which is the Company's functional and presentation currency.

Transactions in foreign currencies are recorded at the foreign exchange rate prevailing at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the reporting date are translated at the foreign exchange rate prevailing at that date. Exchange differences arising on the settlement of monetary items or on reporting monetary items at rates different from those at which they were initially recorded during the period or in previous financial statements, are recognized in the consolidated income statement.

5.2.2.5. JOINT VENTURES

A joint venture is a joint arrangement whereby the parties that have joint control of the arrangement (i.e. joint ventures) have rights to the net assets of the arrangement. Joint control is the contractually agreed sharing of control of an arrangement, which exists only when decisions about relevant activities require the unanimous consent of the parties sharing control.

The results, assets and liabilities of joint ventures are incorporated in the Group's consolidated financial statements using the equity method of accounting, except when the investment is classified as held for sale, in which case it is accounted for in accordance with IFRS 5 – Non-current Assets Held for Sale and Discontinued Operations. Under the equity method, an investment in a joint venture is initially recognized in the consolidated statement of financial position at cost and adjusted thereafter to recognize the Group's share of the profit or loss and other comprehensive income of the joint venture. When the Group's share of losses of a joint venture exceeds the Group's interest in that joint venture (which includes any long-term interests that, in substance, form part of the Group's net investment in the joint venture), the Group discontinues recognizing its share of further losses. Additional losses are recognized only to the extent that the Group has incurred legal or constructive obligations or made payments on behalf of the joint venture.

Any excess of the Group's share of the net fair value of the identifiable assets, liabilities and contingent liabilities over the cost of acquisition, after reassessment, is recognized immediately in profit or loss. Unrealized gains and losses resulting from transactions between the Group and the joint venture are eliminated to the extent of the interest in the joint venture.

Where a Group entity transacts with a joint venture of the Group, gains and losses are eliminated to the extent of the Group's interest in the relevant associate or joint venture.

5.2.2.6. INTANGIBLE ASSETS

RESEARCH AND DEVELOPMENT COSTS

Research and development costs are currently expensed as incurred. Development costs incurred are recognized as intangible assets if, and only if, all of the following conditions have been demonstrated:

- The technical feasibility of completing the intangible asset so that it will be available for use or sale;
- The intention to complete the intangible asset and use or sell it;
- The ability to use or sell the intangible asset;
- How the intangible asset will generate probable future economic benefits;
- The availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- The ability to measure reliably the expenditure attributable to the intangible asset during its development.

Due to uncertainties inherent to the development and registration with authorities of the Group's Idylla™ platform and its tests, the Group considers that the conditions for capitalization are not met until the regulatory procedures required by authorities have been completed. Development costs incurred after the recognition criteria are met are in general not material. As such, development expenditure not satisfying the above criteria and expenditure in the research phase of internal projects are recognized in the consolidated income statement as incurred.

SEPARATELY ACQUIRED INTANGIBLE ASSETS

Separately acquired intangible assets include patents and licenses, and purchased IT and software licenses. These intangible assets are capitalized based on the costs incurred to acquire and bring to use the specific asset.

Intangible assets are amortized in accordance with the expected pattern of consumption of future economic benefits derived from each asset. Practically, intangible assets are amortized on a straight-line basis over their estimated useful lives as per the table below:

	Estimated useful life
Patents	Patent life
Licenses	3 to 20 years
ICT, software	3 to 5 years

Intangible assets are carried in the consolidated balance sheet at their initial cost less accumulated amortization and impairment losses, if applicable.

5.2.2.7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are initially recognized in the consolidated balance sheet at their acquisition cost, including the costs directly attributable to the acquisition and the installation of the asset.

Each item of property, plant and equipment is recorded at historical cost less accumulated depreciation and impairment losses, if applicable. A pro rata straight-line depreciation method is used to reflect the pattern in which the asset's future economic benefits are expected to be consumed. Practically the term over which items of property, plant and equipment is depreciated depends on the estimated useful life of each asset category, as per the table below.

	Estimated useful life
ICT, laboratory and manufacturing equipment	3 to 7 years
Fittings and leasehold improvements	The shorter of rent duration and 10 years
Idylla™ systems for internal use and Idylla™ systems for rent	5 years
Other	10 years

The Group records as manufacturing and other equipment under construction all the physical equipment, including custom-designed equipment and generic pieces of equipment, and related costs, such as borrowing costs, certain specific engineering expenses, incurred for their design, build-up and installation and validation costs, until it is ready for its intended use. Manufacturing and other equipment under construction is carried at cost and is not depreciated until it is ready for its intended use.

Normal maintenance and repair costs of property, plant and equipment are expensed as incurred. Other subsequent expenses are capitalized, only when it is probable that future economic benefits associated with the items will flow to the Group and the cost of the item can be measured reliably, such as the replacement of an identified component of an asset.

An item of property, plant and equipment and any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on de-recognition of the asset (calculated as the difference between the net proceeds from disposal and the carrying amount of the asset) is included in the income statement when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year-end and adjusted prospectively, if appropriate.

5.2.2.8. IMPAIRMENT OF TANGIBLE AND INTANGIBLE ASSETS, OTHER THAN GOODWILL

The Group assesses, at each reporting date, whether there is an indication that an asset may be impaired. If any indication exists, or when annual impairment testing for an asset is required, the Group estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's or cash-generating unit's (CGU) fair value less costs of disposal and its value in use.

The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. When the carrying amount of an asset or CGU exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's (CGU's) recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset (CGU) does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the consolidated income statement.

5.2.2.9. INVENTORY

Inventories are valued at the lower of cost and net realizable value. The cost of inventories is determined on a first in, first out (FIFO) basis.

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.

Idylla™ systems kept as inventory are held for expected commercialization, including systems placed at clients for demo purposes or at customer sites under the Group's Early Adaptor Program. On a regular basis a review of the aging of the systems is performed in order to mitigate the obsolescence risk of the systems and to guarantee that the net realizable value remains higher than the carrying amount.

5.2.2.10. FINANCIAL INSTRUMENTS

FINANCIAL ASSETS

The Group has financial assets classified in the following categories: financial assets at fair value (through OCI or through P&L) and financial assets at amortized cost. The classification depends on the entity's business model for managing the financial assets and the contractual terms of the cash flows. Management determines the classification of its financial assets at the time of initial recognition.

Purchases or sales of financial assets that require delivery of assets within a time frame established by regulation or convention in the market place are recognized on the settlement date, i.e., the date that an asset is delivered by or to an entity.

Financial assets are initially measured at fair value. Transactions costs that are directly attributable to the acquisition of financial assets (other than financial assets at fair value through profit or loss) are added to the fair value of the financial

assets, as appropriate, on initial recognition. Transactions costs directly attributable to the acquisition of financial assets at fair value through profit or loss are recognized immediately in profit or loss.

AT AMORTIZED COST

Financial assets (such as loans, trade and other receivables, cash and cash equivalents) are subsequently measured at amortized cost using the effective interest method, less any impairment if they are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest.

The effective interest method is a method of calculating the amortized cost of a debt instrument and of allocating interest income over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the debt instrument, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

Trade and other receivables after and within one year are recognized initially at transaction cost and subsequently measured at amortized cost, i.e. at the net present value of the receivable amount, using the effective interest rate method, less allowances for impairment.

AT FAIR VALUE

For assets measured at fair value, gains and losses will either be recorded in profit or loss or OCI. For investments in equity instruments that are not held for trading, the Group has made an irrevocable election at the time of initial recognition of its participation in MyCartis to account for the equity investment at fair value through other comprehensive income (FVOCI).

After initial measurement, the investment in equity instruments is subsequently measured at fair value with unrealized gains or losses recognized in other comprehensive income and accumulated in reserves. As the Group's management has elected to present fair value gains and losses on equity investments in OCI, there is no subsequent reclassification of fair value gains and losses to profit or loss following the derecognition of the investment. Dividends from such investments continue to be recognized in profit or loss as other income when the Group's right to receive payments is established.

DERECOGNITION

A financial asset is primarily derecognized when the contractual rights to receive cash flows from the asset have expired or when the owner of the asset transferred its rights to receive cash flows and substantially all the risk and rewards of ownership of the financial asset to another party. If the Group neither transfers nor retains substantially all the risks and rewards of ownership and continues to control the transferred asset, the Group recognizes its retained interest in the asset and an associated liability for amounts it may have to pay. If the Group retains substantially all the risks and rewards of ownership of a transferred financial asset, the Group continues to recognize the financial asset and also recognizes a collateralized borrowing for the proceeds received.

IMPAIRMENT OF FINANCIAL ASSETS

The Group assesses on a forward-looking basis the expected credit losses associated with its financial assets carried at amortized cost. The impairment methodology applied depends on whether there has been a significant increase in credit risk. For trade receivables, the group applies the simplified approach permitted by IFRS 9 – Financial Instruments, which requires expected lifetime losses to be recognized from initial recognition of the receivables. The amount of the allowance is deducted from the carrying amount of the asset and is recognized in the income statement.

FINANCIAL LIABILITIES

All financial liabilities are recognized initially at fair value net of directly attributable transaction costs. The Group's financial liabilities include trade and other payables, borrowings, leases and a convertible bond.

The Group has financial liabilities classified as financial liabilities measured at amortized cost. The Group's outstanding convertible bond is included on the balance sheet, based on the fair value at issuance.

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest rate method.

The effective interest method is a method of calculating the amortized cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

DERECOGNITION

The Group derecognizes financial liabilities when, and only when, the Group's obligations are discharged, cancelled or they expire. The difference between the carrying amount of the financial liability derecognized and the consideration paid and payable is recognized in profit or loss.

CONVERTIBLE DEBT

The liability component of the convertible bond is measured at its fair value (i.e. discounting its contractual cash flows using market benchmark rate and market credit spread for a similar debt) minus transaction costs that are allocated to the host debt component and is accounted for at amortized costs.

EQUITY INSTRUMENTS

Equity instruments (e.g. share capital and employee warrant plans) issued by the Group are recorded at the fair value of the proceeds received, net of transactions costs.

The equity component of the convertible bond is the embedded share conversion option. This component is initially measured as the difference between the nominal amount of the convertible bond minus the initial fair value of the liability component and the allocated transaction costs, and is not remeasured subsequently.

5.2.2.11. CASH AND CASH EQUIVALENTS

Cash and cash equivalents include cash in hand, deposits held at call with banks, other short-term bank deposits with a maturity of or less than three months, and which are subject to an insignificant risk of changes in value.

5.2.2.12. INCOME TAXES

Income taxes include all taxes based upon the taxable profits of the Group including withholding taxes payable on transfer of income from group companies and tax adjustments from prior years and deferred income taxes.

CURRENT TAX

Current 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 calculate 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 TAX

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date. Deferred tax liabilities are recognized for all taxable temporary differences, except when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

Deferred tax assets are recognized for all deductible temporary differences, the carry-forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profits will be available against which the deductible temporary differences, and the carry-forward of unused tax credits and unused tax

losses can be utilized, except when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

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 profits 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.

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 (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority.

R&D INVESTMENT TAX CREDITS

Current IFRSs have no specific accounting principles with respect to the treatment of investment tax credits as these are scoped out of IAS 20 Accounting for Government Grants and Disclosure of Government Assistance and IAS 12 Income Taxes. As a result, the Group developed an accounting policy in accordance with IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors, whereby it opted to follow the analogy to IAS 12. In following that analogy, there will be immediate recognition of an income tax credit and deferred tax asset when the Group satisfies the criteria to receive the credits. The recognition of the income tax credit is accounted for in the income statement under the line 'Income taxes'.

Recognized research and development tax credits in Belgium can be effectively repaid if a company has not been able to offset the tax credit against the corporation tax for the last five consecutive tax years. Therefore in 2022, EUR 0.3m of the Group's tax credit on research and development has become a short-term receivable.

5.2.2.13. EMPLOYEE BENEFITS

SHORT-TERM EMPLOYEE BENEFITS

Short-term employee benefits include salaries and social security contributions, social taxes, paid vacation and bonuses. They are recognized as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period are shown as other current liabilities.

POST-EMPLOYMENT BENEFITS

Due to the fact that the Belgian law prescribes that the employer would guarantee a minimum rate of return on the contributions, such plans are classified as defined benefit plans under IFRS.

The cost of providing benefits is determined using the Projected Unit Credit (PUC) method, with actuarial valuations being carried out at the end of each reporting period.

Re-measurement, comprising actuarial gains and losses, the effect of changes to the asset ceiling (if applicable) and the return on plan assets (including interest), is reflected immediately in the statement of financial position with a charge or credit recognized in other comprehensive income in the period in which they occur. Re-measurement recognized in OCI (Other Comprehensive Income) is reflected immediately in retained earnings and will not be reclassified to P&L in subsequent periods. Past service costs are recognized in profit or loss in the period of a plan amendment. Net interest is calculated by applying the discount rate at the beginning of the period to the net defined benefit liability or asset.

Defined benefit costs are categorized as follows:

- Service costs (including current service cost, past service cost, as well as gains and losses on curtailments and settlements);
- Net interest expense or income; and

- Re-measurement gains and losses.

The Group presents the first two components of defined benefit costs in P&L. Curtailment gains and losses are accounted for as past service costs.

The retirement benefit obligation recognized in the consolidated balance sheet represents the actual deficit in the Group's defined benefit plans. Any surplus resulting from this calculation is limited to the present value of any economic benefits available in the form of returns from the plans or reductions in future contributions to the plans.

SHARE-BASED PAYMENT ARRANGEMENTS

The Group operates equity-settled share-based payment plans. The fair value of the employee services received in exchange for the grant of stock options is determined at the grant date using an appropriate valuation model (Black-Scholes Merton model).

The total amount to be expensed over the vesting period, with a corresponding increase in the 'share-based payment reserve' within equity, is determined by reference to the fair value of the stock options granted, excluding the impact of any non-market vesting conditions (for example, profitability and sales growth targets). Non-market based vesting conditions are included in assumptions about the number of stock options that are expected to become exercisable. At each reporting date, the entity revises its estimates of the number of stock options that are expected to become exercisable. It recognizes the impact of the revision of original estimates, if any, in the income statement, and a corresponding adjustment to equity over the remaining vesting period.

The proceeds received net of any directly attributable transaction costs are credited to share capital (par value) and share premium when the stock options are exercised.

5.2.2.14. PROVISIONS

The Group recognizes provisions when it has a present obligation, legal or constructive, as a result of past events, when it is probable, defined as more likely than not, that an outflow of resources will be required to settle the obligation and when a reliable estimate of the amount can be made.

Where the effect of the time value of money is material, the amount is the present value of expenditures required to settle the obligation. Impacts of changes in discount rates are generally recognized in the financial result.

5.2.2.15. REVENUE RECOGNITION

The Group recognizes revenues from the sale of the Idylla™ platform, related cartridges and services as well as revenues generated from collaboration arrangements in accordance with IFRS 15 Revenue from contracts with customers.

IFRS 15 specifies how and when a company should recognize revenue and requires entities to provide users of financial statements with more informative, relevant disclosures. The standard provides a single principles-based five-step model to be applied to all contracts with customers as follows:

- Identify the contract(s) with a customer
- Identify the performance obligations in the contract
- Determine the transaction price
- Allocate the transaction price to the performance obligations in the contract
- Recognize revenue when (or as) the entity satisfies a performance obligation

Transactions with customers and collaboration partners may include multiple deliverables (performance obligations). The Group evaluates whether the obligations towards its customers or collaboration partners are distinct on a stand-alone basis or in the context of the contract. If the Group determines that multiple performance obligations exist, the transaction

price is allocated to each performance obligation based upon the best estimate of the stand-alone selling prices of each obligation.

The Group recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration the Group expects to be entitled to in exchange for those goods or services.

If the services rendered exceed the payment, accrued income is recognized. If the payments exceed the services rendered, deferred income is recognized. The Group decided to keep old terminology; accrued income instead of contract asset and deferred income instead of contract liability.

COLLABORATION REVENUE

The Group provides multiple products or services to its customers as part of a single collaboration arrangement, such as research, development, manufacturing, commercialization and licensing. Each component of such arrangement is reviewed to assess if the component should be considered as a distinct performance obligation within the context of the contract. If a performance obligation is considered to be distinct, then the revenue related to it is accounted for separately from the other performance obligations; otherwise, it is combined with other performance obligations until the Group identifies a bundle of obligations that is distinct.

The amount of revenue recognized is the amount allocated to the satisfied performance obligation taking into account variable consideration. The transaction price may include upfront (license) payments, milestone payments and/or compensation for research and development services. Variable consideration that is considered in the transaction price typically relates to milestone and royalty payments The estimated amount of variable consideration is included in the transaction price only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. As soon as the uncertainty is resolved, the variable component of the transaction price (mainly milestone payments and success fees) is included in the transaction price based on the appropriated timing of revenue recognition of the related performance obligation. In certain situations, the Group may receive contingent payments after the end of its period of continued involvement. In such circumstances, the Group would recognize 100% of the contingent revenues when the contingency is resolved and collection is reasonably certain. Royalty-based revenues are recognized when the royalty is earned, or when the underlying goods or services are sold. Payment schedules differ from arrangement to arrangement but no element of financing is deemed present. Therefore the transaction price is not adjusted for the effects of a significant financing component.

Revenue linked to performance obligations relating to development work and e.g. clinical validation are recognized over time as the services are rendered to the customer based on the progress over the activities, i.e. a rato the services performed.

In case of performance obligations relating to licensing intellectual property (IP), the Group assesses if it grants a right to access the IP as it exists throughout the license period or a right to use the IP as it exists at the point in time at which the license is granted. If the performance obligation is to grant a right to access, then the related revenue is recognized over the license period; otherwise, it is recognized at a point in time, i.e. when the license period starts or when the customer starts using the IP. The Group assesses if the license provided can be considered as being distinct in the context of the contract. If not, the license will have to be bundled with the research and development services. Currently all milestone payments are development milestones and are considered to be distinct, hence recognized at a point in time. If one would conclude that the license is not a distinct performance obligation, the receipt of a development milestone will have to be recognized pro rata the completion of the research and development services to be provided under the agreement.

Unless up-front fees are paid in exchange for products delivered or services performed and, therefore, control over the related services has been transferred to the buyer in a separate transaction, such fees are not recognized as revenue at a point in time but rather over time (even if they are non-refundable) pro rata over the expected performance period under each respective arrangement.

The Group makes its best estimate of the period over which it expects to fulfil its performance obligations, which may include technology transfer assistance, research and development activities, clinical, medical and regulatory activities, manufacturing and commercialization activities.

Cost reimbursements resulting from collaboration agreements, or a similar type of compensation received for costs incurred under R&D collaborations are recorded as R&D services as the related costs are incurred and upon agreement by the parties involved. The corresponding expenses are generally recorded under research and development expenses. Revenues from R&D Services are in general recognized over the duration of the collaboration agreement, if relevant subject to when the required services are provided or costs are incurred.

License fees include technology access fees to the Idylla platform technology. A distinction is made between right to use and right to access fees. Right to use fees are fees paid to use the IP as it exists when the license is granted, which means that the revenue recognition will happen at a point in time. Right to access fees are fees paid to access IP throughout a certain license period, which means that the revenue recognition will happen over time. A contingent consideration received by the Group upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part either on the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity.

A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with the Group's performance required to achieve the milestone or the increase in value to the collaboration resulting from the Group's performance, related solely to the Group's past performance, and is reasonable relative to all of the other deliverables and payments within the overall collaboration arrangement.

PRODUCT RELATED REVENUE

PRODUCT SALES

Revenues from the sale of goods are recognized when the Group has transferred control over the goods to the buyer according to the incoterms agreed with such customers, i.e. performance obligation is satisfied at a point in time.

The transaction price (revenue) from the sale of goods is the amount of the amount of the consideration to which the Group expects to be entitled in exchange for transferring the goods to the customer. This includes fixed amounts and variable amounts, such as returns and allowances, trade discounts and volume discounts. The variable consideration is only recognized as part of revenue to the extent it is highly probable that a significant reversal of revenue will not occur when the associated uncertainty is subsequently resolved.

REAGENT RENTAL CONTRACTS

The Group also puts its products available to customers under the form of an Idylla™ Reagent Rental Agreement whereby the Group delivers the console and instruments, together the Idylla™ system, and the customer commits to purchase a minimum required volume (consumption) of cartridges over a defined period. The price of the Idylla™ system is included as a mark-up premium in the price of the cartridges and is as such received over the period when the cartridges are purchased. Under these contracts the Group bundles the following multiple elements together: the use of the Idylla™ system, the servicing of the system and the consumption of Idylla™ cartridges. The use of the Idylla™ system is considered to be a lease and therefore the consideration under the reagent rental agreement will have to be allocated between the lease component and the other components (servicing and consumption of Idylla™ cartridges) using a relative fair value approach.

There is no binding cartridge volume commitment from the customer that will result in a full reimbursement of the Idylla™ systems price over the term of the agreement. However, there is a minimum annual consumption of cartridges indicated by the customer on the basis of which the mark-up premium for the Idylla™ system usage is determined, ensuring a proper compensation for the usage of the Idylla™ system. The minimum annual consumption of cartridges is evaluated at each reporting date. If the minimum indicated consumption is not met, the Group has the right to increase the sales prices and/or the volume commitments for the cartridges. The Group also has the right to terminate the agreement with a notice period if the minimum annual cartridge consumption is not met, without any additional indemnity. The customer has the option to terminate the agreement at any given time before the agreed contractual term with a notice period during which the customer will be required to purchase or pay a part of the agreed minimum annual cartridge commitment, in proportion to the notice period. No additional indemnity will be required. Since the minimum purchase requirements are not contractually enforceable, the lease component present in these contracts are generally to be considered as

contingent payments. The price invoiced to customers for an Idylla™ cartridge includes a cost for the use and servicing of the Idylla™ system by the customer. Customers are invoiced based on received sales orders for Idylla™ cartridges. Revenue allocated the Idylla™ cartridges will only be recognized when the Idylla™ system is delivered to the customer and the customer obtained control over the cartridges.

The significant risks and rewards for the Idylla™ systems are not transferred to the customer at signing of the agreement. The revenue of the cartridges, the Idylla™ systems and servicing thereof is consequently recognized gradually when cartridges are delivered to the customer.

REGULAR RENTAL CONTRACTS

The Group also rents out Idylla™ systems, whereby the customer pays a regular rental fee for the temporary use of the Idylla™ system since there is no transfer of ownership. Under this type of rental contracts, the Idylla™ system revenue is considered as pure rental income and is recognized linearly over the term of the rental contract. Upon expiry of the rental contract, the rented out Idylla™ systems return to the Group.

SERVICE REVENUE

Under service revenue, Biocartis classifies the revenue generated by service contracts as well as the revenue generated by one-off repairs. Service revenue is recognized over time, linearly for capital sales and in line with the service contract term, which includes regular annual preventive maintenance. For reagent rental contracts the service revenue is also recognized over time but in line with the cartridge consumption which equals the usage of the system.

5.2.2.16. GRANTS

Government grants are not recognized until there is reasonable assurance that the Group will comply with the conditions attaching to them and that the grants will be received. Any outstanding receivables related to these grants are recorded as grants receivable.

R&D GRANTS

On certain specific research and development projects, the costs incurred are partially reimbursed by IWT (Institute for the Promotion of Innovation by Science and Technology in Flanders), the Flemish Agency for Innovation & Entrepreneurship under its Strategic Transformation Support ('STS') program, the European Commission or other institutional funds. These grants are recognized in profit or loss on a systematic basis over the periods in which the Group recognizes as expenses the related costs which the grants are intended to compensate. They are presented as other operating income.

INVESTMENT GRANTS

Grants from the STS program relating to investments in property, plant and equipment and intangible assets are deducted from the cost of the related asset. The grant is recognized in profit or loss over the life of a depreciable asset as a reduced amortization expense.

5.2.2.17. LEASES

Lease contracts as defined by IFRS 16 Leases, are recorded in the balance sheet, which leads to the recognition of an asset representing a right-of-use of the asset leased during the lease term of the contract and a liability related to the payment obligation.

The Group applies a single recognition and measurement approach for all lease, expect 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.

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 re-measurement 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. If there is no reasonable certainty that the Group will obtain ownership by the end of the lease term, the right-of-use asset shall be fully depreciated over the shorter of the lease term and its useful life. The right-of-use assets are also subject to impairment, refer to the accounting policies in note 5.2.2.8.

LEASE LIABILITIES

The corresponding liability to the lessor is included in the consolidated balance sheet as a financial liability. At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of the lease payments to be made over the lease term. The lease payments include 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 terminating the lease, if the lease term reflects the Group exercising the option to terminate. Variable lease payments that do not depend on an index or a rate are recognized as expenses in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because 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 re-measured if there is a modification, a change in lease term, a change in the lease payments (e.g. changes to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset.

SHORT-TERM LEASES AND LEASES OF LOW-VALUE ASSETS

The Group applies the short-term lease recognition exemption for leases that have a lease term of 12 months or less from the commencement date. It also applies the lease of low-value assets recognition exemption for assets that have a value in new of below EUR 5,000. Lease payments on short-term and low-value leases are recognized as expense.

5.2.2.18. BORROWING COSTS

Borrowing costs directly attributable to the acquisition, construction or production of an asset that necessarily takes a substantial period of time to get ready for its intended use or sale are capitalized as part of the cost of the asset. All other borrowing costs are expensed in the period in which they occur. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

5.2.3. Critical accounting estimates, assumptions and judgments

5.2.3.1. CRITICAL ACCOUNTING ESTIMATES, ASSUMPTIONS AND JUDGMENTS

When preparing the consolidated financial statements, judgments, estimates and assumptions are made that affect the carrying amount of certain assets, liabilities, revenues and expenses. These include the going concern assessment, the valuation of the share-based payment transactions, the valuation of employee benefits and actuarial assumptions underlying such calculations and the revenue recognition for multiple element arrangements, upfront fees and reagent rental contracts. These estimates and assumptions have been reviewed for each year and are reviewed on a regular basis, taking into consideration past experience and other factors deemed relevant under the then prevailing economic conditions. Changes in such conditions might accordingly result in different estimates in the Group's future consolidated financial statements.

CRITICAL JUDGMENTS

Going concern

The going concern valuation rules were used both for the statutory annual accounts and for the consolidated annual accounts of the Company and this notwithstanding the existence of losses carried forward. Pursuant to article 3:6 of the new Code of Companies and Associations the board of directors motivates the use of going concern valuation rules as follows:

The past years, the Company continued to execute on its growth strategy, building strong fundamentals that are expected to lead to sustainable profitability as it continues to scale. Between 2016 and 2022, commercial cartridge volumes have grown at a compound annual growth rate of 54%. Biocartis' technology is widely validated, and the global installed base has grown to 2,085 Idylla™ instruments. Revenue and gross profit from product sales and instrument servicing have grown at a compound annual growth rate of 26% and 23%, respectively between 2016 and 2022. The Company offers a broad menu of more than 10 tests in over 70 countries across the world and has a healthy pipeline of novel high value-added tests. Biocartis has invested in fully automated manufacturing and demonstrated its ability to scale. In 2022, the revenue in the Company's core oncology business increased by 30% and the gross profit on product revenues grew 132%, reflecting a gross margin of 34% compared to 16% in 2021. Consequently, the operating cash burn (Earnings before interest and taxes plus capital expenditure), was reduced significantly from EUR 56.6 million in 2021 to EUR 38.5 million. The publicly disclosed outlook for 2023 clearly demonstrates that the Company is committed to further grow revenues, improve gross margins, and reduce the operating cash burn in 2023 and beyond.

On 16 January 2023, the Company completed the comprehensive recapitalization announced on 1 September 2022, adding EUR 36.1 million to the year-end cash position of EUR 26.1 million. The cash and cash equivalents available at the start of 2023 therefore amounted to EUR 62.2 million.

Based on the projected cash burn for 2023, Biocartis expects to have sufficient cash resources to fund its activities until the annual general meeting of the Company in 2024, which is the applicable horizon for the going concern assessment. However, the cash projections include certain cost saving measures to ensure compliance with the covenant of the convertible term loan, which requires the Company to maintain a minimal liquidity of EUR 10 million as described in section 5.2.29.2 of the consolidated annual accounts. The board of directors acknowledges that there is inherent uncertainty in projecting future cashflows, particularly in the current economic climate. In case of a breach of the minimum liquidity covenant, the board considers that there is a material uncertainty linked to obtaining a waiver and hence having sufficient liquidities to fulfill its obligations over the applicable horizon. In the event of adverse deviation from the current cash flow projections, Biocartis has the ability to extend the cash runway to continue to operate at least until the annual general meeting of the Company in 2024 by further reducing its operating expenses and cut back on planned investments in various areas of the business, or by securing additional financing.

As a result, the board of directors is of the opinion that the application of valuation rules assuming the Group's ability to operate as a going concern are justified.

Furthermore, and although no assurance can be given, the board of directors expects that Biocartis will be able to attract additional financing needed to fund its activities until the Company generates positive net cash flows, based on the established track record of strong growth and on the Group's long-term financial projections.

Revenue recognition relating to collaboration arrangements

Assessing the indicators for revenue recognition under collaboration arrangements requires judgement to determine (i) the nature of the contractual performance obligations and whether they are distinct or should be combined with other performance obligations, and (ii) the pattern of transfer of each promised component identified in the contract, using methods based on key assumptions such as forecasted costs and development timelines of the collaboration arrangements for the assessment of satisfaction of the performance obligation.

For all performance obligations linked to licensing agreements, the Group makes an assessment about whether or not the license is to be considered as a distinct performance obligation or not. The Group determines whether a promise to grant a license of intellectual property is distinct from other promised goods or services in the contract. As such, the Group assesses whether the customer can benefit from a license of intellectual property on its own or together with readily available resources (i.e., whether it is capable of being distinct) and whether the Group's promise to transfer a license of intellectual property is separately identifiable from other promises in the contract (i.e., whether it is distinct in the context of the contract). The assessment of whether a license of intellectual property is distinct is based on the facts and

circumstances of each contract, e.g. interdependencies between the license and other services in the contract, the continuing involvement of the Group after the license has been granted.

If the transfer of the license is considered to be a separate performance obligation, revenue relating to the transfer of the license is recognized at a point in time or over time depending on the nature of the license, i.e. granting a right to use the intellectual property or the right to access the IP. Basically, the Group assesses whether the customer has the right to use the intellectual property as it exists at a certain period in time or whether it has access to the intellectual property as it exists at any time during the license period, where the latter requires more on-going activities from the Group.

CRITICAL ACCOUNTING ESTIMATES AND ASSUMPTIONS

There are no major sources of estimation uncertainty as defined under IAS 1.125 in preparing these consolidated accounts.

5.2.3.2. OPERATING SEGMENTS

The segment information is represented in a consistent manner with the internal reporting to the executive management, enabling decision making of allocating resources to the segment and evaluating financial performances of the segment.

At this moment, all of the Group's activities relate to Idylla™ and as such there is only one operating segment. The reporting to the key decision makers is currently done at the global level.

In addition, substantially all non-current assets of the Group are located in the country of domicile (Belgium) per 31 December 2022.

5.2.4. Revenue

The Group's revenue recognized under IFRS 15 can be aggregated as follows:

In EUR 000	Years ended 31 December, 2022		2022	2021
	At a point in time	Over time		
Collaboration revenue				
R&D services	0	10,505	10,505	5,868
License revenue	0	100	100	185
Milestones	463	0	463	0
	463	10,605	11,068	6,053
Product related revenue				
Idylla™ System Sales revenue	4,178	0	4,178	5,045
Idylla™ System Rental revenue	4,994	0	4,994	3,824
Cartridge revenue	35,864	0	35,864	31,618
	45,036	0	45,036	40,486
Service revenue				
Idylla™ System Service revenue	928	448	1,377	1,730
	928	**448**	**1,377**	**1,730**
Total	**46,428**	**11,053**	**57,481**	**48,269**

For details related to the movements in accrued and deferred income related to collaboration agreements, we respectively refer to notes 5.2.20 and 5.2.27.

R&D service revenue is recognized over time as the services are rendered to the customer based on the progress over the activities i.e. a rato the services performed. Over the reporting period, the majority of the collaborations for which revenues were recognized, included a quarterly or monthly payment structure. Consequently, the Group recognized either an accrued income or deferred income on the balance sheet over the course of the reporting period.

In general, customers do not have a right-of return and/or are entitled to refunds in the context of product related sales.

The below table corresponds to the revenue expected to be recognized in the future relating to (partially) unsatisfied performance obligations. This table excludes potential future R&D service revenue of pending collaborations for which the associated services are performed on an hourly invoicing basis (IFRS 15.121).

In EUR 000	Expected revenue Years ended 31 December,	
	2022	2021
2022	0	535
2023	2,660	80
2024	1,259	0
2025	227	0
2026	0	0
After 2026	0	0
Total	4,146	615

The aggregate amount of the transaction price allocated to collaboration arrangements that are partially or fully unsatisfied as at 31 December 2022 is EUR 0.5m.

5.2.4.1. SUMMARY OF COLLABORATION REVENUES

Below is a description of the main collaboration arrangements from which the Group generated revenue in 2022, for more details on the accounting policy of collaboration revenue we refer to note 5.2.2.15.

BRISTOL-MYERS SQUIBB

Biocartis and Bristol-Meyers Squibb (BMS) have a collaboration under which one or more projects can be initiated in the area of MSI testing. In Q1 2019, a first project agreement under the master collaboration agreement was signed with the objective to register the Idylla™ MSI test as a companion diagnostic with the US FDA. In Q1 2020, another project agreement under the master collaboration agreement was signed with the objective to register the Idylla™ MSI test in the People's Republic of China. The elements included in these CDx agreements consists of milestone payments and R&D services. In Q4 2022, a third project agreement was signed with the objective to register the Idylla™ IDH2 CDx Assay as a companion diagnostic with the US FDA.

Based on the contractual dispositions, we assessed the following:

- The arrangement consists of the following performance obligations: development activities and services and the supply of Idylla™ assays and Idylla™ systems.
- The transaction price is currently composed of a fixed part, being quarterly installments and a variable part being milestone payments. The variable component of the transaction price will only be included as revenue when the related uncertainty is resolved.
- The transaction price has been allocated to the different performance obligations based on the stand-alone selling prices. The performance obligation related to development activities and services are recognized over the estimated service period based on a pattern that reflect the transfer of the development activities. The milestone payment will be treated as a change in transaction price as soon as the revenue constraint assessment is resolved. The milestone payments will be allocated to the performance obligation. Performance obligations relating to the supply of Idylla™ components are satisfied at a point in time, when the control over development components are transferred.

In relation to the collaboration agreement with BMS, the Group recognized R&D service revenues over time a rato to the services performed.

GENEPRODX

Biocartis and GeneproDx have signed a collaboration in Q4 2020, aimed at the development and commercialization of GeneproDx's novel genomic test ThyroidPrint on Biocartis' rapid and easy to use molecular diagnostics platform Idylla™. Upon commercialization of GeneproDx's novel genomic test ThyroidPrint, GeneproDx will make royalty payments to Biocartis based on net sales. Consequently, the elements included in this agreement consist of upfront license revenue, R&D services and product related revenue.

Product revenue recognized under this agreement is shown under product related revenue as it relates to the placement of Idylla™ systems and cartridges.

Based on the contractual dispositions, we assessed the following:

- The arrangement consists of the following performance obligations: license to use IP, development services and the supply of Idylla™ assays and Idylla™ systems
- The transaction price is currently composed of a fixed part, being the license fee and a variable part being the royalty revenue and product related revenue.
- The transaction price has been allocated to the different performance obligations based on the stand-alone selling prices. The performance obligation relating to granting the right to use the IP is satisfied at a point in time, i.e. at the start of the license period. Performance obligations relating to development activities and services are satisfied over the estimated service period based on a pattern that reflects the transfer of the development activities. The royalty-based revenues are recognized when the royalty is earned, or when the underlying goods are sold. Performance obligations relating to the supply of Idylla™ components are satisfied at a point in time, when the control is transferred.

In 2022, the Group recognized R&D service revenue. The recognized R&D service revenue relates to the billing of fixed amounts for each hour of service.

ASTRA ZENECA

Biocartis and Astra Zeneca UK Limited have signed a new collaboration in Q2 2022, aimed at the development and validation of the Idylla™ EGFR Mutation Test as a Companion Diagnostic (CDx) test for TAGRISSO®, as well as the use of the Idylla™ EGFR Mutation Test for IUO testing in the NeoADAURA trial. The project is entered pursuant to the In Vitro Diagnostics Master Collaboration Agreement, dated November 27, 2019 between the Parties. The elements included in this agreement consist of milestone payments and R&D services.

Based on the contractual dispositions, we assessed the following:

- The arrangement consists of the following performance obligations: development activities and services and the supply of Idylla™ assays
- The transaction price is currently composed of a fixed part, being quarterly installments and a variable part being milestone payments. The variable component of the transaction price will only be included as revenue when the related uncertainty is resolved.
- The transaction price has been allocated to the different performance obligations based on the stand-alone selling prices. The performance obligation related to development activities and services are recognized over the estimated service period based on a pattern that reflect the transfer of the development activities. The milestone payment will be treated as a change in transaction price as soon as the revenue constraint assessment is resolved. The milestone payments will be allocated to the performance obligation. Performance obligations relating to the supply of Idylla™ components are satisfied at a point in time, when the control over development components are transferred.

In 2022, the Group recognized R&D service revenue. The recognized R&D service revenue mainly related to the billing of fixed amounts for each hour of service.

5.2.4.2. REVENUES BY MAJOR COUNTRIES AND CUSTOMERS

In EUR 000	Years ended 31 December, 2022	2021
Country of domicile	**582**	**618**
Belgium	582	618
Total all foreign countries, of which	**56,899**	**47,651**
United States of America	16,317	10,966
China	1,885	1,491
Spain	4,464	3,452
France	4,794	4,320
Great Britain	5,503	7,938
Germany	4,323	3,625
Rest of the world	19,613	15,859
Total	**57,481**	**48,269**

Revenue in the above table is assigned according to the location of the Group or parent company of the customer.

In 2022 there was no customer representing 10% of the total recognized revenue, the 5 largest clients together represent 29% of the revenue. In 2021 there was one customer representing 10% of the total recognized revenue, the 5 largest clients together represented 22% of the revenue.

5.2.5. Other operating income

In EUR 000	Years ended 31 December, 2022	2021
R&D project support (VLAIO & IWT grants)	459	2,054
Other project grants (EU)	-	-
Other income	36	4,576
Total	**495**	**6,630**

Other income of EUR 0.5m related to grants received in connection with the development of the new Idylla™ Flex technology that that separates the generic components of an Idylla™ test from the test-specific components. The Idylla™ FLEX technology shortens the development time of new Idylla™ assays, allowing to bring them to the market much faster and is expected to facilitate the use of Idylla™ tests in therapy decisions and molecular surveillance. The Idylla™ IDH1-2 Mutation Assay Kit (RUO) is the first test developed using the Idylla™ FLEX technology. The assay was launched among selected customers and will be made available for partnerships with pharmaceutical companies, clinical research organizations and reference labs conducting research in the course of 2023.

In 2021, other income included an insurance claim of EUR 4.6m for damages caused by the fire in a warehouse in July 2021.

5.2.6. Cost of sales

The cost of goods sold in relation to the product sales is as follows:

In EUR 000	Years ended 31 December, 2022	2021
Employee benefit expenses	-8,315	-9,510
Material, lab consumables & small equipment	-13,242	-16,282
Depreciation and amortization	-4,150	-4,243
Royalty expense	-1,375	-1,728
Facilities, office and other	-2,717	-2,159
Total	**-29,799**	**-33,922**

The cost of goods sold decreased by EUR 4.1m or 12% from EUR 33.9m in 2021 to EUR 29.8m in 2022, while product revenue increased by 11%. The decrease of the cost of goods sold is attributable to economies of scale the increased utilization of the automated high-throughput manufacturing line ML2. In 2021, production on the ML2 line was constrained because of the shortage of reagents during the first half of the year and because of the forced 2-month production stop after the fire on 30 July 2021. The production of certain assays was transferred to the ML1 line to preserve customer supply as much as possible, but the manufacturing capacity on the ML1 line is significantly lower and the manufacturing cost significantly higher than on the ML2 line. In 2022, more than 90% of all assays were transferred from the older manufacturing line ML1 to ML2, resulting in a significant reduction of the manufacturing cost per cartridge. In 2023, ML1 will be decommissioned.

5.2.7. Research & development expenses

In EUR 000	Years ended 31 December, 2022	2021
Employee benefit expenses	-24,622	-26,585
R&D consultancy & subcontracting	-5,734	-10,383
Laboratory and cartridge expenses	-215	-2,955
Quality, regulatory and intellectual property	-520	-669
Facilities, office & other	-3,047	-2,835
ICT	-576	-380
Travel, training & conferences	-403	-139
Depreciation and amortization	-3,277	-4,108
Total	**-38,393**	**-48,054**

Subcontracting includes expenses in relation to services provided by research and development providers such as services related to the development of assay cartridges, instrument and console of the various diagnostic platforms, manufacturing equipment design and engineering services.

Laboratory and cartridge costs include consumables and prototype costs related to the development of diagnostic platform prototypes and assays.

The remaining expenses relate to quality, regulatory, patenting, building facilities, ICT, office, maintenance of equipment, logistics, travel, training and conferences.

2021 was a year of exceptional investment in R&D, in part because of the carry-over of projects that were delayed in 2020 following the pandemic outbreak, but also because of increased investments in further menu expansion and diversification, including a.o. the development of the Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD and the continued investment in the transfer of assays from the ML1 line to the ML2 line. In 2022, investments in R&D were cut back and included the development and the launch of the CE-IVD Idylla™ Genefusion panel, the Idylla™ IDH1-2 Mutation Assay Kit (RUO) and certain content partner tests.

5.2.8. Sales & marketing expenses

In EUR 000	Years ended 31 December, 2022	2021
Employee benefit expenses	-13,099	-11,971
S&M consultancy & subcontracting	-623	-662
Sales and promotional expenses	-854	-591
Business development	-860	-572
Facilities, office & Other	-1,248	-955
Travel, training & conferences	-2,087	-964
Depreciation and amortization	-1,529	-702
Impairment of receivables	-294	-346
Total	**-20,595**	**-16,763**

Sales and promotional expenses relate to costs of external market research, advertisement, and promotional activities related to the Group's products.

The increase of EUR 3.8m in sales & marketing reflected normalized commercial activities post the pandemic and the full year impact of the restructuring of the US commercial operations implemented at the end of 2021.

5.2.9. General & administrative expenses

In EUR 000	Years ended 31 December, 2022	2021
Employee benefit expenses	-11,061	-10,994
External advice	-897	-785
Facilities, office & other	-1,825	-1,814
Human resources	-1,129	-1,306
Travel, training & conferences	-179	-60
Depreciation and amortization	-1,144	-601
Total	**-16,236**	**-15,560**

In EUR 000	Years ended 31 December, 2022	2021
Other expenses		-3,244
Total		**-3,244**

External advice expenses include fees, service and consulting expenses related to legal, human resources, investor relations, accounting, audit and tax services. Facilities, office & other include office, insurance and other miscellaneous expenses used in general and administrative activities.

G&A expenses increased EUR 0.7m, reflecting inflation and increased facility costs. In Q4 of 2022, the organization was streamlined to offset the expected continued inflation of costs in 2023, including the mandatory indexation of salaries in Belgium of 11%, effective January 2023.

In 2021, other expenses entirely relate to the write-off of materials and finished products lost in the fire that occurred in July 2021.

5.2.10. Employee benefit expenses

In EUR 000	Years ended 31 December, 2022	2021
Short term employee benefits	-55,807	-57,254
Post-employee benefit expense	-530	-678
Termination benefits		-367
Share-based payments	-760	-760
Total	**-57,097**	**-59,059**

Employee benefit expenses include payroll expenses of fixed employees, interim staff and consultants in a permanent position. The employee benefit expenses amounted to EUR 57.1m in 2022 compared to EUR 59.1m in 2021, a year-over-year decrease of 3%. This decrease is predominantly a consequence of the decrease in headcount, as can be seen in the table below. In Q4 of 2022, the organization was streamlined to offset the expected continued inflation of costs in 2023, including the mandatory indexation of salaries in Belgium of 11%, effective January 2023. Among others, the workforce was reduced by 16% across the entire organization since 31 December 2021.

The headcount can be presented as follows:

	As of 31 December, 2022	2021
Operations staff	148	227
Research and development staff	198	218
Marketing and sales staff	93	91
General and administrative staff	87	83
Total headcount	**526**	**619**
Average full-time equivalents	**546**	**579**

The average FTE equals sum of the day-to-day FTE divided by the number of days. The average FTE's in the table above is calculated including fixed employees, interim staff and consultants. The average FTE's of fixed employees only is 506 for 2022.

5.2.11. Financial income and expense

In EUR 000	Years ended 31 December, 2022	2021
Interest expense	-11,187	-9,320
Other financial expense	-61	-168
Total	**-11,248**	**-9,488**
Other financial result	-6,442	1,077
Total	**-6,442**	**1,077**
Financial result, net	17,690	-8,411

Net financial expenses increased to EUR 17.7m in 2022 compared to EUR 8.4m in 2021 and included the impact of the recapitalization.

Expenses in relation to the Company's convertible bonds consist of EUR 8.0m coupon payment in 2022 (consisting of EUR 4.6m coupon payment and EUR 3.4m of debt appreciation), compared to 8.3m in 2021. The bonds, issued in May 2019, were amended in 2022. The amendment included a.o. the extension of the maturity date from May 2024 until November 2027, a mandatory conversion of 10% of the principal amount and the capitalization of remaining coupons at the maturity date until

2027. The mandatory conversion, effected on 16 December 2022, resulted in a EUR 0.5m lower interest expense compared to 2021.

Following the amendment of the existing convertible bonds, an offer was launched to exchange such amended convertible bonds for new 4.5% second lien secured convertible bonds, which resulted in an increase of interest expenses of EUR 1.6m, consisting of EUR 1.5m debt appreciation and EUR 0.1m interest payment.

Furthermore, a convertible term loan of EUR 30.1m was issued in 2022, of which EUR 18.1m was drawn in 2022, resulting in an interest expense of EUR 0.6m, consisting of EUR 0.27m debt appreciation and an interest payment of EUR 0.37m. The convertible term loan matures on 9 August 2026 and in includes the quarterly payment of interest at 8.75% plus EURIBOR with a minimum of 1.5%. The conversion price amounts to 90% of the volume weighted average price on the day preceding the conversion date or EUR 0.9.

The total interest and debt appreciation expense associated with the convertible term loan and the two convertible bonds amounted to EUR 10.2m.

In accordance with IFRS, the amendment and the exchange were considered as an extinguishment of the existing 4% convertible bonds and the issuance of the new 4.5% convertible bonds. The difference between the derecognized existing bonds and the new convertible bonds was recorded as a loss of EUR 7.3m in the income statement and is included in the other financial result. The loss mainly consists of EUR 33.1m associated with the embedded derivative of the new 4.5% convertible bonds, reflecting the fair value of the conversion option and EUR 6.5m of transaction expenses, offset by the difference of EUR 30.2m, between the outstanding liability before and after the exchange and the gain of EUR 2.1m on the repurchase of existing bods at a discount to their nominal value. Using the Black-Scholes model, the fair value of the conversion option included in the new 4.5% convertible bonds was calculated on 16 November 2022, the date at which the conversion price of the new convertible bonds was fixed. The assumptions used in the valuation model included a 4-year historical volatility of 53%, a risk-free interest rate of 2.6%, the price of the Biocartis share of EUR 1.008 on 16 November 2022, the conversion price of EUR 1.125 and the 4-year term of the new convertible bonds.

The total transaction expenses related to all recapitalization transaction amounted to EUR 9.9m, of which EUR 6.5m is related to the extinguishment of the existing 4% convertible bonds and the issuance of the new 4.5% convertible bonds and included in the other financial result. The transaction expenses related to the convertible term loan amounted to EUR 1.0m and were capitalized and EUR 2.4m were deferred to 2023, since these costs are linked to the recapitalization transactions that were completed on 16 January 2023.

Other financial result also consists of non-realized exchange gains and losses, these gains amounted to 0,8m in 2022 compared to EUR 1.0m in 2021, due to a decrease in dollars on our bank account and fluctuations in the exchange rates of foreign currencies.

5.2.12. Loss per share

The Group has stock option plans and convertible debt that may be settled in common shares of the Group and which are considered anti-dilutive given that the Group's operations were loss making over the reporting period. As such, the basic and diluted loss per share are equal.

The basis for the basic and diluted loss per share is the net loss for the year attributable to the owners of the Group.

	Years ended 31 December,	
	2022	2021
Profit/loss for the period attributable to the owners of the Group (in EUR 000)	-65,381	-71,472
Weighted average number of ordinary shares for basic loss per share (in number of shares)	60,546,465	57,545,663
Basic loss per share (EUR)	-1.08	-1.24

5.2.13. Intangible assets

The Group's intangible assets comprise acquired patents, licenses and software. The carrying amounts for the periods presented can be summarized as follows:

In EUR 000	Patents and licenses	ICT software	Total
Year ended 31 December 2021			
Opening net carrying value	5,574	71	5,645
Additions	0	68	68
Disposals	0	0	0
Disposal depreciations	0	0	0
Amortization expense	-577	-69	-646
Closing net carrying value	**4,997**	**70**	**5,067**
As at 31 December 2021			
Cost	12,292	1,805	14,097
Accumulated amortization	-7,295	-1,736	-9,031
Net carrying value	**4,997**	**70**	**5,067**
Year ended 31 December 2022			
Opening net carrying value	4,997	70	5,067
Additions	241	128	368
Disposals	0	0	0
Disposal amortizations	0	0	0
Amortization expense	-579	-86	-665
Closing net carrying value	**4,659**	**111**	**4770**
As at 31 December 2022			
Cost	12,533	1,932	14,465
Accumulated amortization	-7,874	-1,822	-9,696
Net carrying value	**4,659**	**111**	**4,770**

Patents and licenses primarily include a number of technology licenses acquired by the Group from Philips in 2010 relating to the Group's flagship diagnostic platform Idylla™. The carrying amount per 31 December 2022 is EUR 3.5 (2021: EUR 4.0m). The remaining useful life is 6 years.

Amortization expense on intangible assets is shown in the income statement under research and development expenses.

5.2.14. Property, plant and equipment

The Group's property, plant and equipment comprise ICT equipment, laboratory equipment, manufacturing equipment, Idylla™ systems for internal use, furniture and fixtures, leasehold improvements, other property and equipment, equipment under construction, right-of-use assets and Idylla™ systems for rent. The carrying amounts are as follows:

In EUR 000	ICT equipment	Laboratory equipment	Manufacturing equipment	Systems for internal use	Furniture and fixtures	Leasehold improvements	Other property and equipment	Equipment under construction	Assets held under lease	Systems for rent	Right-of-use assets	Total
Opening carrying amount	**377**	**791**	**2,763**	**1,384**	**281**	**153**	**0**	**130**	**0**	**6,718**	**27,502**	**40,099**
Additions	15	258	1,262	413	15	187	0	76	0	3,419	1,987	7,631
Disposals	0	-19	-359	-262	0	0	0	0	0	-1,627	0	-2,267
Disposal depreciation	0	4	0	219	0	0	0	0	0	683	0	905
Depreciation charge of the period	-140	-296	-751	-570	-68	-74	0	0	0	-2,186	-5,116	-9,199
Transfer gross carrying amount	0	0	0	0	0	0	0	0	0	0	0	0
Transfers depreciations	0	0	0	0	0	0	0	0	0	0	0	0
Currency translation gross carrying amount	0	0	0	42	2	0	0	0	0	0	8	52
Currency translation depreciations	0	0	0	-20	0	0	0	0	0	0	-7	-27
Closing carrying amount	**251**	**738**	**2,915**	**1,207**	**230**	**266**	**0**	**206**	**0**	**7,006**	**24,374**	**37,193**
As at 31 December 2021												
Cost	2,040	3,302	11,218	6,131	825	2,972	29	206	0	12,037	47,091	85,851
Accumulated depreciation	-1,789	-2,564	-8,303	-4,925	-595	-2,706	-29	0	0	-5,030	-22,717	-48,659
Carrying amount	**251**	**738**	**2,915**	**1,206**	**230**	**266**	**0**	**206**	**0**	**7,006**	**24,374**	**37,192**
Opening carrying amount	**251**	**738**	**2,915**	**1,206**	**230**	**266**	**0**	**206**	**0**	**7,006**	**24,374**	**37,192**
Additions	56	135	805	323	17	85	0	5	0	3,163	723	5,313
Disposals	0	-11	0	-32	0	0	0	0	0	-2,476	-7,098	-9,616

In EUR 000	ICT equipment	Laboratory equipment	Manufacturing equipment	Systems for internal use	Furniture and fixtures	Leasehold improvements	Other property and equipment	Equipment under construction	Assets held under lease	Systems for rent	Right-of-use assets	Total
Disposal depreciation	0	7	115	15	0	0	0	0	0	1136	7,165	8,438
Depreciation charge of the period	-101	-321	-1,142	-517	-63	-75	0	0	0	-2,290	-5,307	-9,816
Transfer gross carrying amount	0	0	0	0	0	0	0	0	0	0	0	0
Transfers depreciations	0	0	0	0	0	0	0	0	0	0	0	0
Currency translation gross carrying amount	0	0	0	32	1	0	0	0	0	0	7	40
Currency translation depreciations	0	0	0	-17	0	0	0	0	0	0	-7	-24
Closing carrying amount	**206**	**548**	**2,693**	**1,011**	**186**	**275**	**0**	**211**	**0**	**6,540**	**19,857**	**31,527**
As at 31 December 2022												
Cost	2,096	3,426	12,024	6,455	844	3,057	29	211	0	12,724	40,722	81,588
Accumulated depreciation	-1,890	-2,878	-9,330	-5,443	-658	-2,782	-29	0	0	-6,184	-20,866	-50,061
Carrying amount	**206**	**548**	**2,693**	**1,011**	**185**	**275**	**0**	**211**	**0**	**6,540**	**19,856**	**31,527**

The most significant addition to Property, plant and equipment are predominantly related to manufacturing equipment, right-of-use assets and capitalized Idylla™ systems sold under reagent rental and similar agreements.

The Right-of-use assets consist out of the following categories:

In EUR 000	As of 31 December, 2022	2021
Non-current assets		
Right-of-use assets - buildings	8,434	9,789
Right-of-use assets - manufacturing equipment	9,596	12,075
Right-of-use assets - cars	1,769	2,432
Right-of-use assets - office furniture	5	20
Right-of-use assets - other	52	58
Total right-of-use assets	**19,857**	**24,374**

The table below provides a split of the depreciation charges by asset class:

In EUR 000	Years ended 31 December, 2022	2021
Depreciation expense per type right-of-use assets		
Buildings	1,699	1,573
Manufacturing equipment	2,479	2,476
Cars	1,082	1,040
Office furniture	15	15
Other	33	12
Total depreciation expense	**5,307**	**5,116**

The Group's current lease agreements do not include material residual value guarantees and/or material extension and termination options that could have a substantial impact on the conducted lease measurement assessment. Underlying leas measurements will be updated should there be a reasonably likelihood that certain extension and/or termination options are to be exercised.

5.2.15. Financial participation

The Group holds a convertible note from GeneproDx, with maturity date of 25 January 2023 (i.e. 2-year duration) and a coupon of 10%. The convertible note from GeneproDx was issued early 2021 and was issued to the Group as payment for the license granted by the Group to GeneproDx at the end of 2020, which was recorded in 2020 as a receivable under „other current assets".

The Group also holds a secured convertible loan from SkylineDx, with maturity date 7 June 2024 (i.e. 2-year duration). The principal amount of EUR 10m will be made available to the Group in tranches, based on different project-based milestones throughout the collaboration. In 2022, two tranches for a total of EUR 2.5m were drawn. The Group is entitled to receive interest on the outstanding balance at a nominal interest rate of 10% annually.

5.2.16. Investments in joint ventures

The Group holds an investment in one joint venture at the end of the reporting period:

Name of joint venture	Principal activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2022	2021
Wondfo-Cartis Ltd.	Commercialization	China	50%	50%

Wondfo-Cartis Ltd. was established in January 2019 for the commercialization of the Idylla™ platform. The Group's net investment increases to EUR 2.5m in 2022. The joint venture is accounted for using the equity method in the consolidated financial statements as set out in the Group's accounting policies in note 5.2.2.5.

Summarized financial information of the joint venture is set out below. The summarized financial information below represents amounts in the joint venture's financial statements. They have been modified to reflect adjustments made by the entity when using the equity method, including fair value adjustments and adjustments for differences in accounting policy, but not adjusted for the Group's share.

Summarized statement of financial position:

In EUR 000	As of 31 December, 2022
Non-current assets	4,022
Current assets	6,147
Total assets	**10,168**
Non-current liabilities	0
Current liabilities	1,090
Total liabilities	**1,090**

Summarized statement of comprehensive income:

In EUR 000	Year ended 31 December, 2022
Operating income	970
Operating expenses	-2,702
Financial result, net	-35
Income taxes	0
Result of the year	**-1,767**
Other comprehensive income	0
Total comprehensive income	**-1,767**
Share in total comprehensive income	-884

Based on the above, the carrying amount of the investment in joint ventures presented in the consolidated statement of financial position reconciles as follows:

As per 31 December 2021	**2,344**
Investments of the year	1,000
Share of the result of the year	-884
Share of the other comprehensive income	0
Dividends received	0
Elimination of unrealized gains and losses	78
Foreign exchange differences	0
As per 31 December 2022	**2,538**

As of the date of this report, there were no material contingent liabilities related to the joint venture. Following the establishment of the joint venture, both shareholders further provided additional capital contributions to the joint venture. In 2022, each shareholder contributed an additional EUR 1.0m.

5.2.17. Deferred tax assets and r&d investment tax credit

Deferred taxes related to the long-term portion of investment tax credit on research and development and amount to EUR 1.7m per 31 December 2022 (2021: EUR 1.6m). Recognized research and development tax credits in Belgium can be effectively repaid if a company has not been able to offset the tax credit against the corporation tax for the last five consecutive tax years. In 2022, EUR 0.3m of the Group's tax credit on research and development has become a short-term receivable, see note 5.2.19.

In EUR 000	As of 31 December, 2022	2021
Tax credit research and development	1,603	1,572
Other	62	23
Total	**1,664**	**1,595**

5.2.18. Inventories

The inventory can be summarized as follows:

In EUR 000	Per 31 December, 2022	2021
Inventory		
Raw materials	5,617	5,870
Semi-finished products	1,446	465
Finished products	11,842	9,771
Total	**18,905**	**16,106**
Amount recognized as an expense	**-29,799**	**-33,922**

Finished products included cartridges and systems held for expected commercialization, including systems placed under trial at customers under the Group's early adaptor program.

As per 31 December 2022, EUR 2.0 m of the total inventory value was older than 12 months (2021: EUR 2.0m) for which EUR 0.6m impairment was recognized (2021: EUR 0.5m). It is the expectation that a significant part of the current inventory will be sold within the next 12 months.

5.2.19. Trade and other receivables

Trade and other receivables are broken down as follows:

In EUR 000	As of 31 December, 2022	2021
Trade receivables	17,816	17,032
Allowance for doubtful receivables	-1,119	-826
Total	**16,697**	**16,206**

	As of 31 December, 2022	2021
VAT receivables	1,898	2,448
Tax credit research and development	318	330
Other receivables	20	3,777
Total	**2,236**	**6,555**

Trade receivables have increased from EUR 16.2m per 31 December 2021 to EUR 16.7m per 31 December 2022.

At the reporting date, the Group had approximately EUR 16.3m (2021: EUR 13.2m) trade and other receivables that were past due but were not impaired. In 2022 an allowance for doubtful receivables was recorded for EUR 1.1m (2021 EUR 0.8m) and no trade receivables were impaired.

The Group applies the simplified approach of IFRS 9 to measure expected credit losses using a lifetime expected loss allowance for all trade receivables and contract assets. To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics (e.g. country) and the days past due. The expected loss rates are based on the payment profiles of receivables over a period of 12 months before 31 December 2021 or 1 January 2021 respectively and the corresponding historical credit losses experienced within this period. Based on this, the Group concluded that historical losses are very limited considering the high credit quality of the partners with whom the Company is working.

A short-term tax credit of EUR 0.3m (2021: EUR 0.3m) on research and development has been recognized in other receivables as this portion of the tax credit is to be received by the Group since it has not been able to offset that portion of the tax credit against the corporation tax for the last five consecutive tax years.

Other receivables included VAT receivables and amongst others amounts recorded for the government capital grant by STS Strategic Transformation Support) related to the investments in the second cartridge manufacturing facilities in Mechelen.

5.2.20. Other current assets

Other current assets are broken down as follows:

In EUR 000	As of 31 December, 2022	2021
Accrued grant income	601	486
Accrued collaboration income	565	75
Other accrued income	29	29
Deferred charges	4,775	2,146
Total	5,971	2,736

Other current assets included accrued income mainly related to Flemish government grants for EUR 0.6 m (2021: EUR 0.5m). The Group evaluates continuously if it fulfils the specific conditions as per specific grant agreements to justify that none of the grants receivables are to be impaired.

For more details on the revenues and collaboration agreements, please see note 5.2.4. Accrued collaboration income includes upfront payments from collaboration partners in relation to amongst others strategic licensing, development and/or commercialization collaborations.

Deferred charges also included costs related to the new convertible term loan and the new 4.5% convertible bonds, which will be capitalized in 2023 in conjunction with the second drawdown of the convertible term loan for EUR 12m and the funding of the newly subscribed 4.5% convertible bonds for a total of EUR 25m.

	Accrued collaboration income
As per 31 December 2020	**1,209**
Invoiced	-1,129
Recognized in profit or loss	-5
As per 31 December 2021	**75**
Invoiced	-391
Recognized in profit or loss	880
As per 31 December 2022	**565**

5.2.21. Cash and cash equivalents

The cash and cash equivalents are as follows:

In EUR 000	Per 31 December, 2022	2021
Cash and cash equivalents		
Cash at bank and on hand	24,925	52,322
Total cash and cash equivalents	**24,925**	**52,322**
Total restricted cash	1,200	1,200
Total cash and cash equivalents for cash flow purposes	**26,125**	**53,522**

The restricted cash related to a deposit on a debt service reserve account as a security for the lease of the Idylla™ cartridge manufacturing lines.

5.2.22. Share capital

ISSUED SHARE CAPITAL

As of 25 November 2014, the Company became the parent company and reporting entity of the Group. Previous to that date, Biocartis SA was the parent company and reporting entity.

The table below summarizes the share capital and the outstanding shares of the Company as at 31 December 2021 and 31 December 2022. The shares are fully paid-up shares.

The number of issued and outstanding shares and the corresponding share capital is as follows:

	Biocartis Group NV			
	Number of common shares issued and outstanding	Legal share capital in EUR000	Historical share capital adjustment EUR000	Total share capital in EUR000
At 31 December 2020	**57,545,663**	**575**	**-221,232**	**-220,657**
Convertible bond - incentivized conversion				
At 31 December 2021	**57,545,663**	**575**	**-221,232**	**-220,657**
Share issue - contribution in kind 6 September 2022	810,734	8		8
Capital increase by contribution in kind	228,234			
Share issue - rights offering 2 December 2022	33,476,932	336		336
Share issue - conversion convertible term loan		2		2
Share issue - mandatory conversion convertible bond 16 December 2022	928,136	9		9
At 31 December 2022	**92,989,699**	**931**	**-221,232**	**-220,302**

During 2022, the following capital transactions took place:

- On 6 September 2022, the capital was increased through the contribution in kind of a fee of EUR 1m in exchange for the commitment made by certain funds and accounts managed or advised by Highbridge Capital Management LLC and funds managed or advised by Whitebox Advisors LLC, to purchase any portion of the New Money Amount of the additional 4.5% Convertible Bonds that would be not purchased by other holders of the existing 4% convertible Bonds.
- On 31 December 2022, EUR 0.2m of the new convertible term loan was converted into new commons shares, together with accrued interest.
- On 2 December 2022, the Company raised EUR 25.1m following a rights issue, fully paid by an increase in share capital of EUR 0.3m and an increase in share premium of EUR 24.8m.
- The mandatory conversion of the convertible bond resulted in an increase in share capital of EUR 0.01m and an increase in share premium of EUR 10.8m

VOTING RIGHTS

Each share gives the holders thereof the right to one vote. The shares are indivisible in respect of the Company and the Company only recognizes one owner per share as regards the exercise of the voting rights.

DIVIDENDS

The Company has not declared or paid any dividends on its shares. Currently, the board of directors expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future.

5.2.23. Share based payments

The table below provides an overview of the movement in stock options since 31 December 2020:

	2013 Plan	2015 Plan	2017 Plan	2018 Plan	2020 Plan	2020B Plan	Total

Total outstanding at 31 December 2020	**293,375**	**210,052**	**1,212,365**	**570,935**	**695,476**	**860,000**	**3,842,203**
Options granted	0	0	0	0	145,000	90,000	235,000
Remaining pool*	12,160	434	0	0	324,676	320,000	657,270
Options exercised	0	0	0	0	0	0	0
Options forfeited	-119,375	0	-60,467	-39,066	-12,875	0	-231,783
Options cancelled	0	0	0	0	0	0	0
Total outstanding at 31 December 2021	**174,000**	**210,052**	**1,151,898**	**531,869**	**682,601**	**860,000**	**3,610,420**
Options granted from remaining pool of prior year	0	0	0	0	222,000	0	222,000
Options exercised	0	0	0	0	0	0	0
Options forfeited	-23,104	-69,988	-1,151,898	-61,758	-56,502	0	-1,363,250
Options cancelled	0	0	0	0	0	0	0
Total outstanding at 31 December 2022	**150,896**	**140,064**	**0**	**470,111**	**626,099**	**860,000**	**2,247,170**
Of which remaining pool*	12,160	434	0	0	102,676	320,000	435,270

*Remaining pool are share options created under the plan which have not (yet) been granted and accepted by any beneficiary, and which have not been cancelled for any reason

2013 PLAN

The 2013 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options. A maximum of 1,000,000 shares can be issued to employees, consultants and management of the Group, of which 987,840 options were granted per 31 December 2022. In 2022 23,104 options were forfeited. A total of 150,896 options are still outstanding per 31 December 2022 of which:

- 0 options have an exercise price of EUR 8.1309
- 0 options have an exercise price of EUR 13.28
- 44,986 options have an exercise price of EUR 10.442
- 93,750 options have an exercise price of EUR 12.14
- 12,160 options were not yet granted and remain in the pool

The weighted average remaining contractual life is 2.01 years. The key terms of the 2013 Plan are:

- Options have the form of warrants of the Company
- Options are granted for free
- Exercise price: the board of directors determines the exercise price when the stock options are granted to a selected participant.
- Granted stock options only become exercisable after vesting and can only be exercised during the full remaining lifetime of the stock options and then only during the following periods:
  - As of 16 March until 31 March
  - As of 16 September until 30 September
  - And as of 1 December until 15 December
- Option term: 10 years after the creation of the plan (expiry is in 2023) but upon grant of the option contractually reduced to 7 years.

- Vesting: time based vesting over 4 years (on a monthly basis; that is 1/48 per month), subject to acceleration in case of a change of control event.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumptions:

	Grants 2013	Grants July 2014	Grants November 2014	Grants August 2015	Grants July 2017	Grants December 2017
Number of warrants granted	680,340	20,000	20,000	30,000	50,000	187,500
Number of warrants not vested at 31/12/2022	0	0	0	0	0	0
Exercise price	EUR 9.35	EUR 9.35	EUR 8.13	EUR 13.28	EUR 10.44	EUR 12.14
Expected dividend yield	0	0	0	0	0	0
Expected stock price volatility	25%	30%	30%	31%	36%	35%
Risk-free interest rate	0.7%	0.2%	0.1%	0.1%	0.3%	0.2%
Expected duration	3.5 years	2.8 years	2.6 years	2.3 years	3.5 years	3.5 years
Forfeiture rate	0%	0%	0%	0%	0%	0%
Fair value	EUR 1.78	EUR 1.87	EUR 1.56	EUR 2.70	EUR 2.53	EUR 2.80

The weighted average risk-free interest rates used are based on government bond rates at the date of grant with a term equal to the expected life of the options. The stock price volatility is determined by reference to the Nasdaq Biotech Index (NBI).

2015 PLAN

On 15 January 2015, an option plan was established, pursuant to which 217,934 options were issued. This plan was cancelled by the general shareholders' meeting of the Company on 13 April 2015 and replaced on the same date by a new stock option plan (the '2015 Plan'), enabling the Company to grant a maximum of 262,934 stock options (each stock option having the form of a warrant) to selected staff members (consisting of employees, consultants and members of the management) and directors. The 2015 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options. In 2022, no options were granted, no options were exercised and 69,988 options were forfeited. A total of 140,064 options are still outstanding per 31 December 2022 and the weighted average remaining contractual life is 1.3 years. The key features of the stock options under the 2015 Plan are as follows:

- Options have the form of warrants of the Company
- Options are granted for free.
- Exercise price: The board of directors shall determine the exercise price at the time of the grant of the stock options, based upon the stock exchange price of the underlying shares at the time of the grant or an average price calculated over a previous period.
- Option term: the stock options have a term of 10 years when they were created, but this term will be contractually reduced to seven years.
- Vesting: time based vesting over 4 years (on a monthly basis; that is 1/48 per month), subject to acceleration in case of a change of control event.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumptions:

	Grants 2015	Grants January 2016	Grants March 2016	Grants May 2016	Grants August 2016	Grants November 2016	Grants May 2017	Grants May 2018
Number of warrants granted	72,500	10,000	62,500	15,000	10,000	62,500	15,000	15,000
Number of warrants not vested at 31/12/2022	0	0	0	0	0	0	0	0
Exercise price	**EUR 13.28**	**EUR 12.77**	**EUR 11.52**	**EUR 9.72**	**EUR 7.25**	**EUR 8.50**	**EUR 10.27**	**EUR 12.73**
Expected dividend yield	0	0	0	0	0	0	0	0
Expected stock price volatility	31%	34%	36%	36%	38%	38%	37%	35%
Risk-free interest rate	0.5%	0.8%	0.4%	0.4%	0.7%	0.9%	0.5%	-0.4%
Expected duration	3.4 years	4.6 years	4.6 years	4.5 years	4.4 years	4.2 years	3.9 years	4 years
Forfeiture rate	0%	0%	0%	0%	0%	0%	0%	0%
Fair value	**EUR 3.29**	**EUR 3.85**	**EUR 4.13**	**EUR 2.08**	**EUR 2.52**	**EUR 2.74**	**EUR 3.19**	**EUR 3.37**

The weighted average risk-free interest rates used are based on government bond rates at the date of grant with a term equal to the expected life of the options. The stock price volatility is determined by reference to the Nasdaq Biotech Index (NBI).

2017 PLAN

On 11 September 2017, a warrant plan was established pursuant to which 1,340,000 warrants were issued and granted to Herman Verrelst, chief executive officer of the Company. The 2017 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective warrants. In 2017, 1,340,000 warrants were granted. In 2022 no warrants were exercised and 1,151,898 warrants were forfeited. The key features of the warrants under the Warrant plan 2017 are as follows:

- Warrants are granted for free.
- Exercise price: EUR 9.92.
- Warrant term: determined at the time of the grant of the warrants.
- Vesting: 50% of the warrants will vest over a period of four years (12.5% of the warrants will vest on each of the first four anniversary dates of the date of grant), while the other 50% of the warrants will vest if and to the extent of the CEO achieving certain objective and verifiable key performance indicators.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumption

	Grants December 2017
Number of warrants granted	1,340,000
Number of warrants not vested at 31/12/2022	0
Exercise price	EUR 9.92
Expected dividend yield	0
Expected stock price volatility	32%
Risk-free interest rate	-0.3%
Expected duration	2.5 years
Forfeiture rate	0%
Fair value	EUR 2.14

2018 PLAN

On 10 September 2018, a warrant plan was established by the board of directors pursuant to which 1,335,426 warrants were issued, enabling the Company to grant a maximum of 1,335,426 warrants to selected staff members (consisting of employees, consultants and members of the management) and directors. In 2022, no warrants were granted, no warrants were exercised and 61,758 warrants are forfeited. The key features of the warrants under the Warrant plan 2018 are as follows:

- Each warrant can be exercised for one share.
- Warrants are granted for free.
- The warrants have a term of ten years when they were created, but this term is contractually reduced to seven years.
- The exercise price of the warrant is determined at the time of the grant of the warrants.
- Vesting is time-based between 1 and 3.5 years.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumptions:

	Grants 2018	Grants May 2019	Grants October 2019	Grants December 2019
Number of warrants granted	273,900	97,500	116,050	65,000
Number of warrants not vested at 31/12/2022	0	4,063	18,211	65,000
Exercise price	EUR 1.95	EUR 11.93	EUR 6.48	EUR 6.05
Expected dividend yield	0	0	0	0
Expected stock price volatility	34%	35%	39%	40%
Risk-free interest rate	-0.3%	-0.6%	-0.7%	-0.6%
Expected duration	3.5 years	3.2 years	3.5 years	3.5 years
Forfeiture rate	0%	0%	0%	0%
Fair value	EUR 3.11	EUR 2.34	EUR 1.46	EUR 1.24

2020 PLAN AND 2020B PLAN

In April 2020, two new warrant plans were established by the board of directors, pursuant to which a total of 1,556,976 warrants were issued, enabling the Company to grant these warrants to selected staff members and directors. In 2022

222,000 warrants were granted for the 2020 plan and no warrants were granted for the 2020B plan. No warrants were exercised and 56,502 warrants were forfeited for the 2020 plan.

The main characteristics of the share options are as follows:

- Each warrant can be exercised for one share.
- Warrants are granted for free.
- The exercise price per share option is at least equal to the average closing price of the Company's share on Euronext Brussels during the thirty (30) day period prior to the date of grant.
- The share options in principle have a contractual term of seven (7) years and are subject to a cliff-vesting of minimum three (3) years.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumptions:

	2020B Plan Grant April 2020	2020B Plan Grant April 2021	2020 Plan Grant May 2020	2020 Plan Grant September 2020	2020 Plan Grant November 2020	2020 Plan Grant April 2021	2020 Plan Grant March 2022
Number of warrants granted	450,000	90,000	50,000	110,800	65,000	145,000	222,000
Number of warrants not vested at 31/12/2022	450,000	90,000	0	25,263	54,688	81,564	124,878
Exercise price	EUR 4.18	EUR 4.45	EUR 4.81	EUR 4.81	EUR 4.53	EUR 4.45	EUR 2.75
Expected dividend yield	0	0	0	0	0	0	0
Expected stock price volatility	43%	43%	43%	43%	44%	44%	42%
Risk-free interest rate	-0.5%	-0.6%	-0.5%	-0.7%	-0.7%	-0.6%	0.4%
Expected duration	3.5 years	3.5 years	3.5 years	3.5 years	3.5 years	3.5 years	3.5 years
Forfeiture rate	0%	0%	0%	0%	0%	0%	0%
Fair value	EUR 1.74	EUR 1.39	EUR 1.49	EUR 1.46	EUR 1.51	EUR 1.39	EUR 0.53

ACCOUNTING FOR SHARE-BASED PAYMENT

The shared-based compensation expense recognized in the income statement as such is given below:

	Years ended 31 December,	
In EUR 000	2022	2021
Share based compensation	640	760
Total	640	760

5.2.24. Defined benefit plans

The Defined Benefit plans were calculated via the application of the Projected Unit Credit (PUC) method as from 2016. No change in calculation method in the present year.

Per 31 December 2022, the Defined Benefit plans reflected a net liability and are therefore reported under 'Provisions' in the consolidated statement of financial position.

	Years ended 31 December,	
In EUR 000	2022	2021
Defined benefit obligation	6,306	8,693
Plan assets	-6,102	-8,618
Total	204	75

The Group has used an independent actuary to calculate the defined benefit liability and they provided the following disclosures.

The analysis of the change in the net liability is as follows:

	Net defined benefit liability
As per 31 December 2020	-413
Service cost	678
Pension expense/income	-4
Company contributions	-781
Actuarial gains/losses	595
As per 31 December 2021	75
Service cost	530
Pension expense/income	-1
Company contributions	-786
Actuarial gains/losses	385
As per 31 December 2022	204

The principal assumptions used for the purpose of the actuarial valuation are as follows:

	Years ended 31 December,	
In EUR 000	2022	2021
Discount rate	3.42%	1.26%
Minimum guaranteed interest rate	1.75%	1.75%

The Group has performed a sensitivity analysis taking into account a possible change in the discount rate by 0.5%. The impact of the sensitivity analysis on the net liability is as follows:

	2022	2021
Discount rate +0,5%	-10	5
Discount rate -0,5%	11	-14

The plans assets are fully invested in assurance contracts with a guaranteed return, in terms of risk category these can be best described as bonds.

5.2.25. Financial liabilities

The financial liabilities are summarized as follows:

In EUR 000	Years ended 31 December, 2022	2021
Lease liability	9,051	14,133
Bank borrowings	0	0
Convertible debt	9,293	128,151
Convertible term loan	15,838	
2nd lien secured convertible debt	66,642	
Convertible term loan embedded derivative	934	
Total non-current	**101,759**	**142,284**
Lease liability	5,597	5,878
Bank borrowings	15,000	6,000
Total current	**20,597**	**11,878**
Total Financial liabilities	**122,355**	**154,163**

In 2013, Biocartis NV refinanced about 50% of its Idylla™ semi-automated cartridge manufacturing line in Mechelen (Belgium) via a sale and lease back operation. This lease has a current lease term till 1 June 2021, carries a 3.35% interest rate and includes a purchase option of EUR 0.1m. Per 31 December 2022 the lease has been fully paid.

In 2015, Biocartis NV obtained two new financing facilities for the modifications to the current cartridge production line. The first new facility entails an investment credit for an amount of EUR 0.6m, with a payment term of 5 years and an interest rate of 1.93%. The second one entails a leasing facility for EUR 4.4m that carries a 1.77% interest, includes a purchase option of 1% of the financed amount and has a duration of 54 months. Per 31 December 20212 the lease has been fully paid. EUR 0.1m is outstanding under these two facilities.

In 2016, Biocartis NV obtained a lease financing facility for the development of a second cartridge production line in Mechelen, for EUR 15m. This facility was increased in 2018 with EUR 2.3m. The interest applicable for this facility equals 1.87% and includes a purchase option of 1% of the financed amount. Per 31 December 2022 EUR 4.3m is outstanding under this facility. As a security, a debt service reserve account is to be maintained for the above financing facilities of 2013, 2015 and 2016, the current debt service account amounts to EUR 1.2m.

In 2018, Biocartis NV obtained an investment credit of EUR 1m from a bank to finance mold investments related to its first cartridge manufacturing facility. The investment credit has a payment term of 5 years and an interest rate of 2.53%. In total EUR 0.8m has been withdrawn on this credit facility. Per 31 December 2022 EUR 0.3m is outstanding under this facility.

On 9 May 2019, the Group issued a convertible bond of EUR 150m, with a maturity date of 9 May 2024 (i.e. 5-year duration) and a coupon of 4%. The bond can be converted into new/existing ordinary shares of the Group upon the discretion of the bondholder. Under IAS 32- Financial instruments: Presentation the convertible bond is a compound financial instrument and contains, from the issue's perspective, both a liability (i.e. host debt instrument) and an equity component (i.e. an embedded share conversion option).

On 1 September 2022, Biocartis launched a comprehensive recapitalization, which included the restructuring of the existing convertible debt and the provision of new convertible debt, summarized as follows:

- the amendment of the existing 4% convertible bonds of EUR 135m, including a.o. the mandatory conversion of 10% of these convertible bonds into common shares at the conversion rate of EUR 12.89 and the extension of the maturity date until 9 November 2027
- a new first lien secured convertible term loan of EUR 30.1m, partly used for the buy-back of EUR 16.3m of existing 4% convertible bonds for EUR 13.7m in cash
- an exchange of the amended existing convertible bonds for new 4.5% second lien secured convertible bonds, subject to the subscription of EUR 25m of additional newly issued 4.5% convertible bonds

Following the amendment, the exchange for new convertible bonds and the partial buy-back, the liability associated with the 4% convertible bonds amounts to EUR 9.3m per 31 December 2022.

In 2022, EUR 17.5m was drawn under the new convertible term loan, net of fees. This amount was partly used for the buy-back of EUR 13.7m of the existing 4% convertible bond. This convertible term loan only consists of a liability component and an embedded derivative component. The liability component is measured at amortized cost and the derivative component is measured at fair value through profit and loss. Per 31 December 2022, the liability amounts to EUR 15.8m and the embedded derivative amounts to EUR 0.9m.

On 2 September 2022, an offer to exchange the amended existing convertible bonds was made for new 4.5% second lien secured convertible bonds, subject to the subscription of EUR 25.0m of additional newly issued 4.5% convertible bonds and rights offering with extra-legal preferential rights for the existing shareholders of the Company of EUR 25.1m. EUR 92.1m of the existing 4% convertible bonds were exchanged for the new 4.5% convertible bonds. In accordance with IFRS 9, the exchange has been accounted for as an extinguishment of the original liability and the recognition of a new financial liability, amounting to EUR 66.6m per 31 December 2022. The original equity component associated with the existing convertible bonds was not derecognized.

Following the recapitalization transactions, the financial indebtedness at 31 December 2022 amounted to EUR 122.4m compared to EUR 154.2m at 31 December 2021.

The credit facility and guarantees from BNP Paribas Fortis have been cancelled in 2021 and replaced by a revised credit facility of KBC. This facility consists of a EUR 7.5m straight loan and a EUR 7.5m rollover credit line, both of which were fully drawn on 31 December 2022.

The terms of the loans are summarized in the table below:

Loan	Year	Nominal amount (In EUR 000)	Secured (s) Non secured (ns)	Interest rate	Maturity rate
Lease company	2016	17,319	S	1.87%	7/10/2023
Bank	2018	808	S	2.53%	31/12/2023

The reconciliation between the total of future minimum lease payments of the finance leases at the end of the reporting period and their present value is described in the table below:

In EUR 000	As of 31 December, 2022		2021	
	Minimum lease payments	Present value of minimum lease payments	Minimum lease payments	Present value of minimum lease payments
Lease				
< 1 year	5,736	5,597	6,490	5,878
> 1 and < 5 years	7,092	6,997	12,755	11,578
> 5 years	2,054	2,054	2,857	2,555
Total	**14,882**	**14,648**	**22,103**	**20,012**
Less interests	234	0	2,091	0
Present value	**15,116**	**14,648**	**24,194**	**20,012**

The changes in liabilities from financing activities are summarized in the table below:

In EUR 000	Lease liabilities	Convertible debt	Convertible term loan	2nd lien secured convertible debt	Bank
As per 31 December 2020	25,240	125,260			58
Changes from financial cash flows	-7,031	0			5,942
Capitalized interest		2,891			0
Additions	1,803	0			0
As per 31 December 2021	20,012	128,151			6,000
Changes from financial cash flows	-6,609	-19,413	16,504		9,000
Exchange for new convertible bond		-102,818		65,124	
Capitalized interest		3,373	269	1,518	
Additions	1,246				
As per 31 December 2022	**14,648**	**9,293**	**16,773**	**66,642**	**15,000**

Some more details related to the lease liabilities such as interest expenses, expenses related to short term and low values lease and variable lease payments can be found in the table below. The Group's lease agreements do not include material restrictions or financial covenants.

	Years ended 31 December,	
In EUR 000	2022	2021
Depreciation expense of right-of-use assets	-5,294	-5,284
Interest expense on lease liabilities	-513	-577
Rent expense - short-term & low value leases	-102	-83
Rent expense - variable lease payments	0	0
Total amounts recognized in profit or loss	-5,909	-5,944

PLEDGED ASSETS

The Company entered into a comprehensive recapitalization, which among others included a new convertible term loan and new 4.5% convertible bonds. The convertible term loan and 4.5% convertible bonds benefit from (a) guarantees from the Company's wholly-owned subsidiaries Biocartis NV and Biocartis US Inc. and (b) security in the form of senior all-asset security from the Company, Biocartis NV and Biocartis US Inc. and over the shares of Biocartis NV and Biocartis US Inc. The new convertible bonds benefit from the same security as the convertible term loan, and rank junior to the convertible term loan and the Company's obligations to KBC Bank under the existing credit facilities. The convertible term loans and the KBC credit facilities rank pari passu.

The all-asset security consists of, among others:

A pledge granted by Biocartis Group NV and Biocartis NV over their bank accounts, receivables, business, movable assets, and intellectual property rights

A security interest granted by Biocartis US Inc. on its assets, including, but not limited to all deposit and securities accounts, equipment, general intangibles, instruments, inventory

The KBC Bank credit facilities, the convertible term loans and the new convertible bonds also include a negative pledge that prohibit the Company to create or permit to subsist any security over any of its assets. Except as otherwise permitted, the Company, Biocartis NV and Biocartis US Inc. are also subject to various restrictive covenants and are consequently prohibited from, among others disposing its material assets, incurring financial indebtedness, making investments such as acquisitions, and making loans.

5.2.26. Trade payables and other current liabilities

In EUR 000	As of 31 December, 2022	2021
Trade payables	11,747	11,560
Total trade payables	**11,747**	**11,560**

In EUR 000	As of 31 December, 2022	2021
Provision vacation pay and end-of-year premium & other social debt	8,675	8,109
VAT payable	191	293
Other	44	43
Other current liabilities	**8,910**	**8,445**

The increase in trade payables is associated with timing of payments made to suppliers.

5.2.27. Deferred income

In EUR 000	Years ended 31 December, 2022	2021
Grants	-	-
Partner income	1,344	2,135
Total	1,344	2,135
Current	1,195	1,822
Non-current	149	313

More details on the contract liabilities, we refer to note 5.2.4. Deferred partner income includes upfront payments from collaboration partners in relation to the strategic licensing, development and commercialization collaborations.

	Deferred partner income
As per 31 December 2020	983
Invoiced	1,894
Recognized in profit or loss	-742
As per 31 December 2021	2,135
Invoiced	258
Recognized in profit or loss	-1,049
As per 31 December 2022	1,344

5.2.28. Income taxes

5.2.28.1. COMPOSITION OF TAX EXPENSE

In EUR 000	Years ended 31 December, 2022	2021
Current income tax	-316	-275
Deferred income tax	76	32
Total	-240	-243

5.2.28.2. TAX RECONCILIATION

Tax expenses for the year can be reconciled to the accounting loss as follows:

In EUR 000	Years ended 31 December, 2022	2021
Loss before taxes	-65,621	-71,715
Income tax credit calculated at 25%	-16,930	-19,685
Effect of different tax rates	0	0
Effect of income that is exempt from taxation	-45,016	-2,367
Effect of expenses that are non-deductible in determining tax profit	43,386	746
Effect of unused tax losses and tax offsets not recognized as deferred tax assets	18,560	21,307
effect of tax credit for research and development	-317	-277
Other	77	33
	-240	-243
Adjustments recognized in the current year in relation to the current tax of prior years	0	0
Income tax expense (profit) recognized in loss for the period	**-240**	**-243**

5.2.28.3. UNRECOGNIZED DEFERRED TAX ASSETS

Due to the uncertainty surrounding the Group's ability to realize taxable profits in the near future, the Group has not recognized any deferred tax assets on tax loss carry forwards and temporary differences.

The Group has tax losses available for carry forward of EUR 545.0m (2021: EUR 483.3m). The tax losses of Biocartis NV for EUR 545.0m per 31 December 2022 (2021: EUR 483.3m) in Belgium will not expire as they can be carried forward indefinitely.

5.2.28.4. RECOGNIZED DEFERRED TAX ASSETS

The Group has R&D tax credit, available for carry-forward in Belgium for a total amount of EUR 1.9m (2021: EUR 1.9m) for which a deferred tax asset of EUR 1.9m (2021: EUR 1.9m) has been recognized as the recognition criteria have been met as from 2014. Per 2022, EUR 0.3m of the total R&D tax credit has been classified as a current asset under 'other receivables'.

5.2.29. Financial risk management

5.2.29.1. CAPITAL RISK MANAGEMENT

Capital comprises equity attributable to shareholders, borrowings and cash and cash equivalents. The Group's policy is to maintain a strong capital base in order to maintain investor and creditor confidence and to sustain the future development of the business. The Group's objectives when managing capital are to maintain sufficient liquidity to meet its working capital requirements, fund capital investment and purchases and to safeguard its ability to continue operating as a going concern.

The Group monitors capital regularly to ensure that the statutory capital requirements are met and may propose capital increases to the shareholders' meeting to ensure the necessary capital remains intact.

5.2.29.2. FINANCIAL RISK FACTORS

The Group's activities expose it to a variety of financial risks such as market risk, credit risk, and liquidity risk. The Group's finance department identifies and evaluates the financial risks in close co-operation with the operating units.

The Convertible Term Loan and the 4.5% Convertible Bonds are subject to a minimum liquidity covenant requiring Biocartis Group NV and the guarantors to maintain liquidity on each month-end of at least EUR 10 million and EUR 8 million, respectively.

5.2.29.3. MARKET RISK

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The Group's activities expose it primarily to changes in foreign currency exchange rates and interest rates.

FOREIGN EXCHANGE RISK

The Group is exposed to foreign currency risks primarily through its operating activities. Certain purchase transactions and certain sales transactions of the Group are undertaken in British Pound ("GBP") and US Dollar ('USD'). The Group did not enter into any currency hedging arrangements in order to cover its exposure. The Group is managing its foreign currency risk by matching foreign currency cash inflows with foreign cash outflows. Therefore the sensitivity to certain potential changes in, especially the GBP and USD is limited. Exchange rate exposure towards the foreign currencies can furthermore be managed through the use of forward exchange contracts, based upon management's judgment. The Group has not applied hedge accounting in 2022 and 2021.

Financial assets included current bank accounts and petty cash. Financial liabilities included trade payables and accruals in foreign currency.

In EUR 000	Years ended 31 December, 2022	2021
Liabilities		
USD - United States	1,339	2,573
GBP - Great Britain	12	3
Assets		
USD - United States	4,446	99,169
GBP - Great Britain	943	2,690

The Group performed a sensitivity analysis for the two most significant currencies (USD, GBP). The impact of an increase or decrease in value by 10% of GBP and USD is not material.

INTEREST RATE RISK

The interest rate risk is limited as the Group has only long-term borrowings with a fixed interest rate. Changes in interest rates will not increase/decrease profit or loss or other comprehensive income.

OTHER MARKET RISK

The Group is not exposed to equity price risk or commodity price risk as it does not invest in these classes of investments.

CREDIT RISK

Credit risk arises from cash and cash equivalents, short-term bank deposits, as well as credit exposure to collaboration partners. Credit risk refers to the risks that counterparty will default on its contractual obligations resulting in financial loss to the Group.

The Group has a limited number of collaboration partners and therefore has a significant concentration of credit risk. However, it has policies in place to ensure that credit exposure is kept to a minimum and significant concentrations of credit exposure are only granted for short periods of time to high credit quality collaboration partners. Credit exposure

with regard to R&D partnering activities is concentrated with a limited number of creditworthy partners. In 2022 there is no costumer representing 10% of the total recognized revenues.

None of the financial assets reported in the notes above have been pledged as collateral, and no financial assets have been received as collateral. The only financial asset pledged is the EUR 1.2m guarantee for the lease, reported under cash and cash equivalents. Cash and cash equivalent and short-term deposits are invested with highly reputable banks and financial institutions. The maximum credit risk to which the Group is theoretically exposed as at the reporting date, is the carrying amount of the financial assets.

LIQUIDITY RISK

The Group's main sources of cash inflows are obtained through capital increases, loans, grants and collaboration agreements. Cash is invested in low risk investments such as short-term bank deposits. Ultimate responsibility for liquidity risk management rests with the Board of Directors, which has built, what it considers to be an appropriate risk management framework for the management of the Group's short, medium and long-term funding and liquidity requirements. The Group mainly makes use of liquid investments in current (Euro and foreign currency) accounts, short term deposit accounts and fiduciary deposits. Instruments used possess high grade credit ratings, capital reimbursement guarantees and limited time horizons up to a maximum of 12 months.

The Group maintains a credit facility of EUR 15.0m as described in note 5.2.25. In addition, the Group also has access to a bank guarantee line of EUR 1.5m of which EUR 1.4m has been taken up as per 31 December 2022. The ability of the Group to maintain adequate cash reserves to sustain its activities in the medium term is highly dependent on the Group's ability to raise further funds from collaboration agreements, product sales, obtaining grants as well as the sale of new shares. As a consequence, the Group can potentially be exposed to significant liquidity risk in the medium term.

Analysis of contractual (undiscounted) maturities of financial liabilities at 31 December is as follows (amounts in EUR 000):

	As of 31 December,					
	2022			2021		
In EUR 000	Trade payables	Financial liabilities	Other current liabilities and accrued expense	Trade payables	Financial liabilities	Other current liabilities and accrued expense
Less than 1 year	11,747	20,547	8,910	11,560	11,878	8,445
1-3 years		5,123			8,068	
3-5 years		18,270			138,510	
5+ years		112,517			2,555	
Total	**11,747**	**156,457**	**8,910**	**11,560**	**161,011**	**8,445**

5.2.30. Fair value

The fair value of the financial assets has been determined on the basis of the following methods and assumptions:

- The carrying amount of the cash and cash equivalents and the current receivables approximate their value due to their short term character;
- Other current financial assets such as current other receivables are being evaluated on the basis of their credit risk and interest rate. Their fair value is not significantly different than its carrying amount on 31 December 2022 and 2021.
- The fair value of the financial liabilities has been determined on the basis of the following methods and assumptions:

- The carrying amount of current liabilities approximates their fair value due to the short-term character of these instruments;
- Loans and borrowings are measured based on their interest rates and maturity date. Most interest bearing debts have fixed interest rates and their fair value is subject to changes in interest rates and individual creditworthiness. The fair value measurement is classified as level 2.

FAIR VALUE HIERARCHY

The Group uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

- Level 1: quoted (unadjusted) prices in active markets for identical assets and liabilities
- Level 2: other techniques for which all inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly
- Level 3: techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data

The Group has one financial instrument (MyCartis) carried at fair value in the consolidated balance sheet on 31 December 2022 and 2021.

Except for the borrowings (financial liabilities, see note 5.2.25), the carrying amount of the financial assets and liabilities approximate their fair values. The borrowings with a carrying amount of EUR 117.7m (2021: EUR 154.2m) have a fair value of EUR 120.8m (2021: EUR 154.2m).

5.2.31. Contingencies

LEGAL CLAIMS

The Group is currently not facing any outstanding litigation that might have a significant adverse impact on the Group's financial position.

POTENTIAL CLAW BACK OF GOVERNMENT GRANTS RECEIVED

The Group recognizes grant income from Flemish, Dutch and European grant bodies when all contractual conditions are met. The government institutions may however perform an audit afterwards which may result in a (partial) claw back of the grant. The Group deems that the claw back risk is remote in view of the continuous monitoring of the contractual conditions. Currently the Group has fulfilled all the existing conditions relating to the recognition of its grant income. Contracts with these grant bodies also typically include clauses that define the need for future validation of the project results after completion of the initial grant term during which the subsidized expenses or investments have been incurred and for which the grant was earned. Should this validation not occur or be deemed inadequate, the grant bodies have the right to reclaim funds previously granted.

ROYALTIES

With respect to the Group's licensing agreements, the Group could in the future experience instances where royalty claims on sales of licensed products under these agreements exceed royalties reported by the Group.

5.2.32. Commitments

5.2.32.1. CAPITAL COMMITMENTS

Capital commitments relate mainly to the upgrade of the current cartridge production lines located in Mechelen (Belgium) for which the Group is engaged in several contractual arrangements with specified suppliers (2022: EUR 0.6m; 2021: EUR 1.4m). The Group had no other material commitments to capital expenditures on 31 December 2022.

5.2.32.2. OPERATING COMMITMENTS

The Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 6.7m (2021: EUR 11.9m). It is expected that the majority of the commitments will be fulfilled in 2023.

5.2.32.3. RELATED-PARTY TRANSACTIONS

Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes. The remuneration of key management, transactions with the joint venture and a list of the subsidiaries are disclosed below. There were no other transactions with related parties.

5.2.32.3.1. REMUNERATION OF DIRECTORS AND MEMBERS OF THE EXECUTIVE MANAGEMENT

For details on the remuneration of directors and members of the executive management, we refer to Part 4 'Corporate Governance report', '5. Remuneration report'.

5.2.32.3.2. JOINT VENTURES

Transactions with related parties are made at arm's length. The main transactions relate to product sales towards the Group's joint venture.

5.2.32.3.3. SUBSIDIARIES

Details of the Company's subsidiaries at 31 December 2022 are as follows:

Name of subsidiary	Principal activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2022	2021
Biocartis NV	Develop and market diagnostic platforms	Generaal de Wittelaan 11 B - 2800 Mechelen (België)	100%	100%
Biocartis US Inc	Market diagnostic platforms	30 Montgomery Street, 9th Floor, Suite 970 Jersey City, NJ 07302 USA	100%	100%
Biocartis S.r.l.	Market diagnostic platforms	Milano (MI) Corso Vercelli 40 CAP 20145 Italy	100%	100%

There are no significant restrictions on the ability to access or use assets, and settle liabilities, of the Group, except for the debt service reserve account which is held as a security for the lease of the Idylla™ cartridge manufacturing line. This debt service reserve account has a carrying value of EUR 1.2m and is reflected under cash and cash equivalents.

5.2.33. Events after the balance sheet date

The below important events occurred after the reporting date:

- Announcement on 16 January 2023 of the completion of the final steps of the comprehensive recapitalization transactions, adding EUR 36.1m to the 2022 year-end cash position of EUR 26.1m.
- Announcement on 9 February 2023 of the launch among selected customers of the Idylla™ IDH1-2 Mutation Assay Kit Test (RUO), the first test developed with the new Idylla™ FLEX technology that separates the generic components of an Idylla™ test from the test-specific components
- Announcement on 22 February 2023 of the resignation of Mr. Roald Borré as Director of the Company and the appointment of Mr. Bryan Dechairo as a new independent Board member and member of the Audit Committee of the Company

There were no further important events between 31 December 2022 and the approval date of this annual report.

5.2.34. Relevant standards and interpretations published, but not yet applicable for the annual period beginning on 1 January 2022

- IFRS 17 Insurance Contracts (applicable for annual periods beginning on or after 1 January 2023)
- Amendments to IFRS 17 Insurance contracts: Initial Application of IFRS 17 and IFRS 9 – Comparative Information (applicable for annual periods beginning on or after 1 January 2023)
- Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current and Non-current Liabilities with Covenants (applicable for annual periods beginning on or after 1 January 2024, but not yet endorsed in the EU)
- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting Policies (applicable for annual periods beginning on or after 1 January 2023)
- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates (applicable for annual periods beginning on or after 1 January 2023)
- Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction (applicable for annual periods beginning on or after 1 January 2023)
- Amendments to IFRS 16 Leases: Lease Liability in a Sale and Leaseback (applicable for annual periods beginning on or after 1 January 2024, but not yet endorsed in the EU). The Group currently beliefs that the above mentioned standards will not have a material impact on the consolidated financial statements of the Group.

5.3. Statutory annual accounts

5.3.1. Abbreviated statutory annual accounts

The statutory annual accounts of Biocartis Group NV are presented in an abbreviated form. The full statutory annual accounts, drawn up in accordance with Belgian GAAP, are still to be filed with the National Bank of Belgium. The statutory auditor, Deloitte Bedrijfsrevisoren CVBA, represented by Nico Houthaeve, has issued an unqualified audit opinion regarding the statutory annual accounts. A copy of the statutory annual accounts and this annual report can be obtained upon request. An electronic version of these documents is available on the Biocartis website (www.biocartis.com).

5.3.2. Activity biocartis group nv

Biocartis Group NV was incorporated on 24 November 2014 and is the ultimate parent of the Biocartis group. The Biocartis group is active in developing innovative molecular diagnostic platforms providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. The Biocartis group is developing and marketing a rapidly expanding test menu on its Idylla™ platform addressing key unmet clinical needs with a focus on oncology.

Biocartis Group NV is an active holding company: it maintains a portfolio of financial participations and is also actively involved in the management thereof by providing various legal, financial and other services.

5.3.3. Income statement and balance sheet Biocartis Group NV

5.3.3.1. INCOME STATEMENT

In EUR 000	Years ended 31 December, 2022	2021
Revenues	6,420	6,584
Other operating income	263	354
Total operating income	**6,683**	**6,938**
Services and other goods	-7,448	-2,651
Salaries, social security contributions and pensions	-3,488	-4,031
Other operating expenses	-3	-3
Operating expenses	**-10,939**	**-6,685**
Financial income	3,374	776
Financial expenses	-179,842	-35,159
Result from continuing operations	**-180,724**	**-34,130**
Income taxes	-2	-3
Net result	**-180,726**	**-34,133**

5.3.3.2. BALANCE SHEET

In EUR 000	As of 31 December 2022	2021
Financial fixed assets	**369,066**	**422,003**
Non-current assets	369,066	422,003
Trade receivables	0	0
Other receivables	13,290	108,492
Cash and cash equivalents	8,576	9,665
Transitory accounts	187	44
Current assets	22,053	118,201
Total assets	**391,119**	**540,204**
Legal share capital	930	575
Share premium	440,205	550,289
Accumulated deficit	-180,726	-148,045
Total equity	260,409	402,819
Financial debt	125,104	135,000
Non-current liabilities	125,104	135,000
Financial debt	0	0
Trade payables	3,876	562
Provision taxes	0	113
Salaries, social security contributions and pensions	818	924
Accrued charges	912	786
Current liabilities	5,606	2,385
Total equity and liabilities	**391,119**	**540,204**

5.3.4. Discussion of statutory accounts

5.3.4.1. INCOME STATEMENT

Total operating income in 2022 amounted to EUR 6.7m (2021: EUR 6.9m) and consists mainly of expense recharged to the Biocartis Group NV subsidiaries. Operating expenses recorded in the period under review amounted to EUR 10.9m (2021 EUR 6.7m) and consisted of salaries, social security contributions and pensions expenses for EUR 3.5m (2021: EUR 4.0m) and of expenses for services and other goods of EUR 7.4m (2021: EUR 2.7m). Services and other goods mainly consisted of recurring general and administrative expenses.

Financial income amounted to EUR 3.4m (2021: EUR 0.8m) and consisted of interest income on the financial advances to the Biocartis group subsidiaries and on the cash and equivalents held by Biocartis Group NV. In 2022, the mandatory conversion of the existing 4.5% convertible bonds resulted in a financial income of EUR 2.9m.

On the other hand, financial expenses amounted to EUR 179.8m (2021: EUR 35.2m) and contained interest expenses related to the 4% convertible bond of EUR 4.6m compared to EUR 5.4m in 2021. Interest expenses related to the new 4.5% convertible bond amount to EUR 0.6m and interest expenses related to the convertible term loan amount to EUR 0.4m. The financial expenses also include bankers fees related to the refinancing transactions of EUR 7.4m and conversion costs of EUR 0.4m. Another item is the impairment loss recorded on financial fixed assets for a total amount of EUR 166m following an analysis of the recoverable amount of such financial fixed assets. The analysis included a review of the valuation of Biocartis Group NV to determine the need for an impairment because of a durable and lasting reduction in value.

The net result after taxes for the period ended 31 December 2022 amounts to EUR -180.7m (2021: EUR -34.1m).

5.3.4.2. BALANCE SHEET

5.3.4.2.1. ASSETS

The financial fixed assets included shares of the wholly owned subsidiaries for EUR 364.0m (Biocartis NV, Biocartis US Inc. and Biocartis S.r.l.) and of the China joint venture for EUR 2.5m. Biocartis took a participating interest of EUR 2.5m following the subscription of convertible notes issued by its collaboration partner SkylineDx for EUR 2.5m.

Other receivables amounted to EUR 13.3m (2021: EUR 108.5m) and mainly related to amounts receivable from the Biocartis Group NV subsidiaries, mainly related to financial advances. Cash and equivalents amounted to EUR 8.6m per 31 December 2022 (2021: EUR 9.7m). Deferred charges related to prepaid expenses.

5.3.4.2.2. EQUITY

Total equity per 31 December 2022 amounted to EUR 260.4m (2021: EUR 402.8m) and the legal share capital and share premium amount to respectively EUR 0.9m (2020: EUR 0.6m) and EUR 440.0m (2020: EUR 550.3m). On 1 September 2022, Biocartis launched a comprehensive recapitalization, including the mandatory conversion of the existing 4% convertible bonds and the issuance of new common shares for EUR 25m, the effects of which are included in both share capital and share premium.

5.3.4.2.3. FINANCIAL LIABILITIES

The financial liabilities are related to the convertible bonds and convertible term loan and amount to EUR 125.1m in 2022 (2021: EUR 135m). The decrease results from the partial completion of the comprehensive recapitalization. Post year-end, on 16 January 2023, the recapitalization transactions were completed and included the second drawdown of the convertible bond for EUR 12m and the issuance of new 4.5% convertible bonds for EUR 25m.

5.3.4.2.4. OTHER LIABILITIES

As per 31 December 2022, trade payables amounted to EUR 3.9m (2021: EUR 0.6m), payables for salaries, social security contributions and pensions to EUR 0.8m (2021: EUR 0.9m) and transitory accounts to EUR 0.9m which mainly includes accrued interests for the interest coupon payment of the new convertible bond.

5.3.4.2.5. TOTAL ASSETS AND LIABILITIES

Total assets and on the other hand total liabilities amounted per 31 December 2022 to EUR 391.1m (2021: EUR 540.2m).

5.3.5. Appropriation of results

The statutory accounts of the Company reported a net loss of EUR 180.7m for the year 2022. The Board of Directors proposes to carry forward the statutory net loss of EUR 180.7m of 2022 to the following financial year.

5.3.6. Going concern valuation rules

For the going concern valuation rules, we refer to section 5.2.3.1

5.4. Auditor's report

Biocartis Group NV

Statutory auditor's report to the shareholders' meeting for the year ended 31 December 2022 – Consolidated financial statements

The original text of this report is in Dutch.

In the context of the statutory audit of the consolidated financial statements of Biocartis Group NV ("the company") and its subsidiaries (jointly "the group"), we hereby submit our statutory audit report. This report includes our report on the consolidated financial statements and the other legal and regulatory requirements. These parts should be considered as integral to the report.

We were appointed in our capacity as statutory auditor by the shareholders' meeting of 14 May 2021, in accordance with the proposal of the board of directors ("bestuursorgaan" / "organe d'administration") issued upon recommendation of the audit committee. Our mandate will expire on the date of the shareholders' meeting deliberating on the financial statements for the year ending 31 December 2023. We have performed the statutory audit of the consolidated financial statements of Biocartis Group NV for 8 consecutive periods.

Report on the consolidated financial statements

Unqualified opinion

We have audited the consolidated financial statements of the group, which comprise the consolidated statement of financial position as at 31 December 2022, the consolidated income statement and consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated cash flow statement for the year then ended, as well as the summary of significant accounting policies and other explanatory notes. The consolidated statement of financial position shows total assets of 114 277 (000) EUR and the consolidated income statement shows a loss for the year then ended of 65 381 (000) EUR.

In our opinion, the consolidated financial statements give a true and fair view of the group's net equity and financial position as of 31 December 2022 and of its consolidated results and its consolidated cash flow for the year then ended, in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

Basis for the unqualified opinion

We conducted our audit in accordance with International Standards on Auditing (ISA), as applicable in Belgium. In addition, we have applied the International Standards on Auditing approved by the IAASB applicable to the current financial year, but not yet approved at national level. Our responsibilities under those standards are further described in the "Responsibilities of the statutory auditor for the audit of the consolidated financial statements" section of our report. We have complied with all ethical requirements relevant to the statutory audit of consolidated financial statements in Belgium, including those regarding independence.

We have obtained from the board of directors and the company's officials the explanations and information necessary for performing our audit.

We believe that the audit evidence obtained is sufficient and appropriate to provide a basis for our opinion. We believe that the audit evidence obtained is sufficient and appropriate to provide a basis for our opinion.

Material uncertainty relating to going concern

We draw attention to note 5.2.3.1 to the consolidated financial statements, which indicates that the Company needs to respect a covenant of maintaining a minimal liquidity of EUR 10 million to avoid its borrowings under the convertible bonds agreements to become payable. In the event that its projected future cashflows and potential cost saving measures are not or not timely realized, or that no alternative financing measures are found, the company's ability to continue operating as a going concern will depend on obtaining a waiver from the lenders. This indicates that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these matters. In addition to the matter described in section "Material uncertainty relating to going concern", we have determined the following key audit matter in our audit.

Key audit matters	How our audit addressed the key audit matters
Recapitalization transaction The Group completed a comprehensive recapitalization transaction (the 'Recapitalization Transaction') in January 2023 through which the Group obtained capital to support its near-term liquidity position and its growth for the foreseeable future. The Recapitalization Transaction provided for the following: • Deleveraging via a partial equitization of the 4.00% convertible bonds due 2024 equal to 10% of notional amounts outstanding, and maturity extension by 3,5 years to November 2027. • Allowing holders of the existing convertible bonds to exchange into new second lien secured convertible bonds, subject to their commitment to participate pro-rata in a fully backstopped EUR 25 million investment into additional new convertible notes. • Allowing existing shareholders to participate in the growth of the Company by taking part in a fully covered rights issue of EUR 25 million, which was backstopped in full by certain new investors and an investment banking institution. • Certain existing holders of new convertible notes providing a new senior secured term loan of EUR 30 million. The Recapitalization Transaction is non-recurring in nature and involved significant amounts as it relates to presentation and disclosure in the annual report for the current period. Significant accounting and valuation judgments from management are required in order to prepare the financial statements in accordance with International Financial	We regularly interacted with management and the board on the group's initiatives around financing and liquidity, of which the comprehensive Recapitalization Transaction was an integral aspect. We have read relevant meeting minutes to assess accuracy and completeness of the various components of the Recapitalization Transaction. We reviewed and evaluated for accounting considerations the contractual terms of the financial instruments involved in the Recapitalization Transaction through our independent review of the various agreements. We utilized our internal specialists that specialize in International Financial Reporting Standards (IFRS) with regards to accounting for financial instruments. Their involvement encompassed inquiries of the Company and its external accounting advisor of probing questions around the accounting for the Recapitalization Transaction and assisting the core audit engagement team in forming a conclusion on the appropriate accounting and disclosure of the Recapitalization Transaction. We utilized our internal valuation specialists in order to assist us with forming a conclusion on the appropriate use of key valuation assumptions and judgments in the measurement of the various components of the Recapitalization Transaction. We critically assessed the adequacy of the company's disclosures on the Recapitalization Transaction as disclosed in the annual report.

Reporting Standards (IFRS) linked to the accounting and disclosure of the Recapitalization Transaction therein. As a result of the foregoing, the audit of the accounting consequences of the Recapitalization Transaction required specific audit procedures to be performed in response to the associated accounting and measurement judgments used by management. Our audit procedures were tailored to be responsive to the complexities involved in the accounting, therefore, making it a key audit matter for our audit. The company's disclosure in relation to the Recapitalization Transaction is in part 5, note 5.2.25 *Financial Liabilities*.	

Responsibilities of the board of directors for the preparation of the consolidated financial statements

The board of directors is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium and for such internal control as the board of directors determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the board of directors is responsible for assessing the group's ability to continue as a going concern, disclosing, as applicable, matters to be considered for going concern and using the going concern basis of accounting unless the board of directors either intends to liquidate the group or to cease operations, or has no other realistic alternative but to do so.

Responsibilities of the statutory auditor for the audit of the consolidated financial statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a statutory auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISA will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

During the performance of our audit, we comply with the legal, regulatory and normative framework as applicable to the audit of consolidated financial statements in Belgium. The scope of the audit does not comprise any assurance regarding the future viability of the company nor regarding the efficiency or effectiveness demonstrated by the board of directors in the way that the company's business has been conducted or will be conducted.

As part of an audit in accordance with ISA, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from an error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;

- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the group's internal control;

- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors;

- conclude on the appropriateness of the use of the going concern basis of accounting by the board of directors and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our statutory auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our statutory auditor's report. However, future events or conditions may cause the group to cease to continue as a going concern;

- evaluate the overall presentation, structure and content of the consolidated financial statements, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

- obtain sufficient appropriate audit evidence regarding the financial information of the entities and business activities within the group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the audit committee regarding, amongst other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the audit committee with a statement that we have complied with relevant ethical requirements regarding independence, and we communicate with them about all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated to the audit committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our report unless law or regulation precludes any public disclosure about the matter.

Other legal and regulatory requirements

Responsibilities of the board of directors

The board of directors is responsible for the preparation and the content of the directors' report on the consolidated financial statements and other matters disclosed in the annual report on the consolidated financial statements.

Responsibilities of the statutory auditor

As part of our mandate and in accordance with the Belgian standard complementary to the International Standards on Auditing (ISA) as applicable in Belgium, our responsibility is to verify, in all material respects, the director's report on the consolidated financial statements and other matters disclosed in the annual report on the consolidated financial statements, as well as to report on these matters.

Aspects regarding the directors' report on the consolidated financial statements

In our opinion, after performing the specific procedures on the directors' report on the consolidated financial statements, this report is consistent with the consolidated financial statements for that same year and has been established in accordance with the requirements of article 3:32 of the Code of companies and associations.

In the context of our statutory audit of the consolidated financial statements we are also responsible to consider, in particular based on information that we became aware of during the audit, if the directors' report on the consolidated financial statements is free of material misstatement, either by information that is incorrectly stated or otherwise misleading. In the context of the procedures performed, we are not aware of such material misstatement.

Statements regarding independence

- Our audit firm and our network have not performed any prohibited services and our audit firm has remained independent from the group during the performance of our mandate.

- The fees for the additional non-audit services compatible with the statutory audit, as defined in article 3:65 of the Code of companies and associations, have been properly disclosed and disaggregated in the notes to the consolidated financial statements.

Single European Electronic Format (ESEF)

In accordance with the draft standard on the audit of the compliance of the financial statements with the Single European Electronic Format ("ESEF"), we have also performed the audit of the compliance of the ESEF format and of the tagging with the technical regulatory standards as defined by the European Delegated Regulation No. 2019/815 of 17 December 2018 ("Delegated Regulation").

The board of directors is responsible for the preparation, in accordance with the ESEF requirements, of the consolidated financial statements in the form of an electronic file in ESEF format (“digital consolidated financial statements”) included in the annual financial report.

Our responsibility is to obtain sufficient and appropriate evidence to conclude that the format and the tagging of the digital consolidated financial statements comply, in all material respects, with the ESEF requirements as stipulated by the Delegated Regulation.

Based on our work, in our opinion, the format and the tagging of information in the English language version of the digital consolidated financial statements included in the annual financial report of Biocartis Group NV as of 31 December 2022 are, in all material respects, prepared in accordance with the ESEF requirements as stipulated by the Delegated Regulation.

Other statements

This report is consistent with our additional report to the audit committee referred to in article 11 of Regulation (EU) No 537/2014.

Signed at Zaventem,

The statutory auditor

Deloitte Bedrijfsrevisoren/Réviseurs d’Entreprises BV/SRL
Represented by Nico Houthaeve

6 Glossary & bibliography

6. Glossary

Assay	In the field of diagnostics, an assay is a process or method aimed at determining the presence or amount (quantitative assay) of a certain substance in a sample.
Application	In the context of the Idylla™ platform, an application is a specific Nucleic Acid detection assay (test) that is to run on the system. Applications have their own specific requirements.
Batch Record	The set of records of all relevant process information in any physical or electronic format
Biopsy (solid/liquid)	The Idylla™ platform is capable of processing both solid biopsies (FFPE tissue which is the standard tissue type for solid tumor diagnostics, and fresh (frozen) tissue samples) and liquid biopsies. These are easier to obtain sample types such as blood plasma or urine. Liquid biopsy based assays will facilitate monitoring of treatments and disease progression, and possible earlier disease detection.
Serine/threonine-protein kinase B-raf (BRAF)	BRAF is a protein that, in humans, is encoded by the BRAF gene. The BRAF protein is involved in sending signals within cells and in cell growth. Certain inherited BRAF mutations cause birth defects. Alternatively, other acquired mutations in adults may cause cancer.
CE-mark	The CE-mark is a mandatory conformance mark on many products placed on the market in the European Union. With the CE-marking on a product, the manufacturer ensures that the product is in conformity with the essential requirements of the applicable European Union directives. The letters “CE” stand for ‘Conformité Européenne’ (‘European Conformity’).
Clinical data	Safety and/or performance information that are generated from the clinical use of a medical device.
Companion Diagnostics (CDx)	A companion diagnostic (CDx) is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product
CLIA	The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease (source: https://wwwn.cdc.gov/clia/).
Consumables	Materials that are in direct or indirect contact with final product.
COVID-19	In 2019, a new coronavirus was identified as the cause of a disease outbreak that originated in China. The virus is now known as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease it causes is called coronavirus disease 2019 (COVID-19) (source: mayoclinic.org).
ctDNA	This is circulating tumor DNA.

Deoxyribonucleic acid (DNA)	DNA is a nucleic acid molecule that contains the genetic instructions used in the development and functioning of living organisms.
Distributor	Person or legal entity that furthers the marketing and/or selling of a device from the original place of manufacture to the ultimate user without modifying the device, its packaging or its labelling.
EDTA	EDTA represents Ethylenediaminetetraacetic acid, which is the anticoagulant used for most hematology procedures (like identifying and counting blood cells, blood typing, etc.). Source: ksmedical.com, last consulted on 19 January 2023
Epidermal growth factor receptor (EGFR)	EGFR is a protein found on the surface of certain cells which can cause them to divide. It is found in abnormally high levels on the surface of many types of cancer cells.
Export or distributor markets	Defined as the world excluding European direct markets, US, China and Japan.
Emergency Use Authorization (EUA)	This is an authorization given by the FDA Commissioner pursuant to section 564 of the US Federal Food, Drug, and Cosmetic Act, as amended (the 'FD&C Act'), which allows unapproved medical products or unapproved uses of approved medical products to be used in the United States in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear threat agents when there are no adequate, approved, and available alternatives.
US Food and Drug Administration (FDA)	The FDA is a federal agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the regulation and supervision of, among other things, medical devices.
Formalin fixed, paraffin embedded (FFPE)	FFPE tissues are samples, typically from suspected tumors, that are fixed or mixed with formalin to preserve the structural integrity of the sample. The sample is then embedded into a type of paraffin wax so that it can be sliced into very fine slices, 5-10 microns thick. Treating samples in this manner enables the samples to be stained with dyes to analyze abnormalities in tissue that is suspected of cancer.
Gene signature	RNA expression or gene signature tests are particularly interesting since these often have a high market value. These are based on the differential mRNA expression levels that are calculated into a clinically meaningful score, namely the 'signature' that guides patient management decisions.
Gene fusions	Gene fusions represent an important class of somatic alterations in cancer and have become important biomarkers for cancer diagnosis, prognosis and the selection of targeted therapies. The discovery and research for further understanding of fusion genes across multiple cancer types may provide more effective therapies in the future[61].
ICU	Intensive Care Unit.

Idylla™ Platform	Combination of the Idylla™ Instrument (hardware and software) and the Idylla™ Console (hardware and software) using the Idylla™ cartridge technology.
Idylla™ Cartridge	Refers to the disposable container containing the necessary reagents to perform a test with the Idylla™ system.
Immunoassay	Immunoassays are assays that measure biomarkers through antigen-antibody interaction technologies. In most cases such assays are used to measure biomarkers of the immune system itself, e.g. HCV or HIV antibodies produced by the bodies, which are detected by means of HCV or HIV antigens.
Influenza	Also known as 'the flu' is a highly contagious respiratory tract infection caused by the family of influenza viruses.
In vitro diagnostics or In vitro diagnosis (IVD)	IVD is a diagnostic test outside of a living body in contrast to "in vivo", in which tests are conducted in a living body (for example an X-ray or CT-scan).
Investigational Use Only (IUO)	An Investigational Use Only (IUO) product is an IVD product, in the testing phase of product development that is being shipped or delivered for product testing prior to full commercial marketing.
Kirsten rat sarcoma-2 virus oncogene (KRAS)	KRAS is a protein that, in humans, is encoded by the KRAS gene. Like other members of the Ras family, the KRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyse guanosine triphosphate), and is an early player in many signal transduction pathways. The protein product of the normal KRAS gene performs an essential function in normal tissue signalling, and the mutation of a KRAS gene is associated with the development of many cancers.
KOL	Key Opinion Leader.
Manufacturer	Natural or legal person responsible for the design, manufacture, fabrication, assembly, packaging or labelling of a medical device, for assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on their behalf by a third party.
MDSAP (Medical Device Single Audit Program)	The MDSAP allows medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program's main mission is to "…jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."

Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of - diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of or compensation for an injury, - investigation, replacement, modification, or support of the anatomy or of a physiological process, - supporting or sustaining life, - control of conception, - disinfection of medical devices, - providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
Metastatic Colorectal Cancer (mCRC)	Colorectal Cancer (CRC) is the second most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually. According to the International Agency for Research on Cancer, an estimated 694,000 deaths from CRC occur worldwide every year, accounting for 8.5% of all cancer deaths and making it the fourth most common cause of death from cancer.
Molecular Residual Disease (MRD)	Molecular Residual Disease is a small number of cancer cells left in the body after treatment. These cells have the potential to cause relapse in patients
Molecular diagnostics (MDx)	MDx is a form of diagnostic testing used to detect specific sequences in DNA or RNA that may or may not be associated with disease. Clinical applications of MDx include infectious disease testing, oncology, pharmacogenomics and genetic disease screening.
Micro satellite instability (MSI)	MSI is a genetic hyper-mutability condition resulting from MMR that is functioning abnormally.
Multiplexing	The simultaneous detection of more than one analyte or biomarker from a single sample.
Neuroblastoma RAS viral (v-ras) oncogene (NRAS)	NRAS is a protein that is encoded, in humans, by the NRAS gene. Like other members of the Ras family, the NRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyse guanosine triphosphate) and is an early player in many signal transduction pathways. The protein product of the normal NRAS gene performs an essential function in normal tissue signaling, and the mutation of a NRAS gene is associated with the development of many cancers.
Next-Generation Sequencing (NGS)	Sequencing is the process of determining the precise order of nucleotides within a DNA molecule. It includes any method or technology that is used to determine the order of the four bases—adenine, guanine, cytosine, and thymine—in a strand of DNA. The high demand for low-cost sequencing has driven the development of high-throughput sequencing technologies that parallelize the sequencing process, producing thousands or millions of sequences concurrently. High-throughput sequencing technologies are intended to lower the cost of DNA sequencing beyond what is possible with standard dye-terminator methods.
Performance study	Performance study means a study undertaken to establish or confirm the analytical or clinical performance of a device.

Polymerase chain reaction (PCR)	The specific and exponential amplification of DNA sequences by consecutive thermal cycling steps. Real-time PCR is a form of PCR whereby the amplified sequences are made visible by means of fluorescent labelling in real time, i.e., as they become synthesized. Real-time PCR can be used to estimate the quantity of target DNA sequences in a multiplexed way. PCR and real-time PCR can also be used to detect and quantify RNA sequences after a DNA copy has been made from the RNA sequence by means of a reverse transcriptase enzyme.
Protein	Polypeptide chain built from the 20 natural amino acids. Proteins are synthesized from a messenger RNA copy of a gene and can have many functions in the cytoskeleton of the cell, enzymatic, messenger functions in cells and blood such as immune cytokines, DNA binding proteins that regulate expression, etc.
Prototype	(First) materialization of the intended product.
Regulatory authority	A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and can take legal action to ensure that medical devices marketed within its jurisdiction comply with legal requirements.
Respiratory Syncytial Virus (RSV)	RSV is a major cause of lower respiratory tract infection that is a frequent infection in children.
Research Use Only (RUO)	This is a category of non-approved (i.e. no CE-marking and FDA approval) medical device products that can solely be used for research purposes. Many producers introduce their products first as RUO and/or IUO products, prior to obtaining 510(k) clearance or PMA approval.
Ribonucleic acid (RNA)	RNA, like DNA, is a nucleic acid molecule. RNAs have a variety of different functions in living cells. They can have a scaffolding role in the build-up of complexes (ribosomes, SNRPs), provide sequence recognition (translation, RNA spicing), have catalytic function (ribozymes), act as messengers for protein synthesis (mRNAs), regulate gene expression (miRNAs) or make up the genome of certain viruses.
SARS-CoV-2	The virus that causes COVID-19.
Screening Test	An initial or preliminary test. Screening tests do not tell you if you definitely have a disease or condition. Rather, positive results indicate that you may need additional tests or a doctor's evaluation to see if you have a particular disease or condition.
Sepsis	Sepsis is a potentially life-threatening condition that occurs when the body's response to an infection damages its own tissues. When the infection-fighting processes turn on the body, they cause organs to function poorly and abnormally. Sepsis may progress to septic shock. This is a dramatic drop in blood pressure that can lead to severe organ problems and death. Early treatment with antibiotics and intravenous fluids improves chances for survival (source: mayoclinic.org).

Serine/threonine-protein kinase B-raf (BRAF)	BRAF is a protein that, in humans, is encoded by the BRAF gene. The BRAF protein is involved in sending signals within cells and in cell growth. Certain inherited BRAF mutations cause birth defects. Alternatively, other acquired mutations in adults may cause cancer.
Stakeholder	Interested party.
Surveillance monitoring	Molecular surveillance, where every patient is monitored repeatedly using a molecular test, is a rapidly growing field and represents a significant market opportunity in oncology. The development of an easy-to-use testing solution that can detect patient-specific biomarkers by using a new generation Idylla™ technology aims at decentralizing customized testing and personalized monitoring
White Paper	Customer documentation that explains a specific issue and presents Biocartis standpoint on the matter.

Bibliography

[1] EBITDA + CAPEX (operating loss (EUR 47,047k) plus acquisition of property, plant and equipment (EUR 1,569k) and intangible assets (EUR 368k) minus depreciation and amortization (EUR 10,481k).

[2] HepatoPredict is distributed by Biocartis in Europe as a manual kit mainly addressing centralized expert laboratories, and the test may later be translated into a version on the Idylla™ platform. HepatoPredict is a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation.

[3] AstraZeneca is marketing Tagrisso®, a leading lung cancer therapy approved for patients with resectable and locally advanced or metastatic NSCLC whose tumors have EGFR mutations. EGFR activating mutations are important biomarkers in NSCLC, occurring in 10-15% of all NSCLC patients in the US and the EU, and in 30-40% of all NSCLC patients in Asia (Source: https://www.astrazeneca.com/our-focus-areas/oncology/at-the-forefront-of-lung-cancer-treatment.html, last consulted on 10 June 2022.

[4] The CE-marked IVD Idylla™ Genefusion Panel detects in one single cartridge ALK, ROS1, RET and METex14 skipping, a wide range of actionable targets relevant in non-small cell lung cancer (NSCLC). Designed for use in clinical laboratories, the Panel provides comprehensive testing results within 180 minutes, significantly faster than currently available testing methods which often take days or even weeks before results are available.

[5] The SeptiCyte® RAPID is a fully automated, rapid host-response test5 that distinguishes sepsis from infection negative systemic inflammation in patients suspected of sepsis, providing actionable results in approximately 1 hour, enabling physicians to optimize patient management decisions. Host-response based tests focus on measuring biomarkers that are indicative of the response of a patient's immune system to an infection rather than measuring pathogens that are the cause of the infection.

[6] In addition to blood samples collected in PAXgene blood RNA tubes (per the manufacturer's instructions), this test is now also able to process undiluted EDTA blood samples which are commonly used for most hematology procedures, with results available in about one hour. EDTA represents Ethylenediaminetetraacetic acid, which is the anticoagulant used for most hematology procedures (like identifying and counting blood cells, blood typing, etc.). Source: ksmedical.com, last consulted on 19 January 2023.

[7] Immunexpress Pty Ltd is a Seatle-based molecular diagnostic company focused on improving outcomes for suspected sepsis patients.

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[14] Accès aux tests moléculaires EGFR, RAS et BRAF /Résultats d'une enquête dans 5 régions françaises, appui à la décision, INCa, janvier 2016.

[15] CAGR = Compound Annual Growth Rate. Source: MarketsandMarkets, Molecular Diagnostics Market worth $31.8 billion by 2026.

[16] Source: IMARC Group, Oncology Molecular Diagnostics Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2022-2027.

[17] Company sources on Total Addressable Market (TAM) calculations.

[18] Canaccord, 07 JAN 22 — Industry documents on included industries/countries/companies: Welcome to update city: January conference week preview for our Diagnostics and Tools coverage

[19] Source: www.marketsandmarkets.com, last consulted on 11 March 2023

[20] PCT = Procalcitonin (PCT) assay is a biomarker for systemic inflammation; CRP = C-reactive protein, a biomarker for systemic inflammation. Positive bacteriological cultures, including blood cultures, may not be available before 24 to 48 hours; interpretation of local colonization may be ambiguous; and traditional markers of infection, such as body temperature and white blood cell (WBC) count, may not be specific.

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[44] Cirrhosis is a late-stage liver disease that is characterized by fibrosis (scarring) of the liver tissue. Main causes include alcoholic liver disease (resulting from long term alcohol overconsumption), non-alcoholic steatohepatitis (NASH; linked to obesity and type 2 diabetes) and chronic hepatitis B or hepatitis C infection.

[45] Mutations in the isocitrate dehydrogenase 1 (IDH1) and 2 (IDH2) genes are oncogenic drivers that are frequently found in a variety of human malignancies, including gliomas, acute myeloid leukemia, cholangiocarcinoma, chondrosarcoma and thyroid carcinoma. Source: Han et al. 2020, IDH mutation in glioma: molecular mechanisms and potential therapeutic targets, British Journal of Cancer.

[46] SeptiCyte® RAPID is a CE-marked IVD, developed by Immunexpress Inc in collaboration with Biocartis. Biocartis has the exclusive distribution rights for the EU. The test is not available in all countries. Availability to be checked with local Biocartis representative. The SeptiCyte® RAPID uses SuperScript™ III. The SuperScript III trademark is owned by Life Technologies Corporation.

[47] Quantitative Reverse Transcription PCR. PCR or Polymerase chain reaction is an efficient and cost-effective way to copy (amplify) small segments of DNA or RNA. As such, millions of copies of a section of DNA are made in just a few hours, allowing further analysis for clinicians to diagnose and monitor diseases using a minimal amount of sample, such as blood or tissue. Source: www.genome.gov, last consulted on 22 October 2020.

[48] Based on RT-qPCR analysis, combined with an advanced machine learning algorithm.

[49] This means that the probability of the nodule being malignant drops from 25% to less than 5%, allowing follow-up to be recommended as an alternative to surgery. Info and source: https://thyroidprint.com/en/home-us/, last consulted on 22 October 2020

[50] NPV (Negative Predictive Value) > 95%.

[51] And some European countries.

[52] US FDA, https://www.fda.gov/

[53] Source: MedTech Europe, https://www.medtecheurope.org/news-and-events/default/funding-and-reimbursement/

[54] Source: NILA USA, https://www.nila-usa.org/nila/PAMA.asp

[55] Source: Pacific Bridge Medical, https://www.pacificbridgemedical.com/publication/ivd-registration-reimbursement-china/

[56] FTEs on 31 December of each year (as level may change throughout the year)

[57] Employee with direct reports.

[58] RoHS stands for Restriction of Hazardous Substances. RoHS, also known as Directive 2002/95/EC, originated in the European Union and restricts the use of specific hazardous materials found in electrical and electronic products (known as EEE). Source: www.rohsguide.com

[59] WEEE stands for the Waste of Electrical and Electronic Equipment. The Waste Electrical and Electronic Equipment Directive (WEEE Directive) is the European Community Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) which, together with the RoHS Directive 2011/65/EU, became European Law in February 2003

[60] REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and is a European Union regulation dated 18 December 2006

[61] Source: Stransky et al. The landscape of kinase fusions in cancer. Nat Commun. 5, 4846, 2014; Mertens et al. The emerging complexity of gene fusions in cancer. Nat Rev Cancer 15, 371-381, 2015