BIOCARTIS

ANNUAL REPORT 2021

BIOCARTIS' MISSION IS TO OFFER
RAPID & EASY MOLECULAR DIAGNOSTICS SOLUTIONS
AIMED AT ENABLING **FASTER & MORE ACCURATE**
TREATMENT DECISIONS FOR PATIENTS ACROSS THE GLOBE

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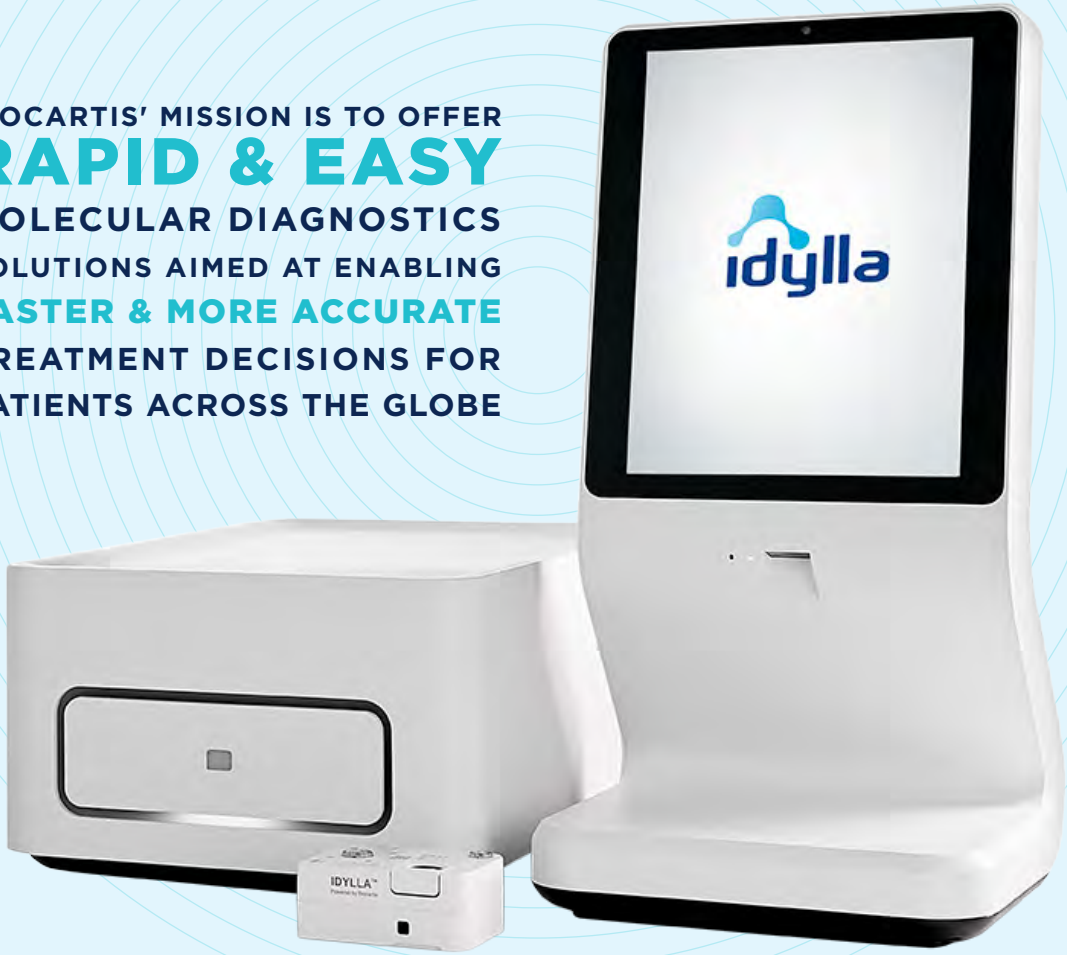


Idylla™
A revolutionary, fully automated system that makes molecular testing convenient and exceptionally fast.
Suitable for any lab.

NOTHING IS SIMPLE
IN ONCOLOGY.
NOTHING
BUT
THIS.

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 2021 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 2021, Biocartis is not yet legally required to report on its environmental, social and governance (ESG)/sustainability performance according to the EU Non-Financial Reporting Disclosure (NFRD) and EU Taxonomy regulation. However, since 2020, Biocartis has been gradually expanding its disclosures on sustainability. The disclosures on sustainability in this 2021 annual report are based, similar to previous years, on the Sustainable Development Goals[1] (SDG), the Global Reporting Initiative (GRI) guidelines[2] as well as the SASB (Sustainability Accounting Standards Board) framework and several principles of the Task-Force on Climate-Related Financial Disclosures. Additionally, certain information requested by SRI (Socially responsible investment) shareholders have been taken into account.

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 (using the Inline XBRL technology, which allows XBRL tagged data) as well as an easily downloadable or printable PDF format. In case of difference in interpretation, 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 difference in interpretation, the English version shall prevail. An electronic version of the annual report 2021 is available on www.biocartis.com under 'investors'. 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 2021 and 31 December 2021. An overview of the securities legislation and listed company reporting requirements can be found on the Belgian Financial Authorities' website, www.fsma.be.

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 labeling

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 labeling for applicable intended uses for each individual Biocartis product.

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.

1.1 Message from the Chairman and CEO

HERMAN VERRELST,
CEO BIOCARTIS

CHRISTIAN REINAUDO,
CHAIRMAN OF THE
BOARD OF BIOCARTIS

"2021 has proven to be an eventful year. A fire and a shortage of raw cartridge materials significantly troubled our cartridge manufacturing, but our teams managed through the situation extremely well and minimized impact to our loyal customers. We were undeniably held back in our ambition to grow much faster. Nonetheless, we were able to deliver a robust 40% volume growth in commercial cartridges for the full year and built out an installed base of close to 2,000 Idylla™ instruments, while exceeding EUR 50m in revenue from core activities. Simultaneously, 2021 was a year of menu expansion: we launched two new tests and signed new partnerships, including the partnership in melanoma with SkylineDx, for high-value test content on Idylla™. We also made important progress in the US, where we submitted our first oncology assay with the US FDA and our partner Immunexpress obtained US FDA 510(k) clearance for SeptiCyte® RAPID on Idylla™. Finally, the continued positive feedback from our customers and new studies re-confirmed the value of Idylla™ to patients.

These growth drivers are all important as we pursue our mission to bring more, better, and faster molecular diagnostics to patients across the globe, through the offering of tests across the entire spectrum of cancer care, from prognosis to surveillance, and in infectious diseases. Looking ahead at 2022, we will continue to grow revenues and lay a solid foundation for profitable growth as we scale our manufacturing capabilities and significantly reduce the cash burn while developing, together with partners, new high value tests on Idylla™.

Growing with and through challenges

In 2021, Biocartis continued its growth pace and placed 331 net new Idylla™ instruments reaching a total global installed base of close to 2,000 Idylla™ instruments at year-end. We also delivered on our target of 40% commercial cartridge growth. We are proud of this growth, despite the many unexpected challenges that Biocartis was presented with during the year 2021. After a very strong performance in the first half of 2021, the fire that broke out at one of the warehouse facilities in Mechelen (Belgium) end of July, and the disrupted supply of cartridge reagent supplies due to the pandemic limited our production capacity. Consequently, we were held back in serving customer demand that remained very strong throughout the year. Nevertheless, our teams did a tremendous job to restart production in two months, once again showing incredible resilience in times of adversity. We believe that as a company, we grew with and through these challenges and came out stronger, ready for the future.

Towards more high-value test content on Idylla™

We are committed to grow towards profitability and keep our focus on adding more high-value test content on Idylla™. In oncology, we launched our unique Idylla™ GeneFusion Assay (RUO) as a rapid lab workflow solution for gene fusion testing of ALK, ROS1, RET, NTRK 1/2/3, as well as MET exon 14 skipping which is increasingly used in research covering lung, thyroid and other cancers. Our new partnerships also supported us towards more high-value test content. We signed an agreement with Dutch and US based SkylineDx in April 2021 for the development of the Merlin Assay on Idylla™, aimed at predicting a patient's risk of nodal metastasis in melanoma. This proprietary test has the potential to make a real difference as a rapid and easy-to-use tool for physicians to identify patients who may safely forgo a biopsy procedure, which is an invasive surgical intervention under general anesthesia often used today to determine prognosis and treatment decisions. Finally, we also expanded our partnership with AstraZeneca with a new commercial agreement to increase access to rapid and easy-to-use Idylla™ EGFR testing products for patients with non-small cell lung cancer that have tumor mutations suitable for a more targeted treatment approach. In infectious diseases, we equally stepped up our efforts and launched our combination panel, the Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD), which detects, in a single cartridge, SARS-CoV-2, Flu A/B and RSV nucleic acids, with results in approximately 90 minutes.

US: first oncology assay submission and US FDA cleared partner test

In our mission to decentralize molecular diagnostic testing and allow in-house testing at virtually any lab, large or small, it is important to obtain regulatory clearance for our in vitro diagnostics (IVD) assays. In April 2021 we submitted our Idylla™ MSI Test to the US FDA for 510(k) clearance. This was a milestone for Biocartis, as it was our first US FDA oncology assay submission. Once the 510(k) clearance is obtained, both large and smaller US labs are expected to benefit from this fast and easy to use Idylla™ MSI testing thanks to the fully automated sample-to-result nature of our platform. As such, we expect to appeal to and penetrate a considerably larger target market. In November 2021, our partner Immunexpress announced that the US FDA granted 510(k) clearance for SeptiCyte® RAPID. Following the commercial launch of this test in Europe in 2020, the US FDA 510(k) clearance opened the path for a full commercial roll-out of this test in the US. This shows how our partners can really benefit from developing their test content on our decentralized Idylla™ platform. For Biocartis, Immunexpress' and Biocartis' commercialization efforts of this test in the US are expected to expand the US Idylla™ installed base and to strengthen cartridge volume growth.

Solid foundation for an attractive growth strategy

The past years we have worked hard to build strong fundamentals: a solid menu of 10+ Idylla™ tests offered in over 70 countries across the world, a healthy pipeline of novel high value-added tests, an installed base of close to 2,000 Idylla™ instruments mainly in oncology, a strongly validated technology and scalable fully automated cartridge manufacturing. Looking ahead to 2022, we will continue to build on those fundamentals, and we are committed to grow revenues, scale manufacturing, improve gross margins and reduce our cash burn on our way to profitability.

Yours sincerely,

HERMAN VERRELST
CHIEF EXECUTIVE OFFICER

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.

LISTED ON EURONEXT BRUSSELS, TICKER BCART

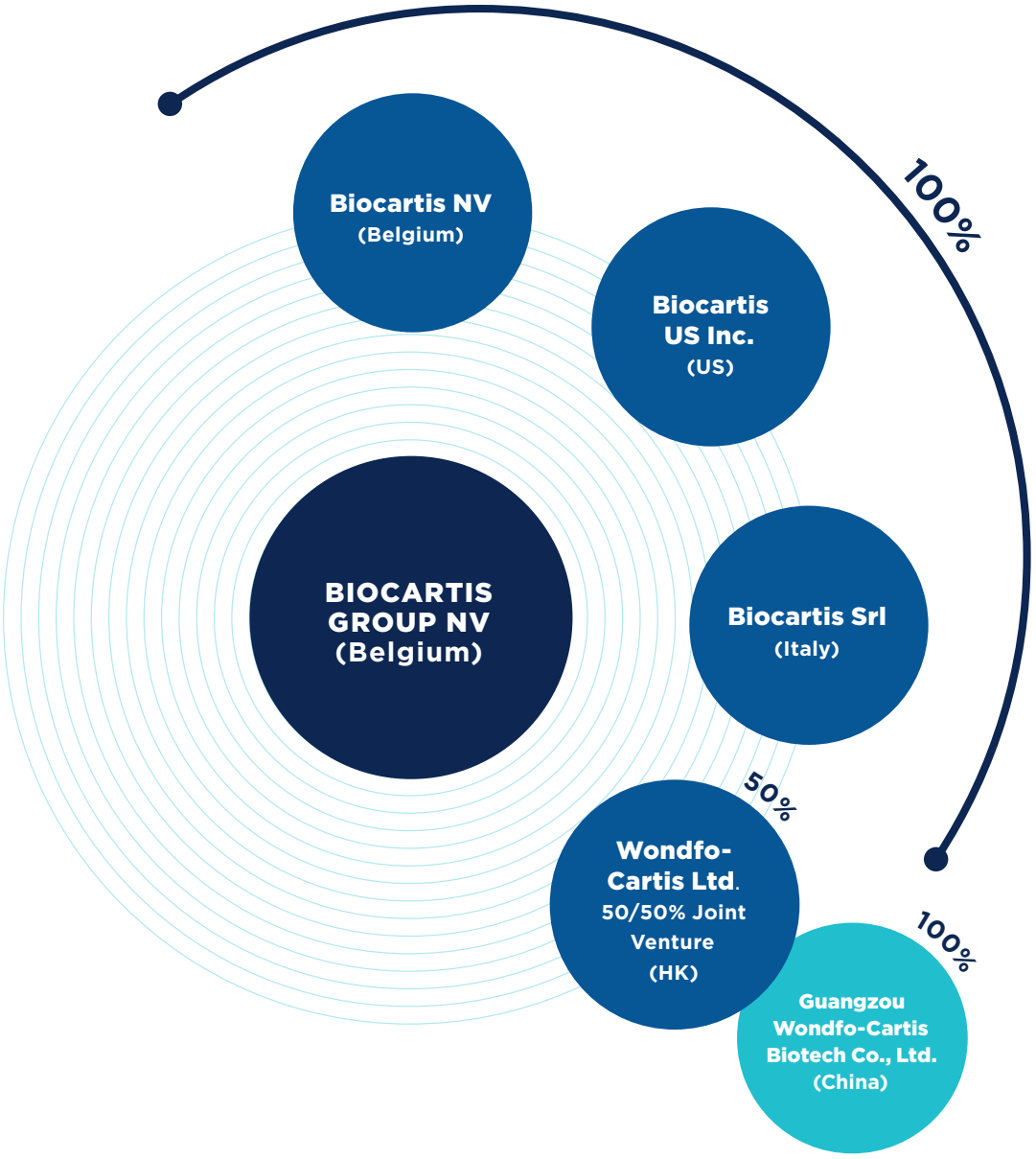
HEADQUARTERED IN BELGIUM (MECHELEN)

COMMERCIALLY ACTIVE IN +70 COUNTRIES

407 EMPLOYEES[3]

SOLID MENU OF ONCOLOGY TESTS

EXPANDING IN INFECTIOUS DISEASES



Biocartis' mission is to offer rapid and easy molecular diagnostic solutions aimed at enabling faster and more accurate treatment decisions for patients across the globe. 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.

Today, the Biocartis group consists of the holding company, Biocartis Group NV, and three wholly owned subsidiaries. The structure of Biocartis as of 31 December 2021 is as follows (see above).

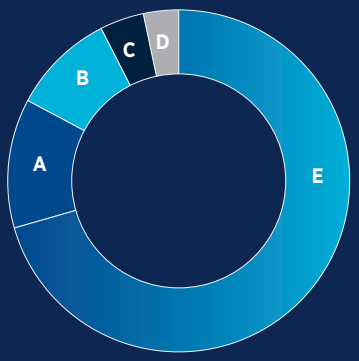
The headquarters of Biocartis Group NV are located in Mechelen, Belgium. The Company was incorporated on 24 November 2014 and is registered in Belgium under enterprise number 0505.640.808 (register of legal entities Antwerp, division Mechelen). In general, the majority of operational activities are centralized in Mechelen (Belgium) on several premises with a total size of approx. 7,000 sqm. In addition, Biocartis has an own team in the US to support its US commercialization, regulatory and clinical efforts. Furthermore, Biocartis' joint venture, WondfoCartis Ltd., was established in 2018 in China as a joint venture owned 50% by Biocartis Group 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 2021 and the transparency notifications received until that date, the shareholder structure of the Company was as follows:

A	Invesco Ltd.[1]	**12.1%**
B	Johnson & Johnson Innovation – JJDC, Inc.[2]	**9.5%**
C	ParticipatieMaatschappij Vlaanderen NV (Flemish Region)[3]	**3.9%**
D	Credit Suisse Group AG [4]	**3.2%**
E	Other institutional and retail investors	**71.2%**



(1) Invesco, Ltd. is not a controlled entity
(2) Johnson & Johnson Innovation-JJDC, Inc., is a wholly owned subsidiary of Johnson & Johnson. Johnson & Johnson is not a controlled entity
(3) The Flemish Region controls ParticipatieMaatschappij Vlaanderen NV
(4) 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

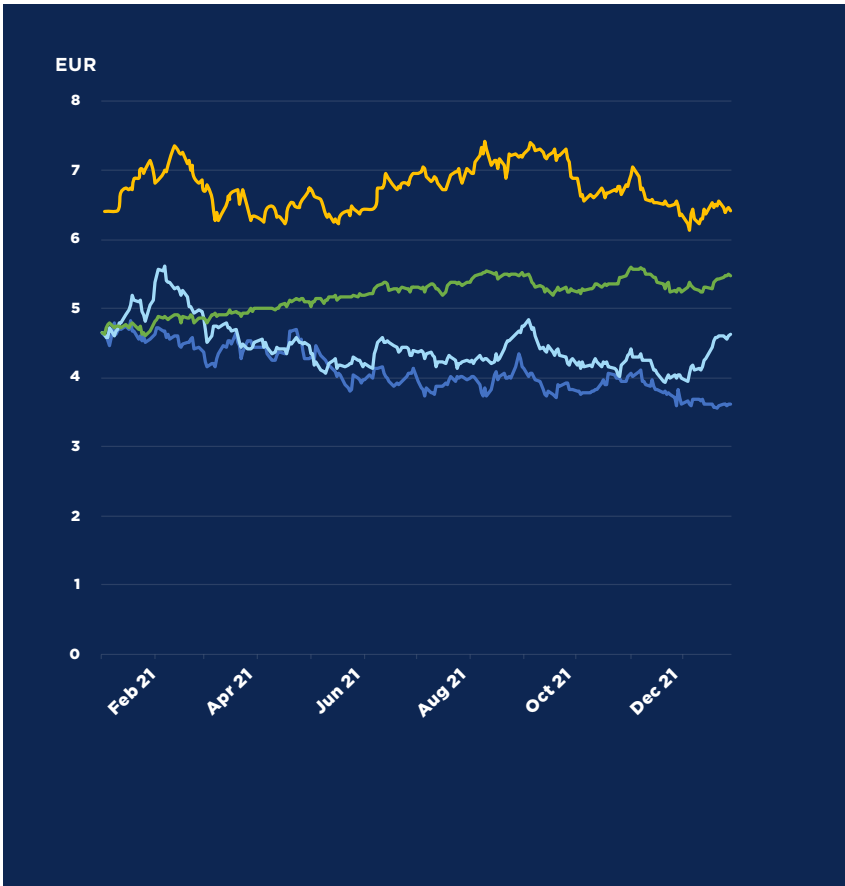
The articles of association of Biocartis Group NV provide for shareholders notification threshold of 3%, 5% or a multiple of 5% (i.e. 10%, 15%, 20%, etc) of the total number of existing voting rights. All transparency notifications are available under the 'investor relations' section on www.biocartis.com.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

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 31 December 2021 was EUR 3.61.



Trading volume

Below is a summary of the 2021 trading volumes of Biocartis' share.

BCART	2021	2020	% Change
Average daily volume	81,743	169,073	-52%
Average daily value	4.11	4.79	-17%
Total traded volume	21,089,678	43,451,721	-51%
Total traded value	89,305,435	208,725,342	-57%

Source: Bloomberg

Analyst coverage

The Biocartis share was covered by five analysts end of 2021. For more recent information about financial analyst ratings, please see the Biocartis investor website.

Broker	Analyst	Rating end 2021
Degroof Petercam	Kris Kippers	Hold
KBC Securities	Lenny Van Steenhuyse	Buy
Kempen & Co	Alexandru Cogut	Neutral
Kepler-Cheuvreux	Daan Vandenberk	Buy
Bryan-Garnier	Dylan van Haaften	Buy

Financial calendar 2022

Date	Event
24 February 2022	Full year results 2021
31 March 2022	Publication Annual Report 2021
To be determined	Q1 2022 Business Update
13 May 2022	Annual General Meeting Biocartis Group NV
1 September 2022	H1 2022 results
To be determined	Q3 2022 Business Update

Investor Relations details

For any investor relation related questions, please contact:

Renate Degrave, Biocartis, Generaal de Wittelaan 11 B, 2800 Mechelen (Belgium), tel. +32 15 631 729, rdegrave@biocartis.com.

1.4 Key achievements in 2021

- Installed base of 1,912 Idylla™ instruments and 323 cartridges sold in 2021, +40% versus 2020
- Revenue from product sales and Idylla™ system services amounted to EUR 42.2m, a year-over-year increase of 27%
- Total revenue of EUR 48.3m, up 12% from 2020
- New partnership agreement with SkylineDx for the development of the Merlin Assay on Idylla™
- Expanded partnership with AstraZeneca to improve access to rapid and easy-to-use Idylla™ EGFR testing products
- Launch of the Idylla™ GeneFusion Assay (RUO)
- First oncology assay US FDA submission with the 510(k) submission of the Idylla™ MSI Test
- Launch of the Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD)
- US FDA 510(k) clearance for SeptiCyte® RAPID on Idylla™ (CE-IVD, US FDA 510(k)) obtained by partner Immunexpress
- 407 employees[6], over 30 nationalities & balanced 50-50% gender diversity

Commercial highlights

Global – The number of commercial cartridges sold in 2021 grew by 40% to 323k from 230k in 2020. Oncology volumes were driven by a strong customer demand in all regions, resulting in +96% growth in the first half of 2021. Cartridge volumes also included a continued contribution from the Idylla™ SARS-CoV-2 Test that was comparable to the second half of 2020. Nevertheless, the global supply of reagents was already disrupted in the first half of 2021, and the fire at one of the Biocartis facilities at the end of July 2021 only added to a constrained production capacity on the Company's high-throughput manufacturing line (ML2). The production on the ML2 line had to be halted for two months and the replenishment of raw materials restrained the growth of the commercial cartridge volume for the full year to 40% as customer demand could only be partly met. The pace at which new Idylla™ instruments were installed equally slowed down because of insufficient cartridge supply needed to onboard new customers. Net new placements of 331 instrument were nevertheless in line with the stated objective for the year and strengthened the global installed base to 1,912 Idylla™ instruments. The ASP (Average Sales Price) of commercial cartridges in 2021 amounted to EUR 96. As expected, the ASP for Idylla™ oncology assays of EUR 105 was diluted by lower prices for the Idylla™ SARS-CoV-2 Test as compared to 2020. Sales related to the Idylla™ SARS-CoV-2 products amounted to 14% of total revenues in 2021.

Europe – Sales in Europe exceeded expectations with a year-over-year overall growth of 69%, driven by continued high growth in oncology as well as a strong sale of the Idylla™ SARS-CoV-2 tests to new, large customers in Norway, the UK and Italy.

US – In the US, the commercialization of Idylla™ products to new customers has not entirely normalized across the country. The Company took the opportunity to restructure its US commercial operations, putting in place new sales leadership to reorientate, expand and retrain its commercial staff. This restructuring, in combination with the overall market environment, temporarily paused new Idylla™ instrument placements and cartridge volumes in oncology stabilized. However, the ASP significantly increased, leading to robust double-digit growth of oncology cartridge revenue. As expected, demand for the Idylla™ SARS-CoV-2 Test reduced from the strong demand in the fourth quarter of 2020 which was characterized by a capacity constrained testing market.

Distributor markets – Of all geographies, in oncology, the distributor markets grew the fastest 2021. Except for a few smaller countries, demand bounced back strongly from 2020, including in Latin-America that was hit hard by the pandemic. Initial commercial sales were accomplished in Russia and

Taiwan, following product registrations in these markets in Q1 2021[4]. Additionally, further to new UK regulations, market authorizations for the Idylla™ platform and oncology assays have been granted by the UK MHRA regulatory agency in December 2021. Furthermore, in November 2021, the Idylla™ SARS-CoV-2 Test was submitted with the UK CTDA and the registration is expected in Q1 2022. Finally, in December 2021, Kazakhstan granted the registration of the Idylla™ platform and oncology assays.

Japan 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. Initial Idylla™ assay registrations in Japan are expected earliest end of 2022.

China commercialization – Following the submission of the Idylla™ Instrument and Console with the China NMPA early 2021, Biocartis received initial feedback. The set-up of local manufacturing capability is nearing completion. Initial Idylla™ assays registrations in China are however not expected before late 2023 due to changed regulatory requirements regarding clinical validation.

Test menu and partnership highlights

Oncology

In 2021, Biocartis progressed both in its test menu and partnerships:

Idylla™ GeneFusion Assay – In March 2021, Biocartis launched the Idylla™ GeneFusion Assay (RUO) as a rapid lab workflow solution for gene fusion testing of ALK, ROS1, RET, NTRK 1/2/3, as well as MET exon 14 skipping which is increasingly used in research related to multiple cancer types including lung cancer, thyroid cancer and others. A CE-IVD launch of the Idylla™ GeneFusion Assay is expected in 2022;

510(k) submission Idylla™ MSI Test – In April 2021, Biocartis announced its first US FDA submission of an oncology assay with the 510(k) submission[6] of its Idylla™ MSI Test for use as an in vitro diagnostic device intended for the identification of microsatellite instability (MSI) status in colorectal (colon) cancer (CRC) to aid in the differentiation between sporadic CRC and potential Lynch syndrome;

Partnership SkylineDx – Also in April 2021, Biocartis announced the signing of a partnership agreement with SkylineDx which targets the development of their novel proprietary test, the Merlin Assay, on the Idylla™ platform, which is aimed at predicting a patient's risk of nodal metastasis in melanoma. The CE-IVD launch of the manual kit of the Merlin Assay in collaboration with SkylineDx for commercialization in Europe by Biocartis is expected this year;

Partnership AstraZeneca – In May 2021, Biocartis announced its expanded partnership with AstraZeneca to improve access to rapid and easy-to-use Idylla™ EGFR testing products at selected hospital sites in European and global distributor markets;

VLAIO grant – Also in May 2021, Biocartis announced the EUR 1.4 million grant it received from VLAIO, the Flanders organization for Innovation & Entrepreneurship, for the ongoing development of a highly innovative technology to be deployed on the Idylla™ platform aimed at enabling the off-line customization of the Idylla™ cartridge;

Partnership Ophiomics – Post the reporting period, on 8 February 2022, Biocartis announced it had signed an agreement with Ophiomics, a Lisbon (Portugal) based biotech company developing a precision medicine portfolio focused on liver cancer. The collaboration will initially focus on the commercialization of HepatoPredict™, a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation. HepatoPredict™ will be 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;

Partnership GeneproDx – RUO launch of the ThyroidPrint© on Idylla™ in collaboration with GeneproDx is expected in 2022;

Partnership LifeArc – RUO launch of the Idylla™ ABC (Advanced Breast Cancer) Assay in collaboration with LifeArc is expected in 2022.

Infectious diseases

In 2021 Biocartis further strengthened its infectious disease menu:

Launch Idylla™ SARS-CoV2/ Flu/RSV Panel – In September 2021, Biocartis announced the launch of its Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD) which detects, in one single cartridge, SARS-CoV-2, Flu A/B and RSV nucleic acids, with results in approximately 90 minutes;

510(k) clearance for SeptiCyte® RAPID – In November 2021, Biocartis announced the US FDA granted 510(k) clearance for SeptiCyte® RAPID[5] (CE-IVD, US FDA 510(k)) which runs on the Idylla™ platform[6] and was developed under the partnership with Immunexpress[7]. The SeptiCyte® RAPID is a fully automated, rapid host-response test[8] 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. In 2022, SeptiCyte® RAPID PLUS, an assay based on SeptiCyte® RAPID that can also distinguish between bacterial and viral infections, is expected to be launched as a CE-IVD.

Idylla™ performance data

During 2021, 34 new Idylla™ papers were published, bringing the total number of Idylla™ papers published end of 2021 to 123. Idylla™'s excellence along with the performance of Idylla™'s EGFR[9] testing solutions was emphasized through several studies and abstracts:

In February 2021, Biocartis announced the publication of two studies[10] by Memorial Sloan Kettering Cancer Center ('MSKCC', New York, US) on the use of Biocartis' Idylla™ EGFR Mutation Assay (RUO) as a rapid first-line testing method before using next-generation sequencing (NGS). Both studies concluded that Idylla™ EGFR testing enables rapid assessment of the most common EGFR mutations with low sample input, even on different sample types, without compromising subsequent more comprehensive NGS testing[11];

In November 2021, Biocartis announced the publication of a study[12] which concluded that the Idylla™ platform contributes to improving patient management decisions for patients with non-small cell lung cancer (NSCLC) through the faster screening of EGFR mutations.

Organizational and operational highlights

Fire Incident - During the night of 30 July 2021, a fire broke out at one of the 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 the year.

Cartridge manufacturing – Transfer of the Idylla™ EGFR Mutation Test (CE-IVD) to the ML2 line was completed during H1 2021, as such concluding the transfer of Biocartis' main oncology assays to the fully automated ML2 line. This is a key driver of cost optimizations within the Company's cartridge manufacturing activities and was demonstrated by a 33% gross margin on assays produced on the ML2 line, despite lower-than-expected production volumes on this line throughout 2021. The Idylla™ SARS-CoV-2 Test and Idylla™ SARS-CoV-2/Flu/RSV Panel are being transferred to the ML2 line in the first half of 2022 and this is expected to further contribute to absorbing fixed manufacturing costs awaiting full capacity utilization of the ML2 line that can produce up to 1m tests annually.

Ordinary and Extraordinary General Shareholders' Meetings – During the ordinary shareholders' meeting held on 14 May 2021, the shareholders of the Company approved all items on the agenda of the annual shareholders' meeting including the approval of the remuneration policy and report, the re-appointment of Herman Verrelst, Chief Executive Officer of the Company, as director of the Company for a term of four years, and the re-appointment of Christian Reinaudo as independent director of the Company for a term of three years. Since there was no deliberation and voting on the items on the agenda of the extraordinary shareholders' meeting because the attendance quorum for such meeting was not reached, Biocartis convened a second extraordinary shareholders' meeting with the same agenda items, for which no attendance quorum applied. During this extraordinary general shareholders' meeting held on 4 June 2021, the shareholders of the Company approved all agenda items, including the renewal of the authorization to the Board of Directors to increase the share capital of the Company by up to 75% of the then current amount of the share capital, during a period of five years.

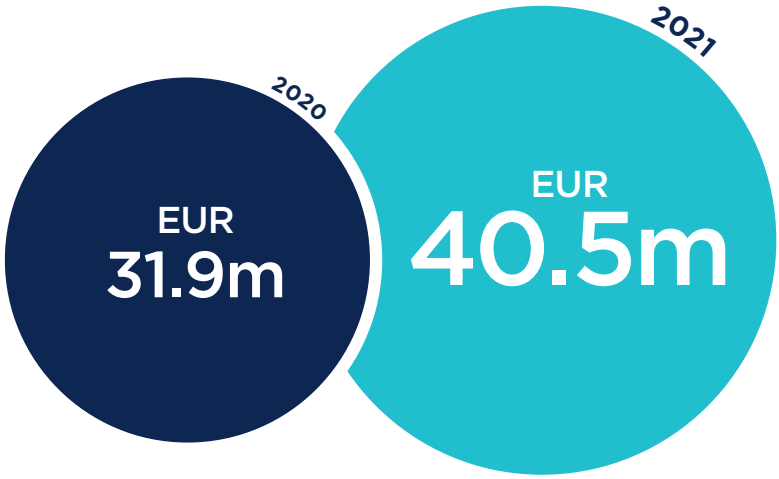
Financial highlights

Product sales revenues

Total product sales increased to EUR 40.5m in 2021, a 27% increase from EUR 31.9m in 2020

- Income from cartridge sales amounted to EUR 31.6m and grew 27% year-over-year. Total cartridge volume of 326k cartridges (+34%) included 323k commercial cartridges (+40%) and 4k R&D cartridges (-69%). As expected, the commercial ASP of EUR 105 in oncology was diluted by the lower pricing of the Idylla™ SARS-CoV-2 Test, resulting in an overall commercial ASP of EUR 96 compared to EUR 102 in 2020. Revenue generated by sales of the Idylla™ SARS-CoV-2 products represented 14% of total revenue.

- The 331 net new installations of the Idylla™ platform was relatively consistent with 2020 (335), but the revenue increased by 25% to EUR 8.9m. The increase was primarily driven by a higher ASP while the proportion of capital sales in total placements of 51% remained comparable (2020: 49.5%).



Cash position

53.5 EUR m

Biocartis' cash position as per 31 December 2021 amounted to EUR 53.5m and included EUR 6.0m drawn-down on short-term credit facilities.

Biocartis intends to significantly reduce its cash burn in 2022 and is investigating multiple options to strengthen its cash position the course of 2022.

Total operating income

Total operating income amounted to EUR 54.9m in 2021 compared to EUR 55.6m in 2020. In addition to grant income of EUR 2.0m, other income included the insurance claim of EUR 4.6m for damages caused by the fire, including the impact of lost revenue. 2020 included a one-off settlement payment of EUR 10.3m (USD 12.0m) received in connection with the termination of the collaboration with Genomic Health, Inc. for the development of the Oncotype DX Breast Recurrence Score® test on Idylla™. The continued growth of the installed base led to a 39% increase in income from system servicing (2021: EUR 1.7m; 2020: EUR 1.2m).

Income from collaborations decreased from EUR 10.0m in 2020 to EUR 6.1m in 2021, in the absence of licensing fees (2020: EUR 1.8m) and because of lower R&D services provided to partners. Despite a growing number of collaborations, the recognition of revenue is strongly depending on and varying with the specific stage of the various development projects

Operational cashflow

Lower total operating income, higher operating expenses and the outstanding collection of most of the fire insurance claim caused the total cash flow used in operating and investing activities to increase from EUR 43.3m in 2020 to EUR 69.5m in 2021.

Cost of goods sold

Cost of goods sold increased to EUR 33.9m, 29% higher than in 2020, driven by 40% higher commercial cartridge volumes. Despite higher cartridge volumes, the gross margin on product sales amounted to 16% in 2021 compared to 18% in 2020. The utilization of the high-throughput automated manufacturing line ML2 was significantly lower than planned as a direct result of the fire and constrained supply of certain reagents. During the forced two-month production stop of the ML2 line, the production of certain assays was transferred to the ML1 line to preserve customer supply as much as possible. The manufacturing capacity on the ML1 line is however significantly lower and the manufacturing cost significantly higher than on the ML2 line. However, even with low production volumes on the ML2 line throughout 2021, the gross margin on assays produced on the ML2 line already reached 33%, clearly demonstrating the Company's ability to scale with unhindered and increasing production on the ML2 line. Additionally, the gross margin also slightly decreased because of lower pricing of the Idylla™ SARS-CoV-2 test products in 2021. Both tests are being transferred to the ML2 line in the first half of 2022 and will generate a contribution to the absorption of fixed manufacturing costs awaiting full capacity utilization of the ML2 line that can produce up to 1m tests annually.

OPEX

Total operating expenses (excluding cost of sales) amounted to EUR 83.6m included a write-off of EUR 3.2m on raw materials and cartridges lost in the fire. Excluding the impact of the fire, operating expenses increased by EUR 4.2m or 6% from EUR 76.1m in 2020. As announced at the beginning of 2021, the Company allowed for exceptional investment in menu expansion and diversification. The pandemic and prioritizing the development of the Idylla™ SARS-CoV-2 Test in 2020 also led to the delay and carry-over of certain projects into 2021.

Key figures 2021

The tables on the right show an overview of the key figures and a breakdown of operating income for 2021. 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.

[1] Including EUR 1.2m of restricted cash (as a guarantee for KBC Lease financing)

Key figures (EUR 1,000)	2021	2020	% Change
Total operating income	**54,898**	**55,559**	**-1%**
Cost of sales	-33,922	-26,284	29%
Research and development expenses	-48,054	-45,783	5%
Sales and marketing expenses	-16,763	-15,736	7%
General and administrative expenses	-15,560	-14,618	6%
Other expenses	-3,244	-	
Operating expenses	**-117,543**	**102,421**	**15%**
Operational result	**-62,645**	**-46,862**	**34%**
Net financial result	-8,411	-15,768	-47%
Share in the result of associated companies	-659	-532	24%
Income tax	243	228	7%
Net result	**-71,472**	**-62,934**	**14%**
Cash flow from operating activities	-65,716	-39,267	64%
Cash flow from investing activities	-3,748	-4,007	22%
Cash flow from financing activities	-1,204	-11,523	-90%
Net cash flow	**-70,668**	**-54,797**	**29%**
Cash and cash equivalents[1]	**53,522**	**123,668**	**-57%**
Financial debt	154,162	150,558	2%

Operating income (EUR 1,000)	2021	2020	% Change
Collaboration revenue	**6,053**	**9,989**	**-39%**
Idylla™ system sales	8,868	7,085	25%
Idylla™ cartridge sales	31,618	24,808	27%
Product sales revenue	**40,486**	**31,893**	**27%**
Service revenue	1,730	1,246	39%
Total revenue	**48,269**	**43,128**	**12%**
Grants and other income	6,629	12,431	-47%
Total operating income	**54,898**	**55,559**	**-1%**

Product sales revenue by type (EUR 1,000)	2021	2020	% Change
Commercial revenue	40,351	30,709	31%
Research & Development revenue	135	1,184	-89%
Total product sales revenue	**40,486**	**31,893**	**27%**

Income statement

Total operating income decreased by EUR 0.7m to EUR 54.9m in 2021. Collaboration revenue amounted to EUR 6m, a decrease of 39% from 2020. License fees amounted to EUR 0.2m compared to EUR 1.8m in 2020, while R&D service revenue decreased by EUR 2.3m from EUR 8.2m in 2020 to EUR 5.9m in 2021.

Revenue from product sales increased with EUR 8.6m or 27% from EUR 31.9m in 2020 to EUR 40.5m in 2021. Both Idylla™ cartridge sales and Idylla™ system revenues increased to EUR 31.6m and EUR 8.9m, respectively (2020: EUR 24.8m and EUR 7.1m). Idylla™ cartridge sales included revenue from the sale of 323k commercial cartridges and of 4k R&D cartridges. Services revenue amounted to EUR 1.7m in 2021 versus EUR 1.2m in 2020, a 39% increase in line with the growing installed base of Idylla™ systems.

Grant income increased to EUR 2.0m in 2021, an increase of EUR 0.9m compared to EUR 1.2m in 2020, and related to the recognition of subsidies awarded in relation to the establishment of a second cartridge manufacturing line, to the development of the Idylla™ SARS-CoV-2 Test and the Idylla™ GeneFusion Assay (RUO), as well as the highly innovative technology to be deployed on the Idylla™ platform aimed at enabling the off-line customization of the Idylla™ cartridge. Other income included a EUR 4.6m insurance claim for damages caused by the fire on 30 July 2021. In 2020, other income included a settlement fee of EUR 10.3m paid by Genomic Health (Exact Sciences) following the termination of the development of the Oncotype DX Breast Recurrence Score® test on Idylla™, and the proceeds of a USD 1.0m loan received under the US Paycheck Protection Program ('PPP'), that was entirely forgiven.

Total operating expenses amounted to EUR 117.5m in 2021, compared to EUR 102.4m in 2020. Within operating expenses, the cost of goods sold increased by EUR 7.6m from EUR 26.3m in 2020 to EUR 33.9m in 2021 as commercial cartridge volumes increased by 40%. The resulting gross margin on product sales amounted to 16% compared to 18% in 2020. The decrease of the gross margin resulted from a lower ASP on the Idylla™ SARS-CoV-2 Test compared to 2020. Prices for COVID-19 testing reduced as expected because the testing capacity was expanded. The lower than planned utilization of the high-throughput automated manufacturing line ML2 also caused gross margin on cartridges to be lower than expected. 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.

Total operating expenses, excluding the cost of goods sold, increased by EUR 7.5m from EUR 76.1m in 2020 to EUR 83.6m in 2021 (including EUR 3.2m inventory write-off from the fire). R&D expenses amounted to EUR 48.1m, an increase of EUR 2.3m compared to 2020. In 2020, several projects were delayed and carried over to 2021. Furthermore, the Company invested in further menu expansion and diversification. These investments included the preparatory work to apply for conformity of our CE-IVD assays under the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) that establishes a new regulatory framework for in vitro diagnostic medical devices. In addition to ongoing projects to broaden the core oncology test menu on Idylla™ and upgrading the functionality of the Idylla™ platform, the Company also developed and launched its Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD) which detects, in one single cartridge, SARS-CoV-2, Flu A/B and RSV nucleic acids. Finally, R&D included the continued investment in the transfer of assays from the ML1 line to the ML2 line as well as continuous improvement projects with a view to optimize the manufacturing output. S&M and G&A expenses increased by EUR 1.0m and EUR 0.9m, respectively, reflecting inflation, the restructuring of the US commercial team and increased facility costs. Other expenses of EUR 3.2m entirely related to the write-off of materials and finished products lost in the fire.

The operating loss for 2021 amounted to EUR 62.6m compared to EUR 46.9m in 2020. Excluding the impact of the settlement fee of EUR 10.3m paid by Exact Sciences in 2020, the increase of EUR 5.5m resulted from higher and exceptional investment in various development projects and the build-out of the commercial and organizational infrastructure.

Net financial expenses in 2021 amounted to EUR 8.4m of which EUR 8.3m related to the outstanding balance of EUR 135m on the convertible bond. In 2020, net financial expenses amounted to EUR 15.8m, which included EUR 9.0m interest and debt appreciation expense and a cash payment of EUR 4.3m in connection with the incentivized exercise of conversion rights in relation to EUR 15 million aggregate principal amount of the convertible bonds.

Balance sheet

On 31 December 2021, total assets amounted to EUR 142.5m, compared to EUR 210.5m at the end of 2020. Non-current assets amounted to EUR 47.4m, compared to EUR 50.5m, mostly because of the net reduction of intangible assets and property, plant and equipment (EUR 3.5m) and an impairment charge of EUR 1.4m, offset by an investment in a convertible note issued by GeneproDx in lieu of payment for the technology access fee due under the collaboration agreement. Financial assets amounting to EUR 2.3m (2020: EUR 2.9m) included the investment in the China joint venture Wondfo-Cartis, which was adjusted by EUR 0.7m for our share in the loss for the year.

End 2021, current assets amounted to EUR 95.1m, a decrease of EUR 64.9m from EUR 160.0m in 2020, mainly because of the reduction in cash and cash equivalents of EUR 70.1m. Trade receivables increased by EUR 2.7m, an increase of 20% year-on-year which mainly resulted from the 27% increase in product revenues compared to 2020. Inventory only increased by EUR 0.4m. Stock levels of finished cartridges and raw materials decreased as a result of the fire and the insufficient supply of reagents to deliver all open customer orders. On the other hand, the inventory of Idylla™ instruments increased awaiting the availability of sufficient cartridges to onboard new customers. Other receivables increased by EUR 2.7m from EUR 4.0m in 2020 to EUR 6.6m in 2021 and included EUR 3.8m of uncollected insurance claims for fire damages. Other current assets decreased by EUR 0.4m.

On 31 December 2021, total financial debt amounted to EUR 154.2 compared to EUR 150.6m end of 2020. The increase resulted from the appreciation of the convertible bond by EUR 2.9m and a EUR 6.0m draw-down on working capital facilities, offset by the scheduled repayment of leasing obligations of EUR 5.2m.

Trade payables decreased by EUR 2.3m to EUR 11.6m in 2021. Other current liabilities increased by EUR 0.9m to EUR 8.4m, partly related to VAT payable as a result of Brexit and increased payroll related provisions as the number of employees (FTE or Full Time Equivalent) increased from 366 in 2020 to 407 in 2021.

Cash flow statement

The cash flow from operating activities in 2021 increased by EUR 26.4m to EUR 65.7m compared to EUR 39.3m in 2020. Apart from the collection of the EUR 10.3m settlement fee paid by Exact Sciences, 2020 was characterized by more cautious spending because of the pandemic and several projects being carried over to 2021, causing the operating loss to increase by EUR 15.8m to EUR 62.6m in 2021. Investments in working capital amounted to EUR 9.6m, a year-on-year increase of EUR 13.0m, in line with the expansion of our commercial activity and a significantly higher amount of trade payables at the end of last year. Furthermore, EUR 3.8m of losses caused by the fire were not yet collected from the insurance carriers on 31 December 2021. Interest expense was EUR 0.9m lower than in 2020 following the decrease of the convertible bond by EUR 15.0m in 2020.

The cash flow from investing activities in 2021 amounted to EUR -3.7m, compared to EUR -4.0m in 2020. Investments in property, plant and equipment amounted to EUR 3.7m in 2021, an increase of EUR 0.7m compared to 2020 and including capitalized Idylla™ systems as well as investments in laboratory and manufacturing equipment.

The cash flow from financing amounted to EUR -1.2m as a result of as a result of the scheduled repayment of lease and other obligations offset by the drawdown of EUR 6.0m on existing working capital facilities.

The total cash flow for 2021 amounted to EUR 70.7m compared to EUR -54.8m in 2020.

1.5 Impact of COVID-19

Business impact and recovery from COVID-19

Since its outbreak in 2020, the pandemic impacted our business in various respects. Initially, the pandemic deprioritized and disrupted cancer care globally. Patient access to hospitals was significantly restricted throughout almost the entire first half of 2020 and customer prospection was severely hampered. Throughout the second half of 2020, testing volumes started to recover and gradually normalized to pre-pandemic levels. In 2021, patient access to hospitals was more sporadically restricted in specific regions with a high surge of COVID-19 cases, which resulted in an overburdened healthcare system and required 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[13] nucleic acids. Together with Septicyte® RAPID, developed in collaboration with Immunexpress, both tests added to the build-out of a broader infectious disease test menu on Idylla™. Furthermore, the partnership with Endpoint Health to develop and commercialize a novel test on Idylla™ will support therapeutic decisions for critical illnesses, adding to our suite of rapid response testing in acute settings such as ICUs for rapid triage and therapy selection for critically ill patients. Furthermore, Idylla™'s unique multiplexing platform capabilities can bring clear unique benefits to partners in the area of syndromic panel testing, one of the fastest growing MDx segments.

Supplier impact

Since the start of the pandemic, we raised our efforts to strengthen our supply chain and mitigate the risk of disruptions that could affect the supply of Idylla™ products to our customers. In 2021, we were nevertheless 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 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. We have increased our efforts to:

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

Environmental impact

Just as in 2020, the main environmental impact of COVID-19 on our activities resulted from restricted travel by our sales teams (sales related travel), general management (business development and investor roadshow travel) as well as employees (commuting to the workplace). In 2021 we continued to limit travel due to a more engrained culture of virtual meetings. Less frequent employee commuting, and the lower utilization of office floor space positively impacted related energy, water use and carbon emissions at Biocartis sites. We also offered employees reusable masks to limit the amount of waste related to the continued pandemic.

Social impact

We supported our employees in a continued pandemic situation with varying COVID-19 measures:

- Our HR and Health & Safety teams continued to closely follow-up on safe working conditions for employees that needed to be on site (including production and technical teams) in full compliance with applicable regulations such as social distancing
- HR & internal communication teams regularly launched internal communication updates on safety measures, travel guidelines and other COVID-19 related rules
- Revision of HR policies and practices including on more flexible telework
- Transformation to a hybrid workspace with appropriate workstations at home and in the office, supported with the right digital communications tools. Office spaces were transformed to blend flex desks, dedicated team meeting rooms, individual workspaces as well as several large new meeting rooms were installed with enhanced digital working tools
- Launch of the employee wellbeing strategy and online platform 'My Health Partner' supporting on mental health and the hybrid way of working. Initiatives included online workshops, webinars, e-learning modules and monthly newsletters for employees and management, as well as the start of several workshop series on home office ergonomics and healthy hybrid working habits
- Further roll-out of a hybrid recruitment and training strategy, blending on-site and virtual activities
- (Re)connection moments for employees through team days on-site or 'virtual coffee moments' online

We will continue our wellbeing program in 2022 by continuously adding new information to the platform, complemented with regular newsletters to keep employees informed of new initiatives.

Long-term impact of COVID-19

- 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.

Government support measures

In 2020, our US subsidiary, Biocartis 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 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. In 2021 Biocartis did not benefit from any other government support measures related to the COVID-19 pandemic.

1.6 Impact of the war in Ukraine

Biocartis has no sales in Ukraine. In Russia, Biocartis works through a local sales distributor who realized first commercial sales in H1 2021 following completion of first product registrations in Russia in Q1 2021. The impact to expected revenue for 2022 from Russian distributor sales that were projected prior to the start of the war, is not material. Supplier exposure is limited to 1 indirect supplier for Idylla™ instrument sub-parts who is based in Russia. Based on the current level of inventory on-hand and on various alternative sources of supply that were identified and are currently being assessed, Biocartis does not expect any material adverse impact on the continued supply of instruments.

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[14] 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[15]. 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[16]. 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[17]. 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 17.8bn in 2021, is expected to grow at a 12.3% compound annual growth rate (CAGR)[18] between 2021-2026. Oncology is the fastest growing sub-segment with a five-year CAGR of 12.6%[19].

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 5 million tests per annum[20], doubling to 10 million with tests in the pipeline. The market potential is vast[21]:

- 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, estimated at USD 28.1bn in 2021, is expected to grow at a CAGR of 7.2%[22] between 2021-2026.

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 capabilities 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)[23]. 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[24], with annual healthcare costs estimated at over USD 65 billion in the US alone[25].

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

2.2 Product strategy

Biocartis’ mission is to offer rapid and easy molecular diagnostic solutions aimed at enabling faster and more accurate treatment decisions for patients across the globe. Our strategy is focused on more, better and faster MDx testing through our decentralized Idylla™ platform that enables rapid access to personalized medicine for patients across the globe.

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™ platform, robust technology with validated performance

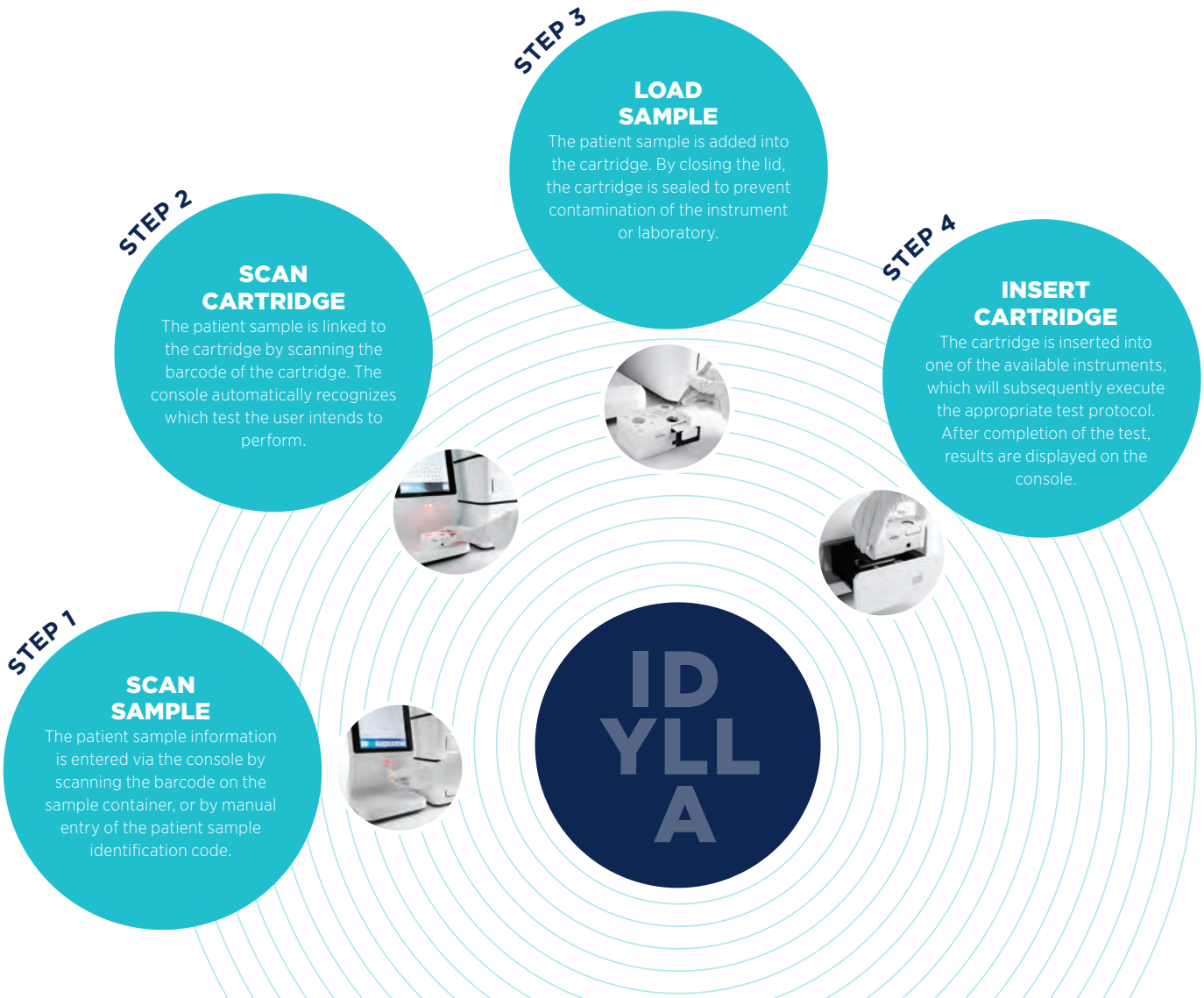
The Idylla™ platform is a fully automated, real-time PCR-based molecular diagnostics system that provides same-day results enabling physicians to make timely decisions on patients' therapy. Idylla™ can be used with multiple sample types, including solid and liquid biopsies.

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 34 new published Idylla™ papers in 2021, bringing the total number of Idylla™ papers to 123 end of 2021.



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.

Screening & diagnosis → **Prognosis & therapy selection** → **Response monitoring** → **Recurrence monitoring**

Gene signatures	Targeted therapy	Pan-tumour	Immuno-oncology	Liquid biopsy
RNA gene signature tests a.o.	Tests detecting spedific tumour mutations used for therapy selection in a specific cander type	Tests for pan-tumour application	Tests supporting immuno-oncology treatments	Tests based on liquid samples
Often high value once validated & clinical value demonstrated	Significant pharma pipeline of new targeted therapies	For therapies based on genetics rather than location of tumour, across multiple cancer types	Many different therapies: immune checkpoint inhibators, cell & viral therapies, vaccines,...	Use in diagnosis, prognosis & molecular surveillance (= therapy selection, response & recurrence monitoring)
Examples: ThyriodPrint (GeneproOx), Merlin Assay (SkylineDx)	**Examples:** Selbora (BRAF), Tagrisso (EGFR) Erbitux (RAS), Vectibix (RAS)	**Examples:** Vitrakvi, Keytruda, Rozlytrek	**Examples:** partnership with Kite (Gilead), Bristol Myers-Squibb (BMS)	Generic or customized panels for molecular surveillance (incl. treatment response monitoring, MRD testing & recurrance monitoring)

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 (Minimal 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 assay, 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. Currently 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™

- Within **thyroid cancer**, approximately 1.2 million thyroid cytology evaluations are reported as indeterminate each year[26], 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 an ongoing partnership with LifeArc for the development of the Idylla™ ABC (Advanced Breast Cancer) Assay targeting a multigene panel of predictive & resistance-inducing mutations

- **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

As per end 2021, Biocartis offered oncology tests for melanoma, colorectal and lung 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 (TKI's) whereas exon 20 insertion mutations may predict resistance to TKI's. 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 TKI's[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

Idylla™ EGFR Mutation Test – Idylla™ EGFR 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.

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[40].

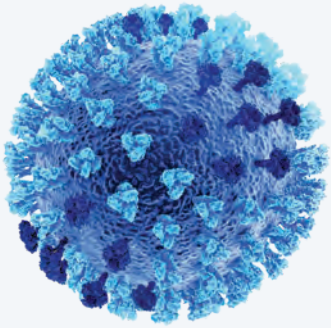
In vitro diagnostic tests

BRAF Mutation 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[41].

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



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 400µl of viral transport media (VTM).

Both tests are CE-IVD marked.

- **SeptiCyte® RAPID**[42]: 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.

- **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™ is a steppingstone towards a broader Biocartis' infectious disease menu, 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 2021, Biocartis had the following partnerships in place (selection, in alphabetical order):

A*STAR - On 10 July 2017, Biocartis announced the renewal of its five-year strategic partnership with ETPL (the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research), where parties will co-invest in the development of jointly selected Idylla™ oncology tests. Biocartis is responsible for the commercialization of the tests under its own label, and ETPL is responsible for the development through Singapore's Diagnostics Development (DxD) Hub.

AMGEN - In February 2016, Biocartis announced its collaboration with Amgen, a leading biotechnology company (NASDAQ: AMGN), with the aim to accelerate access to RAS biomarker information. After a first collaboration to offer its new RAS biomarker tests to hospitals in a selection of countries across the world[43], the partnership was expanded in December 2016 to up to 10 European countries.

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.

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. On 1 October 2020, Biocartis joined the COVID-19 Industry Testing Consortium led by BMS with the aim to improve, innovate and accelerate all aspects of testing, including research, regulatory oversight, clinical implications, reliability and access.

COVANCE - On 23 April 2019, Biocartis announced the global strategic commercialization agreement with Covance, LabCorp's Drug Development business, 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.

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[44] based mRNA-expression classifier[45] test that helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignan[46] . A benign test result[47] 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' SeptiCypte® 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.

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.

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™ Advanced Breast Cancer Panel which is positioned to target a multi-gene panel of predictive and resistance-inducing mutations based on an FFPE sample type. The Idylla™ Advanced Breast Cancer Panel is being prepared for use in research setting (RUO). On 1 September 2020, Biocartis announced to have expanded its agreement with LifeArc. Under the new agreement, LifeArc obtains 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. 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 PMDA.

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.

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 Wondfocartis is 50% owned by Biocartis and 50% owned by Wondfo. Following the submission of the Idylla™ Instrument and Console with the China NMPA regulatory authorities early 2021, Biocartis received initial feedback in the second half of 2021. The set-up of local manufacturing capability is nearing completion. First Idylla™ assays registrations in China are not expected before late 2023 in light of new regulatory requirements regarding clinical validation.

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 exclusively licensed specific third-party technologies. On 31 December 2021, Biocartis' patent portfolio consisted of 31 proprietary patent families comprising issued and pending patents worldwide with patent lives which will expire between 2022 and 2040, and 22 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.

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 2021, Biocartis was active in over 75 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[48], 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 connects with its distributors through a dedicated team of sales employees who organize a number of activities, including product trainings, regular distributor update meetings, access to an online marketing platform, a one-stop-shop for all product marketing materials, as well as join international and local congresses.

- **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 2021, oncology activities here consisted of:

Papers, abstracts and posters

During 2021, 34 new Idylla™ papers were published, bringing the total number of Idylla™ papers to 123. Some highlights:

- In February 2021, Biocartis announced the publication of two studies[49] by Memorial Sloan Kettering Cancer Center ('MSKCC', New York, US) on the use of Biocartis' Idylla™ EGFR Mutation Assay (RUO) as a rapid first-line testing method before using next-generation sequencing (NGS). Both studies concluded that Idylla™ EGFR testing enables rapid assessment of the most common EGFR mutations with low sample input, even on different sample types, without compromising subsequent more comprehensive NGS testing[50];

- In November 2021, Biocartis announced the publication of a study[51] which concluded that the Idylla™ platform contributes to improving patient management decisions for patients with non-small cell lung cancer (NSCLC) through the faster screening of EGFR mutations.

Key expert meetings

In 2021, Biocartis organized a virtual KOL meeting with experts, oncologists and pathologists, to assess current trends and market opportunities in oncology MDx testing. The meeting focused on lung cancer and addressed new targeted therapies as well as new biomarkers in this area. Additionally, the experts endorsed the Idylla™ assay portfolio in lung cancer and highlighted the impact that these tests can bring in patient management decisions for patients with non-small cell lung cancer. In total, 12 experts from seven different European countries attended and shared their insights and vision on the evolution of molecular diagnostics and therapeutics in cancer care.

In terms of infectious diseases, four papers were published in 2021 on the excellent performance of the Idylla™ SARS-CoV-2 Test.

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

A CE-mark is required for broad market access in the EU. Biocartis is compliant with the IVD Directive for manufacturers who place IVD medical devices on the EU market, allowing Biocartis to distribute and sell CE-marked IVD products in the EU and in other countries accepting CE-marked IVD devices.

Today, all Biocartis Idylla™ IVD products carry a CE-mark. In 2021, Biocartis further prepared for the application of the Regulation on IVD medical devices[52] by assessing all current IVD products against the new requirements and ensuring that new IVD products under development are meeting the new standards. Under the new regulation, review by a notified body will be required for a majority of IVD medical devices prior to launch, as well as further on-market surveillance to ensure devices continue to perform as expected.

US: FDA marketing authorization

The US requires rigorous product clearance efforts before market access is granted. Depending upon the risk class of the medical device, either a 510(k) notification or a more stringent Pre-Market Approval (PMA) application may be required. 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[53].

Following the US FDA's different market entry requirements based on the risk class of the medical device, the majority of Idylla™ oncology products require the more stringent Pre-Market Approvals (PMA). For infectious disease tests, often a 510(k) notification or, if applicable, an 'Emergency Use Authorization' (EUA) is required. The Idylla™ instrumentation is exempt from 510(k) premarket notification requirements[54].

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. In 2021, Biocartis received first feedback from NMPA on its registration of 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. First Idylla™ assays registrations in Japan are expected at the earliest by the end of 2022.

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, such as to evaluate or confirm the prevalence of certain mutations, or other research-oriented applications. 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. Although most Idylla™ assays in Biocartis' product offering today contain biomarkers that are already included in the clinical guidelines and are as such mostly already reimbursed by third-party payers, 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[55]. 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[56]. 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 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[57]. 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 risk. 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, may also affect Biocartis' business, financial condition and results of operations. The risks have been subdivided into five categories: strategic and commercial risks, operational risks, legal and intellectual property related risks, regulatory risks and financial risks.

Strategic and commercial risks

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 molecular diagnostics ('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, 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 regulatory approvals and as customers evaluate these new solutions. Failure to compete successfully may have a material adverse effect on Biocartis' business, financial condition and results of operations.

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. Given that Biocartis is extending its offering with tests that target proprietary biomarkers of its partners (be it plate-based tests or tests to be performed on the Idylla™ platform), it will also face competition from companies that offer tests that target 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 above-mentioned systems.

The commercial success of Biocartis will depend on the market acceptance of the Idylla™ platform, the menu of Idylla™ and partner tests it offers and the relevance thereof.

Biocartis launched its Idylla™ platform and its first test, the Idylla™ BRAF Mutation Test, for commercial sale in countries recognizing CE-marked in vitro diagnostic ('IVD') devices at the end of 2014. The CE-mark is a mandatory conformance mark on many products placed on the market in the European Union ('EU'). The letters 'CE' stand for 'Conformité Européenne' ('European Conformity'). Since the end of 2014, Biocartis has launched several additional Idylla™ tests, and it intends to continue to broaden its commercial offering with additional Idylla™ tests and with tests that target proprietary biomarkers of its partners (be it as plate-based tests or tests to be performed on the Idylla™ platform). There can however be no assurance that Biocartis' current products or any such future products will gain acceptance by the market. A number of factors, many of which are outside the control of Biocartis, may affect the market acceptance of such products, including:

- The speed and breadth of building an installed base of Idylla™ platforms, which will, in part, depend on the ability of Biocartis and its partners to commercialize the Idylla™ platform;
- The speed at which customers start using the Idylla™ platform after installation, and the volume of tests they consume on their Idylla™ platform;
- The performance of the products as compared to competing products;
- The breadth and quality of the menu of tests offered by Biocartis and the timing of their development, including as compared to the test menus that competitors are developing;
- Potential delays in the launch of new tests (for further information, see risk factor '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 regulatory approvals in line with its strategy. Biocartis cannot give assurance that it will be able to launch new tests as quickly as it anticipates.');
- The accurate anticipation of patients', healthcare providers' and third party payers' needs and emerging clinical and technological trends;
- The competition (for further information, see risk factor '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 unavailability of the products offered by Biocartis due to regulatory barriers (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 and the United States.');
- The market perception of the performance and quality of the products offered by Biocartis;
- The fact that healthcare providers typically take a long time to adopt new products and testing practices, partly because of uncertainties around third-party coverage and reimbursement, which may be of particular importance for the partner products that Biocartis manufactures and/or commercializes;
- The quality of the current and future service and maintenance organization of Biocartis to support customers;
- The price and reimbursement level from third party payers (for further information, see risk factor 'Biocartis faces uncertainties over the reimbursement for the products that it offers by third party payers 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, which may adversely affect its future profitability.');
- The ability to demonstrate to potential customers the benefits and cost-effectiveness of the products and services it offers relative to others available on the market;
- The ability of Biocartis to develop and maintain relationships with key opinion leaders;
- The ability of Biocartis to hire new sales and marketing personnel where needed and their effectiveness in executing its business strategy; and
- Other potential advantages and disadvantages over alternative (MDx) products and services.

These and other factors present obstacles to commercial market acceptance of the products offered by Biocartis, as well as any future products launched, for which Biocartis will have to spend substantial time and resources to overcome them.

Biocartis faces uncertainties over the reimbursement for the products it offers by third party payers 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, which may adversely affect its future profitability.

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 ('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, even if a 'reimbursement code' is in place for a product, governments 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' business, financial condition, results of operations and prospects. 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 will 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.

Biocartis has entered into, and relies upon, a number of partnerships and alliances, including joint ventures, the termination of which 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.

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, and may materially and adversely affect Biocartis' business, prospects, financial condition and results of operations. Furthermore, disagreements with these partners could require or result in litigation or arbitration, which would be time-consuming, distracting and expensive.

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, there can be no assurance that Biocartis will be able to manufacture 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, which may have a materially adverse effect on Biocartis' business, financial condition and results of operations. For example, on 30 July 2021 a fire broke out at one of Biocartis' warehouse facilities in Mechelen, Belgium which resulted among others in a temporary suspension of the production on one of its manufacturing lines during a period of more than two months. Although Biocartis maintains insurance policies (such as fire insurance and business continuity insurance) at levels which management believes are in line with market practice, not all damages which may occur are always (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 to obtain, or increases the cost of obtaining, renewal of its insurance policies at acceptable terms.

There can be no assurance that the contracted third parties will deliver products on time, or in compliance with the standards that are required by the relevant regulatory authorities, or that they will 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, which may have a materially adverse effect on Biocartis' business, financial condition and results of operations.

Furthermore, Biocartis may need to enter into contractual relationships with other manufacturers for future increased demand of its products, and cannot provide any assurance that it will 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. This may have an adverse impact on Biocartis' manufacturing ability, which may, in turn, have a material adverse effect on Biocartis' business, financial condition and results of operations.

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 regulatory approvals in line with its strategy. Biocartis cannot give assurance that it will 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 decision factor to acquire and use a diagnostic platform, and management believes that offering a broader menu of such tests, including obtaining the required regulatory approvals, 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 regulatory approval for the Idylla™ platform and its menu of tests in a broad range of jurisdictions, which could come with significant investments and registration timelines. There can be no assurance that these products or any further products launched by Biocartis will gain acceptance by the market.

Although Biocartis has a dedicated and experienced research and development team in place to develop tests, there can be no assurance that it will 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 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 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, the termination of which 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 regulatory approval (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 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 regulatory approvals for, the Idylla™ platform and its menu of tests in line with its strategy, which could have a materially adverse effect on Biocartis' business, financial condition and results of operations.

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.

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 is sufficient to support Biocartis' commercial supply of the Idylla™ platform and Idylla™ tests, there can be no assurance that Biocartis' suppliers will at all times be able or willing to continue to provide the components Biocartis needs, at suitable prices 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. 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 regulatory approval, making it difficult and costly for Biocartis to diversify its exposure to single source suppliers.

A breach of security in Biocartis' products or computer systems may compromise the integrity of Biocartis' products, harm Biocartis' reputation, create additional liability and have a material adverse impact on Biocartis' results of operations.

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, 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, and Biocartis' business, financial condition and results of operations could be materially adversely affected.

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 would fail to accurately anticipate the application or interpretation of such laws when developing its products, if it would fail to comply with their requirements (such as evolving encryption and security requirements) or in case of 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 EU and in foreign jurisdictions. Further, Biocartis cannot ensure that Biocartis' privacy and security policies and practices will be found sufficient to protect it from liability or adverse publicity relating to the privacy and security of personal information.

Uncertainties due to COVID-19 pandemic.

Public health epidemics or pandemics, such as the COVID-19 pandemic, could cause significant disruptions to the global economy, including in countries in which Biocartis operates its business. Since its outbreak in 2020, the pandemic impacted our business in various respects. Initially, the pandemic deprioritized and disrupted cancer care globally. Patient access to hospitals

was significantly restricted throughout almost the entire first half of 2020 and customer prospection was severely hampered. Throughout the second half of 2020, testing volumes started to recover and gradually normalized to pre-pandemic levels. 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 required cancer diagnosis and treatment to be delayed. As the duration and severity of the pandemic cannot be predicted with confidence, there can be no assurance that the Company will be able to run its operations without disruptions, as a prolonged impact of the pandemic or the emergence of new variants of the virus may result in increased absence of employees in manufacturing, development and other key positions. The Company's suppliers and partners may be exposed to similar risks, or may be exposed to risks relating to their financial position as a result of the pandemic. This 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 the Company's ability to manufacture its products and deliver them to its customers. These and other risks related to the pandemic could materially and adversely affect the business, financial position, result of operations and prospects of the Company.

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, or in case someone 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 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, which may materially harm Biocartis' business, financial condition and results of operations. 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. Biocartis can however not provide any assurance that no such claims will occur in the future, that it will be able to maintain sufficient insurance coverage on commercially acceptable terms, or that its insurance coverage will provide 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 2021, Biocartis' patent portfolio consisted of 31 proprietary patent families comprising issued and pending patents worldwide whose patent life will expire between 2022 and 2040, and multiple in-licensed patent families providing additional strength to the patent portfolio.

On 31 December 2021, the value of the Idylla™ platform was protected by a group of 53 patent families (31 proprietary patent families and 22 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, there can be no assurance that pending patent applications (whether submitted by Biocartis, or a third party licensor) will 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. There is no assurance that such efforts will 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 these oppositions were unsuccessful or closed without loss of substantial patent rights. Biocartis cannot guarantee that no further oppositions will 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.

There is no assurance that Biocartis' IP rights will not 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. There can be no assurance that Biocartis would prevail in any such litigation, or that the damages or other remedies awarded, if any, would be adequate. The loss of a lawsuit, failure to obtain adequate remedies and/or negative publicity in connection with litigation could have a material adverse effect on Biocartis' business, financial condition and results of operations.

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. There can be no assurance that Biocartis will be able to comply with its obligations under the (sub)licenses, or the (sub)licensors will 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, which, in turn, could have a material adverse effect on Biocartis' business, financial condition and results of operations.

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, which could have a material adverse effect on Biocartis' business, financial condition and results of 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 has, in some cases individually and, in other cases, along with Biocartis' collaboration partners, filed for patent protection for a number of technologies developed under these agreements and may, in the future, file for further IP protection and/or 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.

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, which could have a materially adverse effect on Biocartis' business, financial condition and results of operations.

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, which may have a material adverse effect on Biocartis' business, financial condition and results of operations.

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 and have an adverse effect on Biocartis' results of operations.

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, delay the development and commercialization of its products and may have a material adverse impact on its reputation, business, financial condition and results of operations.

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, any of which could materially and adversely affect Biocartis' business, financial condition, results of operations and prospects.

Regulatory risks

Regulatory agencies such as the us food and drug administration ('FDA') strictly regulate the promotional 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 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 and regulations, including the prohibition on the promotion of an IVD device for a use that has not been cleared or approved by the relevant regulator or supervisory body. Use of a device outside of its cleared or approved indication is known as 'off-label' use. If a relevant governmental authority determines that Biocartis' promotional materials, training or distribution practices constitute promotion of an 'off-label' use, it could request that Biocartis modifies its training or promotional materials or subject Biocartis to regulatory or enforcement actions, which may include the issuance of a warning 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, which could result in significant fines or penalties under other statutory rules and regulations, such as laws prohibiting false claims for reimbursement. In that event, Biocartis' reputation could be damaged and adoption of Biocartis' products could be impaired. 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, it cannot provide any assurance that no competent regulatory agency will hold it responsible for engaging in 'off-label' promotion or other practices. If Biocartis was held so responsible, this may have a material adverse impact on its business, financial condition and results of operations.

Biocartis' business could be significantly and negatively affected by substantial changes to government regulations, particularly in the European Union 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 will be 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 regulatory approval under the IVD Regulation is a new and uncertain process, and Notified Bodies (as defined below) may have limited resources and experience backlogs. Regulation 2022/112 amends 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. Moreover, a sell-off provision is provided for devices which have already entered the supply chain before the end of the transitional period. However, the 26 May 2022 date of application of the IVD Regulation remains unchanged with two major implications:

- Devices which are class A non-sterile (i.e., the Idylla instrument and associated software) must have a CE-marking under the IVD Regulation by the date of application in order to be placed on the market;

- New devices will need to be CE-marked under the IVD Regulation after the date of application. 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 IVD Regulation will influence the way Biocartis conducts business in Europe, and will include, 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 the Idylla™ platform and 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, currently via the European Directive 98/79/EC on in vitro diagnostic medical devices (the 'IVD Directive') and in the future via the IVD Regulation. Under the IVD Directive, the Idylla™ platform and current Idylla™ tests can be 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. 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). 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. 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 could have a material adverse impact on Biocartis' business, financial condition and results of operations while any failure or material delay in obtaining such certification for the currently CE-marked Idylla™ tests, or any other tests which Biocartis commercializes in the European Union between now and the entry into force of the IVD Regulation, 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 regulatory approval under the IVD Regulation is a new and uncertain process, and Notified Bodies may have limited resources and experience backlogs in the transition period leading up to the May 2022 effective date of the new regulation'.

The majority of Biocartis' current and planned Idylla™ tests will require US FDA 510(k) clearance or premarket approval ('PMA') before marketing is permissible in the United States. Although the Idylla™ platform, an automated PCR system, is exempt from 510(k) notification requirements (with limitations), each of the Idylla™ tests will need to undergo significant technical and clinical studies to support submissions for 510(k) clearance or PMA approval. The required scope and size of a study may be larger than expected for this product or for any future products. Studies performed for such regulatory

clearance are expensive and time-consuming. The studies 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 supporting of a PMA. FDA regulation of IVDs, and in particular companion diagnostic (CDx) products, is evolving and not fully clear depending upon the specific product and claimed indications. In the recent past, FDA has required PMA's for genetic mutation tests which require demonstration of a clinical benefit -- either prolongation of life or an effect on treatment. Such studies might require significant follow-up beyond the resources of Biocartis. New legislation has been introduced (sponsored by FDA) that may ease the pathway to commercialization but neither the passage of such legislation, nor the ultimate requirements for approval set out therein, can be predicted. Biocartis attempts to curb this uncertainty by utilizing the Pre-Submission process to gain FDA agreement on requirements in advance, yet regulations and expectations may change during the execution of product studies, significantly changing the requirements applicable to the effort.

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 Directive. In addition, the commencement or completion of any study may be delayed or halted for any number of reasons. There can be no assurance that FDA 510(k) clearance or a PMA approval will be obtained for any of Biocartis' products, on a timely basis, or at all. Any failure or material delay in obtaining clearance or approval may have a material adverse effect on Biocartis' business, financial condition and results of operations. In addition, once a FDA 510(k) or PMA clearance has been obtained, any subsequent modifications to such product (which may be required due to evolving treatment protocols or standards of care), may require new FDA 510(k) clearance or PMA, or may require Biocartis to cease marketing or recall the modified products until clearances are obtained, which may have a material adverse effect on Biocartis' business, financial condition and results of operations.

Similarly, even if Biocartis obtains the relevant marketing authorizations in the European Union or the United States, changes to regulatory requirements in other markets could prevent completion of product registrations in those markets. Biocartis may not obtain regulatory authorizations elsewhere on a timely basis, if at all.

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 of its products, or to comply with ongoing regulations in the countries in which it operates, which, in turn, may have a material adverse effect on its business, financial condition and results of operations.

Seeking and obtaining regulatory approval under the ivd regulation is a new and uncertain process, and notified bodies may have limited resources and experience backlogs in the transition period leading up to the May 2022 effective date of the new regulation.

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 few 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. There can be no assurance that any Notified Body will provide the requisite certification for the currently CE-marked Idylla™ tests, or any of Biocartis' other products which may require certification from a Notified Body in the future, 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. If any of Biocartis' third party distributors in Member States fail to meet the requirements of the IVD Regulation, 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.

Any of the foregoing could be detrimental to Biocartis' reputation and product availability and could materially and adversely affect Biocartis' business, financial condition, results of operations and prospects.

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 have a material adverse effect on Biocartis' business, financial condition and results of operations. In addition, any product recall 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. A future recall announcement could harm Biocartis' reputation with customers and may have a material adverse effect on Biocartis' business, financial condition and results of operations. 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, business, financial condition and results of operations.

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, any changes that lower reimbursements (for further information, see risk factor 'Biocartis faces uncertainties over the reimbursement for the products it offers by third party payers 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, which may adversely affect its future profitability.') or impose increased regulatory requirements for Biocartis' products could materially adversely affect Biocartis' business, financial condition and results of operations.

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. The adoption of some or all of these proposals could have a material adverse effect on Biocartis' business, financial position and results of operations.

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 2021 was EUR 67.3m. As of 31 December 2021, Biocartis had an accumulated deficit of EUR –526.4m. 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.

There can be no assurance that Biocartis will 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, repay or refinance its outstanding convertible bonds with maturity in May 2024, 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 the Biocartis' operations. If Biocartis is unable to obtain adequate financing, its ability to continue to support its business growth and to respond to business challenges could be significantly limited. 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' operating results could be materially adversely affected by unanticipated changes in tax laws and regulations, adjustments to its tax provisions, 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 estimates and judgment are reasonable, they remain subject to review by the relevant tax authorities. Biocartis cannot guarantee that its interpretation will not be questioned by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof by the relevant tax authorities, will not be subject to change. 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 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. An increase of the effective tax rates could have an adverse effect on Biocartis' business, financial position, results of operations and cash flows.

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 US 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, or 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.

The Company has no fixed dividend policy.

The Company has not declared or paid dividends on its shares to date, and it is not expected that the Company will declare or pay dividends in the foreseeable future. In the future, the Company's dividend policy will be determined and may change from time to time upon proposal of the Company's board of directors. Any declaration of dividends will be based upon the Company's earnings, financial condition, capital requirements and other factors considered important by the board of directors. Belgian law and the Company's articles of association do not require the Company to declare dividends. Further financial risks are identified in the IFRS (International Financial Reporting Standards) financial notes included in this annual report.

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.

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 2021 Biocartis initiated a program with a view of developing an integrated sustainability strategy and define relevant KPIs to monitor and measure sustainability in the years to come. As a medical device company, Biocartis' key focus is on enabling more, better and faster molecular diagnostics solutions for patients across the globe. Our current environmental activities are focused on compliance with a large set of European, national and regional regulations covering the environmental impact of our products and their waste. See section 'Climate change and environment' for more information. Social activities are focused on creating a healthy and safe working environment for our employees in a hybrid working environment with increased attention to topics such as training, talent management and wellbeing. See section 'employees' for more information.

As such our current sustainability approach addresses 7 of the 17 Sustainable Development Goals (SDGs). The SDGs were adopted by the United Nations Member States in 2015 and are intended to be reached by 2030.

"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

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 2021:

- Installed base of 1,912 Idylla™ instruments
- Commercial cartridge volume of 323k cartridges sold
- Expansion of the infectious disease test menu on Idylla™ with 510(k) clearance for the SeptiCyte® RAPID on Idylla™ (Immunexpress) and launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD)

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

Promoting lifelong learning of its employees

In 2021:

- 15,842 training hours amongst others through an integrated Quality Management System
- On average 32 training hours per employee

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

A balanced gender diversity

In 2021:

- 407 employees[6] across more than 30 nationalities
- 50% men – 50% women balanced gender diversity

SDG 8: Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all

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

Delivering growth

In 2021:

- 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 2021:

- Full compliance with all applicable new environmental legislation
- Installation of five renewable energy air heat pumps were installed with a total capacity of 96 kW
- Launch of the electric mobility project with a first focus on electric bicycle leasing

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

Building a global Idylla™ ecosystem with partners

In 2021:

- New partnership with SkylineDx (melanoma)
- Expanded partnership with AstraZeneca (lung cancer)
- 510(k) clearance for SeptiCyte® RAPID on Idylla™ with Immunexpress (sepsis)
- 34 new Idylla™ papers were published, to a total of 123 end of 2021.
- Employee fundraising activities for Villa Clementina, working around inclusiveness for children with a disability

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 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 2019, 2020 and 2021, no reports were filed in accordance with the whistleblowing policy. Biocartis did not have any legal proceedings associated with bribery or corruption.

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 operations, supply chain, legal and regulatory and product quality. In 2020 and 2021, business continuity plans demonstrated their effectiveness in the context of several events such as continuity of operations during the COVID-19 pandemic as well as the rapid restart of manufacturing following the fire incident in Biocartis' warehouse facilities in the summer of 2021. Lessons learned from the fire incident have been incorporated into our business continuity plans.

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 2021, the biobank registered more than 6,000 samples (clinical and reference materials) and shipped more than 1,000 samples worldwide. Finally, the biobank also introduced a new tool to facilitate the access of external sample data, which will support a more accurate way of sample selection and the standardization of data management generated at external parties.

3.3 Product responsibility

Ethical marketing

Both its Code of Conduct and its Code of IVD Compliance, included the principle of ethical marketing in which Biocartis states that it strives 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.

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'. 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.

2018	2019	2020	2021
EUR 8,697.60	EUR 9,035.25	EUR 0*	EUR -**

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

**Reporting for 2021 will be completed in 2022. 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 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:

2018	2019	2020	2021
USD 1,734.99	USD 986.99	USD 0*	USD - **

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

**Reporting for 2021 will be completed in 2022. 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:

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on IVD medical devices
- 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 2021, we successfully achieved recertification of the Biocartis QMS against the ISO 13485:2016 standard and full set of MDSAP regulations (Australia, Brazil, Canada, Japan, USA) and issuance of new certificates for Biocartis NV.

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. A major achievement in 2021 was the completion of a multi-year continuous improvement program to improve the efficiency and the effectiveness of our processes.

The suitability and effectiveness of our Quality Management System to ensure safe and effective products is reflected by our solid on- market product performance: 0 product recalls in 2021, 1 in 2020 and 2 in 2019. For none of these cases, patient harm was confirmed.

	2019	2020	2021
Number of product recalls	2	1	0

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 in 2021:

- 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 from employees, customers, suppliers, IT staff, risk assessments, internal audits and service report, 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 with a strong focus on establishing a business impact analysis and business continuity plans
- 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 2021, in the context of the ISO 27001 certification process, a successful audit was performed concluding that, considering the global impact and changes in day-to-day practice as a result of the COVID-19 pandemic, Biocartis is managing the systematic implementation of its information security management well via a controlled and documented approach.

	2019	2020	2021
Total number of personal data breaches	0	1	0
Total number of customers and employees affected by company's personal data breach	N/A	No third-party impact	N/A

Following the implementation of its ISMS, Biocartis is in the process of further finetuning its information security processes, including monitoring, reporting and awareness raising around the topic.

3.4 Employees

"Our hybrid way of working is key to our long-term success and fits our diverse organization well: on-site working in teams combined with focused home office work, while enhancing the work-life balance."

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 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 2021, we further progressed our HR strategy with key developments in:

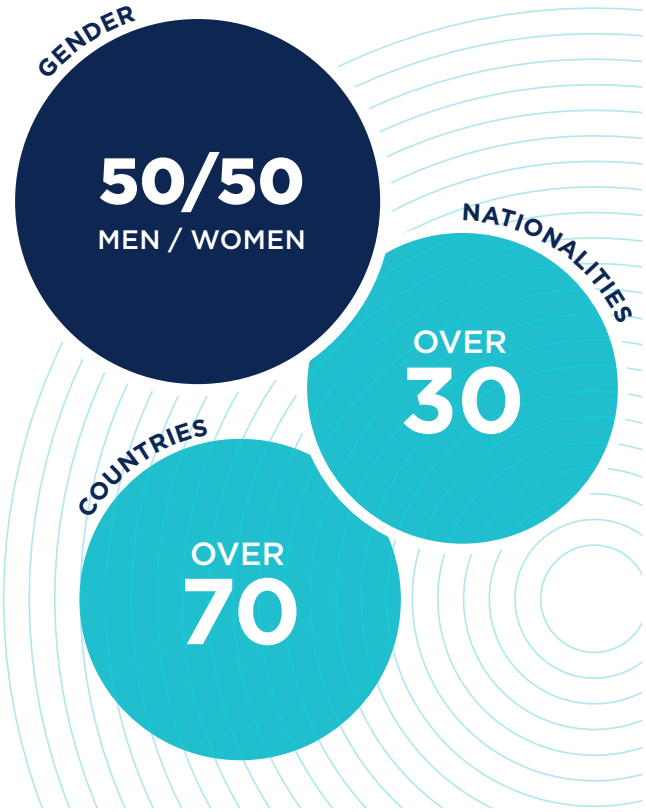
- Adoption of the hybrid way of working within our organizational matrix structure
- Further developing our Learning & Development program with new competencies and skills
- Improving our workforce and succession planning
- Launching our wellbeing strategy based on the pillars 'My Body, My Mind, My Connections, My Environment'

Diversity

With 407 employees[6] of over 30 different nationalities across more than 70 countries at the end of 2021, 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 2021, the gender split across Biocartis remained stable with 50% men and 50% women. In management positions we counted 37% women, a slight decrease from 2020.

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. The COVID-19 pandemic accelerated our transition to a hybrid way of working, providing more flexible work options for our employees.



Gender wage gap

The gender pay gap in the EU stands at 14.1% and in the US at 16% and has only changed minimally over the last decade[58]. It means that women earn 14.1% on average less per hour than men in EU and 16% less per hour than men in the US. 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 2021, the Biocartis 'soup team' got together to cook and sell healthy winter soups on site in Mechelen for the benefit of Villa Clementina, a non-profit project aimed at integrated and inclusive childcare for children with and without disabilities up to the age of 6 years old.

Training and 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. 20 sessions were set up in 2021

For existing employees:

- The Biocartis Academy is our core learning & development program which included trainings 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. In 2021, 3 Learn & Grow sessions took place.
- 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 2021, 44 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.

Launch of the new hybrid working culture

Because of the pandemic, Biocartis launched a new hybrid workplace in 2021 that combines teleworking with working at the office, especially for those functions that require on-site presence. This included:

- **Revision of policies and practices**
- **Creation of a hybrid workspace with appropriate workstations at home and in the office, supported with the right digital communications tools. Office spaces were transformed to blend flex desks, dedicated team meeting rooms, individual workspaces as well as several large new meeting rooms with enhanced digital working tools**
- **Supporting our managers and the new management style required in this hybrid working context through our leadership and wellbeing programs**
- **(Re)connection moments were created through team days on-site or 'virtual coffee moments' online**

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.

In 2021, the COVID-19 pandemic provided the impetus for Biocartis' employee wellbeing strategy based on four pillars: My Body, My Mind, My Connections, My Environment. This strategy aims at launching initiatives focused on mental health and the hybrid way of working. The wellbeing program in 2021 consisted of:

- Launch of the online website 'My Health Partner' offering information and materials around a wide range of wellbeing initiatives
- Online workshops, webinars, interesting articles, e-learning modules, tips & tricks, quizzes and monthly newsletters for employees and management to support the new way of more remote working
- Start of several workshop series on home office ergonomics, healthy hybrid habits, a 'disconnect to re-connect challenge' and even individual screenings on 'how to stay fit and avoid burn out'. The workshop 'healthy hybrid habits' was set up in partnership with AG Health and focused on four topics: 'hybrid working', 'focused homeworking', 'from difficult to possible' and 'building a healthy routine'. On average 40 employees participated per workshop.

Biocartis will continue its wellbeing program in 2022 by continuously adding new information to the platform, complemented with regular newsletters to keep employees informed of new initiatives.

Flex income plan

The Flex Income Plan (FIP) was launched in 2021, giving employees the possibility to convert part of their salary into benefits that fit their personal healthcare and hybrid working needs. Benefits offered in the FIP store include electric bicycle leasing, bicycle repair or bike clothing, ergonomic office supplies, sports membership or equipment, mindfulness trainings or workshops, personal IT devices, etc.

Health and safety

Biocartis is committed to invest in a safe, healthy and environmentally (HS&E) friendly workplace through several tools & activities:

- The Biocartis HS&E Policy aims at compliance with HS&E regulatory requirements and all relevant HS&E risks through a dynamic risk assessment
- Biocartis strives to continuously reduce HS&E risks and improve workplace safety and 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
- Within the Biocartis Safety Management System, HS&E requirements are included in design & development, action plans and goals & objectives, so safe work will be made possible by providing safe tools, personal protective equipment, procedures and other preventive measures, infrastructural as well as organizational, to tackle the identified risks
- 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 2021:

- Safety management risk assessments are performed annually. No legal HS&E regulation breaches were reported in 2021.
- Biocartis employees followed several virtual H&S trainings, including basic rescue trainings, first-aid refreshment trainings, fire safety & spill training and machine & electrical safety. Furthermore, a lot of attention was paid to ergonomics at work through a.o. internal awareness raising campaigns.

Nine occupational accidents with minor injuries occurred in 2021. There were no lethal accidents or working accidents causing disability. Each occurrence led to a root cause analysis and measures were taken to prevent future work accidents, among which a presentation to management with an updated H&S action plan that included:

- Increased H&S awareness raising for employees through monthly ‘walks & talks’ within the manufacturing areas
- Integrating safety as a topic in check-in meetings at the beginning of every production shift
- Monthly discussions on safety related KPIs with management

KPIs

Workforce

STATUS AS PER 31 DEC	2019	2020	2021
Total number of employees (FTE)	**342.7**	**366.3**	**407.1**
Biocartis Group NV	22.4	21.0	23.5
Biocartis NV	277.3	300.9	341.8
Biocartis US, Inc.	43.0	44.4	39.2
Biocartis Italy srl	0	0	2.6
Total number of employees (FTE) by gender	**342.7**	**366.3**	**407.1**
Male	168.1 (49%)	182.4 (50%)	201.9 (50%)
Female	174.6 (50%)	183.9 (50%)	205.2 (50%)
Total number of employees (FTE) by level	**349.9**	**383.8**	**427**
Management positions[59]	63.3	64.3	69.1
Other employees	286.6	319.5	357.9
Total share of women in management positions	**44%**	**43%**	**37%**
Total number of employees (FTE) by age group	**342.7**	**366.3**	**407.1**
Under 30	20.3	31.2	48
30-50	238.1	249.2	275.6
Over 50	84.3	85.9	83.5
Average age workforce	**43.2**	**42.3**	**41.3**
Average age in management positions	**45.1**	**44.4**	**44.3**
Total number of employees (FTE) by work regime	**349.9**	**383.8**	**427**
Full time	324 (93%)	355 (92%)	389 (91%)
Part time	25.9 (7%)	28.8 (8%)	38 (9%)
Total number of new fixed employee hires	**79**	**94**	**106**
Total number of fixed employee departures	**48**	**56**	**58**

Training

	2019	2020	2021
Total training hours followed by employees	(*)	(*)	15,842
Share of employees who benefited from a training during the financial year (training ratio all employees)	(*)	(*)	95%
Average number of training hours per employee	(*)	(*)	32
Share of employees who benefited from an annual individual interview	(*)	(*)	88%

(*) 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 and safety

	2019	2020	2021
Absenteeism rate (in % as nr of absenteeism days versus total working days)	4.44%	4.25%	4.24%
Accident frequency rate (Number of lost time accidents x 1,000,000 / number of hours worked, for fixed employees)	4.57	2.07	17.0
Accident severity rate (Number of days lost to accidents or occupational diseases x 1000 / number of hours worked, for fixed employees)	0.045	0.09	0.19

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[60] directive regarding the Restriction of Hazardous Substances in electrical and electronic equipment
- The WEEE directive[61] 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[62]
- 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

In 2021, Biocartis performed a review of all applicable new environmental legislation (European/Belgian/Flanders regional level) to ensure full compliance. This review included compliance verifications with:

- Compliance verifications with 'VLAREM II - Order of the Flemish Government of 1 June 1995 concerning General and Sectoral provisions relating to Environmental Safety' and biocides regulation
- Updates to the regional Flemish 'Materials Decree/ VLAREMA' regulation requirements
- Updates to the regional Flemish regulation for sustainable management of materials and waste

In 2021, one external review of the environmental legislation was performed by the external environmental coordinator (IDEWE).

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 2021:

- **Energy use:**
  - Today, Biocartis' electricity comes from 36% green and 64% grey energy sources
- **Energy efficiency:**
  - Old energy installations are systematically replaced by greener, energy-efficient applications
  - In 2021, five renewable energy air heat pumps were installed with a total capacity of 96 kW
  - End of 2021, Biocartis initiated the implementation of an energy efficiency audit on site in Mechelen which will be completed in 2022

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 activities and consists of individual units of, or cartridges filled with biocides (disinfectants), 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 2021:

In tons	2019	2020	2021
Hazardous waste	18,8	24,3	43,5
Non-hazardous waste	81,8	86,5	119,2

- 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.

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.
- All wastewater (equalized household wastewater and industrial wastewater) is transported through a separate sewer system to the Mechelen Noord wastewater treatment plant. Before being transported, all hazardous substances are subtracted from the wastewater and sent for further treatment to certified professionals.

Actions and results in 2021:

m^3/year	2019	2020	2021
Water use	2,094	1,611	1,620

Greenhouse gas emissions (GHG)

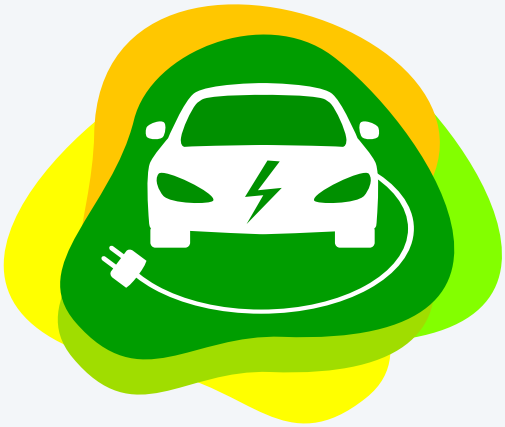
Scope: Biocartis NV, consisting of the company's headquarters and the cartridge manufacturing activities in Mechelen, Belgium (97% of total scope)

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.

In tons CO^2	2019	2020	2021
GHG emission from production and office activities	165,4	137,9	144,2
Of which emissions from employee business travel - flights	1,320	256	171

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.



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. In 2022, this will be completed with the launch of the electric green fleet project, aimed at gradually greening the Biocartis employee car fleet towards a 100% green fleet.

Other

Other actions in 2021 included:

- Environmental permit renewal for the Biocartis 'BC5' building in June 2021
- Replacement of refrigerant gases with a more environmentally friendly version with low 'Global Warming Potential' (GWP) for the new cooling systems that were installed

Despite several actions taken in the domains of energy, water, waste and carbon emissions, Biocartis today does not have an over-arching climate change strategy and targets. One of the main reasons here is because Biocartis leases its buildings from property owner Intervest. This implies that decisions on water, waste and energy management improvements are to be taken jointly with Intervest. In 2021, Biocartis and Intervest had further discussions on the improvement of the energy management of its buildings. This included:

- Intervest's project BECOME[63] to set up a Local Energy Community - (LEC) by making maximum use of local energy production and consumption, with local production being fully sustainable and realized by means of solar panels. The project includes research into an efficient energy management system, sustainable energy production, on-site energy storage, interaction with the power grid and the possibility and impact of a significant electric fleet on site. When fully rolled out, the project will provide a greener energy mix and financial savings for the users (1% - 5% on the total energy bill), combined with a greater independence from the existing electricity grid.
- Collaboration with Intervest around smart metering included the installation of a smart meter at Biocartis connected to an EMS (Energy Monitoring System). The feasibility study was carried out for the photovoltaic installations.

3.6 Supply chain

Our suppliers are critical to delivering on our mission. Biocartis' global supply chain (= tier 1 or direct suppliers) consists of approximately 30 suppliers of various materials, our manufacturing site in Mechelen (Belgium) as well several service providers and sub-contractors.

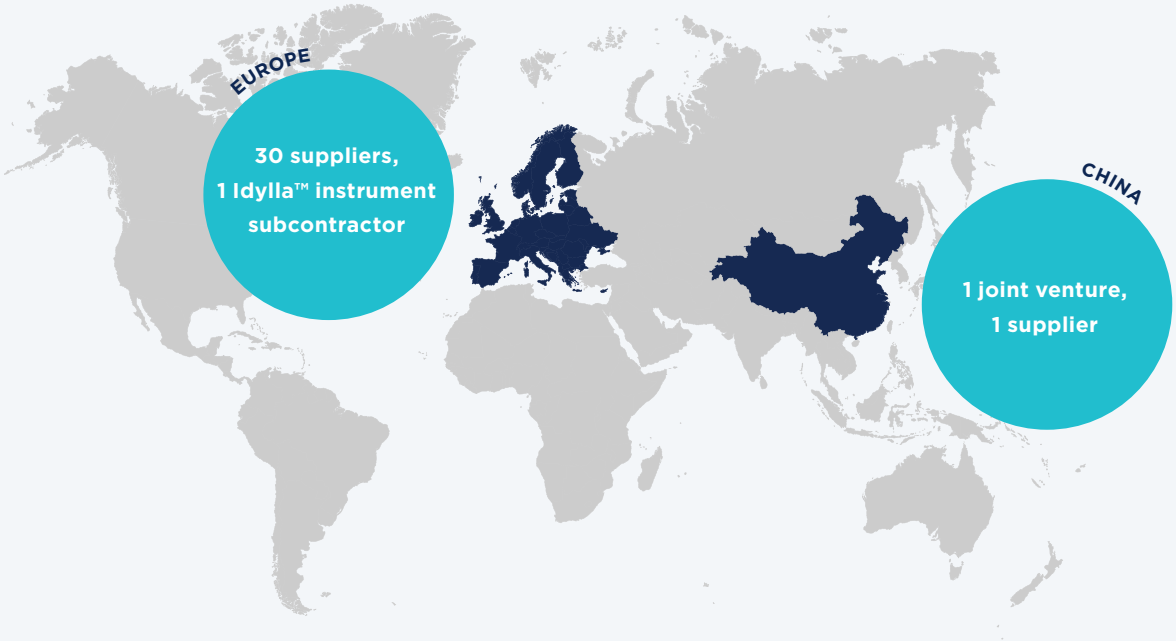
- Most of Biocartis' direct suppliers are based in Europe, including its subcontractor who manufactures the Idylla™ instruments and console.
- In 2021, Biocartis had 1 direct supplier based in China. Additionally, our joint venture WondfoCartis is based in China.

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 workstreams have been further updated in 2021 to minimize future supply risks as well as to support our growing cartridge sales.

Supplier Risk Assessments, Approval Process and Audits

Since the beginning of its operations in Mechelen (BE), Biocartis installed a rigorous Approval Process for its direct suppliers. Before the start of every supplier contract, a risk assessment is implemented to screen on several criteria. Quality is the main focus of our risk assessments, which includes checks on a.o. the verification of ISO certificates. For large suppliers, although this is not included yet in our Supplier Approval Process, compliance with environmental legislation such as ROHS on the Restriction of Hazardous Substances or REACH legislation on the restriction of chemicals can also be checked, as well as the screening of broader sustainability criteria such as proximity which is becoming increasingly important.

Biocartis today has not set specific social or environmental targets with its suppliers but consider it business-critical to work with suppliers who share our commitment to integrity. Therefore, we have put a Code of Conduct in place which covers all external parties, including its suppliers, to adhere to the same high standards of business conduct including respect for human rights, non-discrimination and ethical business behavior.



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' main 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 at direct suppliers. Since 2020, under impulse of the pandemic, audits are now being implemented in a hybrid way, combining on-site and remote inspections. No critical observations were made during the past years.

Further key manufacturing & supply chain focus areas in 2021 were:

- Focused actions to ensure supply chain continuity during the pandemic (see text box)
- Further preparing our supply chain program in the context of anticipated US FDA audit inspections and IVDR regulations

Supply chain continuity during the COVID-19 pandemic

Since the start of the pandemic, we raised our efforts to strengthen our supply chain and avoid any disruptions that could affect the supply of Idylla™ products to our customers. These efforts included:

- Improved internal communications between sales and manufacturing teams to better align supply and demand
- Increasing inventory levels where possible to ensure availability of raw materials by working closely with both existing and new suppliers
- Increasing safety stock levels of finished goods, where possible
- Working closely with preferred transportation partners to continue shipments to our partners and customers across the globe
- Raising our supply chain monitoring systems with weekly and even daily updates by our Supply Chain Teams
- Working with main suppliers to further improve our ability to respond quickly to changing demand

We also refer to the chapter 'Impact of COVID-19', supplier impact.

4.1 Introduction

During 2021, 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 on 31 December 2021.

Name	Position	Start of mandate	End of term
Christian Reinaudo	Chairman, independent director	2018	2024
Herman Verrelst	Chief executive officer, executive director	2017	2025
Luc Gijsens[(1)]	Non-executive, independent director	2018	2022
Ann-Christine Sundell	Non-executive, independent director	2018	2022
Christine Kuslich	Non-executive, independent director	2020	2022
Roald Borré	Non-executive director	2014	2022

Notes:
(1) Permanently representing Luc Gijsens BV.

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 as vice chairman and chairman of the audit committee of Raisio Oyj, chairman of Medix Biochemica Group Oy, board member, chairman of the remuneration and nomination committee and member of the audit committee of Revenio Oyj, member of the board and chairman of the remuneration committee of Immunovia AB, member of the board of Förlags Ab Sydvästkusten, chairman of Actim Oy and holder of AConsult. Mrs. Sundell 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.

Roald Borré started his professional career at the Financieel Economische Tijd newspaper as a financial analyst specialized in high-tech companies, particularly in the ICT and biotech fields. He was responsible for the launch of Wall Street Invest, a weekly with a focus on Nasdaq-listed (mainly) biotech and ICT companies. In 1999, he joined Puilaetco Private Bankers as senior fund manager, where he was in charge of the Biotechnology Fund and managed various investments in the therapeutics and diagnostics field, a position he held until 2006. In 2011, after five years as an entrepreneur, Mr. Borré joined the ParticipatieMaatschappij Vlaanderen as business and fund manager of the TINA fund that focused on industrial projects with a high degree of innovation and the potential to transform, also adding head of equity investments to his responsibilities. Roald is Group Manager Venture Capital at PMV and member of the management committee op PMV NV and PMV FM NV, responsible for the management of Welvaartsfonds. He is on the board of different PMV portfolio companies and a member of several advisory boards. Mr. Borré holds a Masters in financial and commercial sciences (specialization accountancy) from EHSAL Management School, Belgium.

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

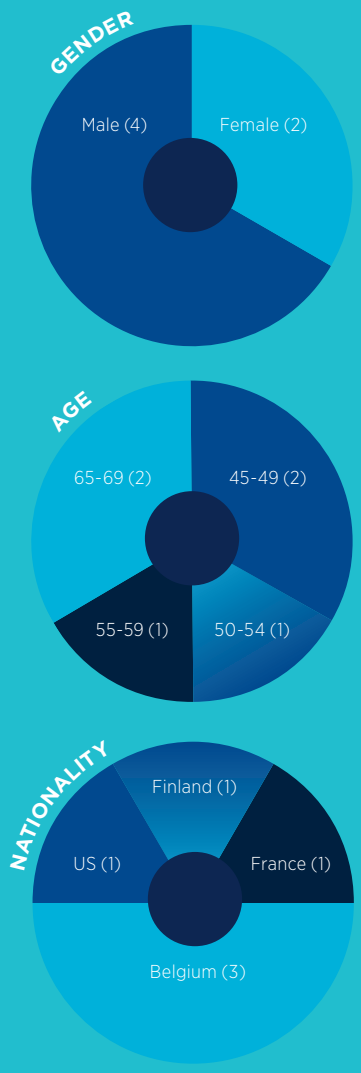
The annual shareholders' meeting held on 14 May 2021 reappointed Christian Reinaudo as independent director of the Company for a term of three years, and reappointed Herman Verrelst as director of the Company for a term of four years. The mandates of Ann-Christine Sundell, Christine Kuslich, Luc Gijsens BV, permanently represented by Luc Gijsens, and Roald Borré will end after the annual shareholders' meeting of 13 May 2022. The proposal of the board of directors to the annual shareholders' meeting regarding the (re-)appointment of directors will be included in the convening notice of the annual shareholders' meeting.

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	67	France
Herman Verrelst	▪ Molecular diagnostics ▪ Software solutions ▪ Entrepreneurship	Male	48	Belgium
Luc Gijsens[(1)]	▪ Finance ▪ Capital markets ▪ Corporate and investment banking	Male	68	Belgium
Ann-Christine Sundell	▪ Life sciences ▪ Diagnostics ▪ Strategy and operations	Female	57	Finland
Christine Kuslich	▪ Molecular diagnostics ▪ Oncology & Infectious disease ▪ Strategy & investment	Female	54	USA
Roald Borré	▪ Corporate finance and M&A ▪ Investment funds ▪ Accounting and auditing	Male	49	Belgium

Notes:
(1) 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.

Activity report

In 2021, the board of directors held thirteen 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 2021 was 100%, save for Christine Kuslich, Ann-Christine Sundell and Roald Borré who were excused during one board meeting. This can be explained by the need to sometimes convene certain board meetings on short notice.

During the meetings of the board of directors, the board among others reviewed Biocartis' oncology and infectious disease strategy, operations, commercial performance, ongoing menu development and the impact of the COVID-19 pandemic and a fire at one of its warehouses on its business. It discussed business development and strategic opportunities and the status of ongoing collaborations, as well as regular updates of the implementation of the integrated quality plan and the cartridge design 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 and to approve the Company's remuneration policy. Moreover, the board discussed the regular updates of the financial performance and the budget for financial year 2022 as well as the Company's long-term financial plan and financing strategy. 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. In addition, the board approved the proposal to the shareholders to renew the authorized capital.

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 2021:

Christian Reinaudo	▪ Agfa Gevaert NV ▪ Domo Chemicals Holding NV
Herman Verrelst	▪ South Bay Ventures (SBV) BV ▪ Opdorp Finance BV[1] ▪ Heran Partners BV ▪ Icometrix BV[2]
Luc Gijsens	▪ 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 ▪ Immunovia AB ▪ Förlags Ab Sydvästkusten ▪ Actim Oy ▪ AConsult
Christine Kuslich	▪ N/A
Roald Borré	▪ Media Invest Vlaanderen NV ▪ Kebony AS ▪ ALZV VZW

Notes: [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 twice in 2021 during the meetings held on 23 February 2021 and 20 April 2021. The extract of the minutes of those meetings is as follows:

Meeting 23 February 2021

"Following the recommendations of the Remuneration and Nomination Committee, the Board discussed the goals for the CEO relating to performance year 2020 (consisting for 50% of the 1-year targets defined in the beginning of 2020, for 25% of the 2-year targets defined in 2019, and for 25% of the 3-year targets defined in 2018) and assessed the degree to which these goals were achieved. The Board was of the opinion that overall 100% of the 1-year targets was achieved, 30% of the 2-year targets was achieved, 40% of the 3-year targets was achieved, and resolved to approve the amount of the variable remuneration for the CEO relating to performance year 2020 on this basis (i.e., an amount of EUR 126,563).

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 2020. The Board considered that overall 100% of the KPIs were achieved. Therefore, after discussion, the Board resolved to approve that 167,500 performance-based share options under the share option plan 2017 relating to the performance year 2020 have vested.

The Board decided to discuss the variable remuneration for the members of the executive management for 2021 during the next Board meeting, it being understood that for the 2-year and 3-year KPIs a phantom stock plan is in place."

Meeting 20 April 2021

"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 2021. For the 1-year target (for 2021), the proposal is to use the same KPIs categories as for 2020, namely the following KPI categories, each time consisting of the specific KPIs as proposed by the Remuneration and Nomination Committee:

- *Financial performance as KPI category (consisting of KPIs relating to operational income growth, gross margin improvement and capping the net cash burn) having a total weight of 30%. In case of achievement of any of the KPIs in this category of 75%, 75% of the percentage of the variable remuneration will be payable, while every incremental percentage of achievement will result in 1% extra being payable (linear increase), provided that the maximum amount payable shall be equal to 125%. In case of an achievement of less than 75% of a certain KPI, no variable remuneration to which such KPI relates shall be payable.*

- *Commercial success as KPI category (consisting of KPIs relating to commercial cartridge volume and installed base growth, as well as relating to growth in the partner business topline) having a total weight of 30%.*

  - *In case of achievement of the KPI relating to commercial cartridge volume and installed base growth 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.*

  - *In case of achievement of the KPI relating to growth in the partner business topline of 75%, 75% of the percentage of the variable remuneration will be payable, while every incremental percentage of achievement will result in 1% extra being payable (linear increase), provided that the maximum amount payable shall be equal to 125%. In case of an achievement of less than 75% 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 development and running a highly performing manufacturing capability as the two KPI categories having a total weight of 12.5% each. No minimum achievement threshold applies to these KPIs.*

- *Advancement of organizational capabilities as KPI category having a total weight of 15%. No minimum achievement threshold applies to these KPIs.*

For the vesting of the CEO's performance-based share options regarding performance year 2021, the Board decided to use the same evaluation mechanism as the mechanism for the 2021 annual bonus plan set out above.

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 2021 can be found in the following Remuneration Report.

The procedure pursuant to Article 7:97 of the Belgian Code of Companies and Associations was not applied in 2021.

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), Roald Borré, and Christian Reinaudo. 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 2021, the audit committee held four meetings which were attended by all members. 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 2020. It also discussed the cooperation with the external auditor of the Company, Deloitte Bedrijfsrevisoren BV, represented by Nico Houthaeve, and proposed to the shareholders' meeting to reappoint the external auditor. The audit committee approved certain non-audit services to be provided by the external auditor. 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 2021 during the last meeting of the audit committee held in 2021. 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 2021, 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, discussed and approved the achievement of the 2020 company goals and related variable remuneration of the executive management, and set the 2021 company goals (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 the workplace transformation program following COVID-19 and health and safety at work, 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 2020 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	48	Chief executive officer (CEO)
Jean-Marc Roelandt[1]	57	Chief financial officer (CFO)
Piet Houwen[2]	54	Chief operating officer (COO)

Notes: [1] 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 25 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, bio-pharmaceuticals 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 2021, 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 2021 as compared to 2020 in this respect. The executive management is surrounded by a diverse middle management team. More information on this can be found under Part 3, sustainability, section 'employees'.

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 2021. Following a clear positive vote by Biocartis' shareholders on the remuneration report of 2020 and the Biocartis remuneration policy, the changes to the remuneration of the directors and members of the executive management in 2021 as compared to 2020 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 2021 as set out in detail in this annual report.

In 2021, 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

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 table 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 2021

Based on what is set out above, the remuneration of the directors for the performance of their director mandate in 2021 is as follows[1]:

Name of Director, position	Fixed remuneration			Variable remuneration		Extra-ordinary items	Pension expense	Total remune-ration	Proportion of fixed and variable remuneration[4]
	Fixed fees [2]	Attendance fees [3]	Fringe benefits	One-year variable	Multi-year variable[4]				
Christian Reinaudo (Chairman)	50,000	31,000	0	0	0	0	0	81,000	Fixed: 100% Variable: 0%
Luc Gijsens BV, repr. by Luc Gijsens (independent)	18,000	28,000	0	0	0	0	0	46,000	Fixed: 100% Variable: 0%
Ann-Christine Sundell (independent)	12,000	31,500	0	0	0	0	0	43,500	Fixed: 100% Variable: 0%
Christine Kuslich (independent)	12,000	25,500	0	0	0	0	0	37,500	Fixed: 100% Variable: 0%
Roald Borré (non-executive)[5]	12,000	26,500	0	0	0	0	0	38,500	Fixed: 100% Variable: 0%

Notes: [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] The value of any share options vested in 2021 have not been taken into account. See the table below for more information on the share options of the directors as per 31 December 2021. [5] 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. As a result, the amounts mentioned here were not paid to Mr. Borré but to charity.

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 2021:

Name of Director, position	The main conditions of share option plans						Information regarding the reported financial year			
	Specification of plan	Award date	Vesting date[1]	End of holding period	Exercise period	Strike price	Opening balance Share options held (of which vested)	During the year [2][3] Share options awarded	Share options vested	Closing balance Share options held (of which vested)
Christian Reinaudo (Chairman)	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 (10,000)	0	5,000 - EUR 15,550	15,000 (15,000)
Luc Gijsens BV, repr. by Luc Gijsens (independent)	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 (independent)	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 (independent)	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0
Roald Borré (non-executive)	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0

Notes: [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] 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 the share options held by the directors is above the current share price of the Company. [3]During 2021, 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., 2021). As of 31 December 2021, Mr. Verrelst held 100,000 shares in the Company with a value of 364,000 euro (rounded).

Remuneration of the members of the executive management in 2021

Total Remuneration

The total remuneration of the members of the executive management in 2021 is as follows[(1)]:

Name of Executive, position	Fixed remuneration			Variable remuneration		Extra-ordinary items	Pension expense[(4)]	Total remune-ration	Proportion of fixed and variable remuneration
	Base salary	Fees	Fringe benefits	One-year variable[(2)]	Multi-year variable[(3)]				
Herman Verrelst (Chairman)	375,000	0	0	59,908	60,150	0	0	495,058	Fixed: 75.7% Variable: 24.3%
Other executives (CFO and COO)	638,362	0	0	63,694	43,345	0	0	745,401	Fixed: 85.6% Variable: 14.4%

Notes:
[(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, except for the 3-year targets for the CEO for 2021 which were defined in 2019 (for more information, see below). The value of any share options vested in 2021 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 2021.

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 2021[(1)].

Name of Executive, position	Description of the performance criteria	Relative weighting of the performance criteria	Information on Performance Targets		Measured performance and total remuneration
			Minimum threshold performance	Maximum performance	
Herman Verrelst (CEO)	Financial performance (consisting of KPIs relating to operational income growth, gross margin improvement and capping the net cash burn)	30%	75%	125%	17.8%
	Commercial success (consisting of KPIs relating to commercial cartridge volume and installed base growth, as well as relating to growth in the partner business topline)	30%	For commercial cartridge volume and installed base growth: 90% For growth in partner business topline: 75%	For commercial cartridge volume and installed base growth: 200% For growth in partner business topline: 125%	13.4%
	Execution and delivery on projects in support of financial and commercial growth	12.5%	N/A	100%	17.4%
	Development and running a highly performing manufacturing capability	12.5%	N/A	100%	10.5%
	Advancement of organizational capabilities	15%	N/A	100%	14.8%
					Total weighted performance: 63.9%, corresponding to EUR 59,906
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 63,694

Notes:
[(1)]Amounts mentioned are gross amounts in Euro.

The table below provides an overview of the total deferred short-term variable remuneration for 2021[1].

Name of Executive, position	Description of the performance criteria	Relative weighting of the performance criteria	Information on Performance Targets		Measured performance and total remuneration
			Minimum threshold performance	Maximum performance	
Herman Verrelst (CEO)	2-year KPIs (set in 2020) in the form of phantom stock	N/A	50%	150%	Total pay-out: 90%, corresponding to EUR 42,337
	3-year KPIs (set in 2019): KPIs relating to total operating income and gross margin on product revenues	50% each	70%	100%	76% for total operating income (corresponding to 38% pay-out) and 32% for gross margin on product revenues (corresponding to 0% pay-out)
					Total weighted pay-out: 38% corresponding to EUR 17,813
Other executives (CFO and COO)	2-year KPIs (set in 2020) in the form of phantom stock	N/A	50%	150%	Total payout: 90%, corresponding to EUR 43,345

Notes:
[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 2021:

Name of Executive, Position	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)
Herman Verrelst (CEO)	2017 Plan	11/9/2017	2018-2021[4]	N/A	1/1/2021 – 11/9/2022	EUR 9.92	1,212,365 (877,365)	0	167,500 time-based (EUR 358,450) + 107,033 performance-based (EUR 229,051)	1,151,898 (1,151,898)
	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	0	60,000	0	60,000 (0)
Marcofin BV, repr. by Jean-Marc Roelandt (CFO)	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	0	30,000	0	30,000 (0)
Scmiles BV, repr. by Piet Houwen	2018 Plan	9/5/2019	2020-2023[5]	N/A	1/1/2023 – 8/5/2026	EUR 11.93	65,000 (28,437)	0	16,250 (EUR 38,025)	65,000 (44,687)
	2020B	30/4/2020	1/1/2024	N/A	1/1/2024 –	EUR 4.18	50,000 (0)	0	0	50,000 (0)

Notes:

[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 2021, no share options were exercised by any members of the executive management. There were 60,467 performance-based share options held by Mr. Verrelst that became null and void.

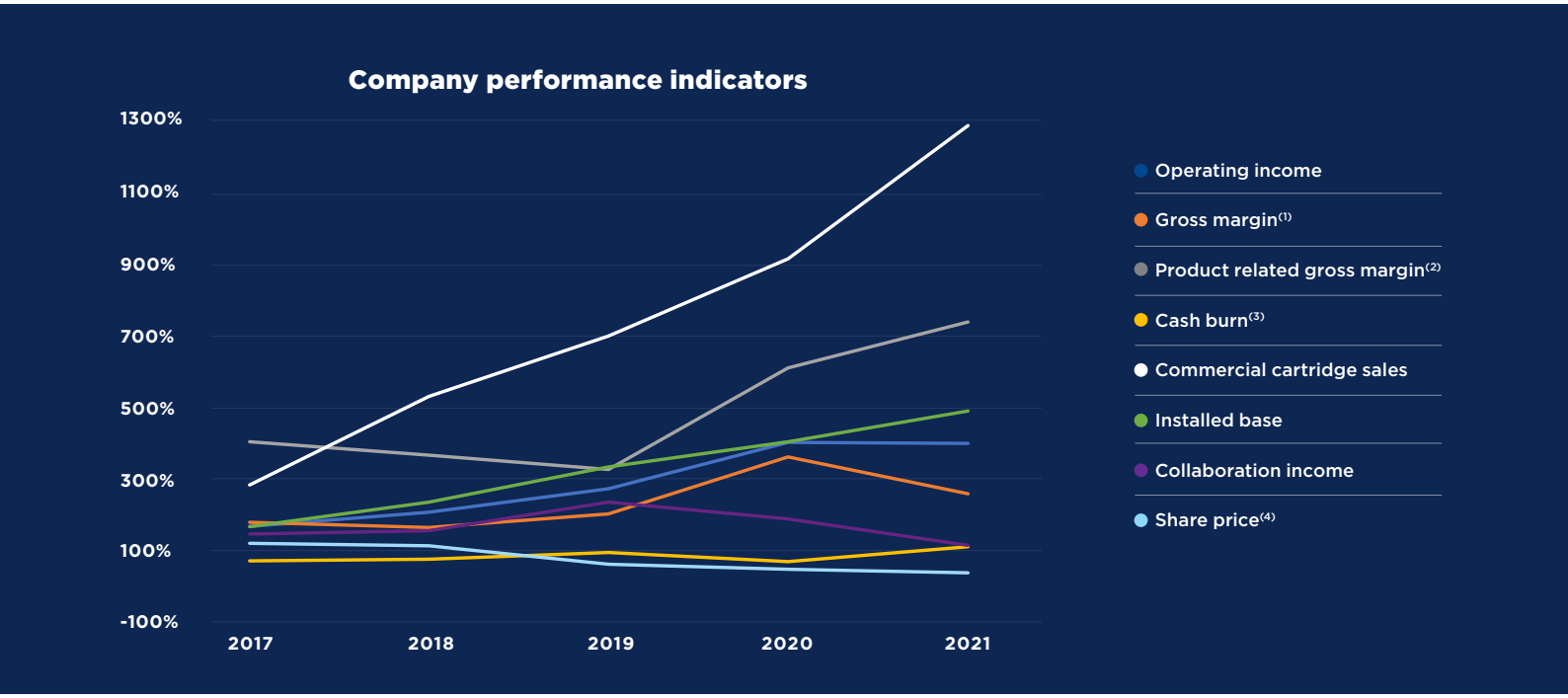
[3] The amount of share options mentioned in this column relates to the total amount initially awarded minus any share options which were already exercised or became null and void before 1 January 2021.

[4] The share options held by Herman Verrelst under the 2017 plan vest as follows: (i) 12.5% of the share options vests on each of the first four anniversary dates of the award date (being 11 September 2017); and (ii) the other 50% of the shares will vest if and to the extent of Mr. Verrelst achieving certain objective and verifiable key performance indicators established by the board during performance years 2018 to 2021.

[5] 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.

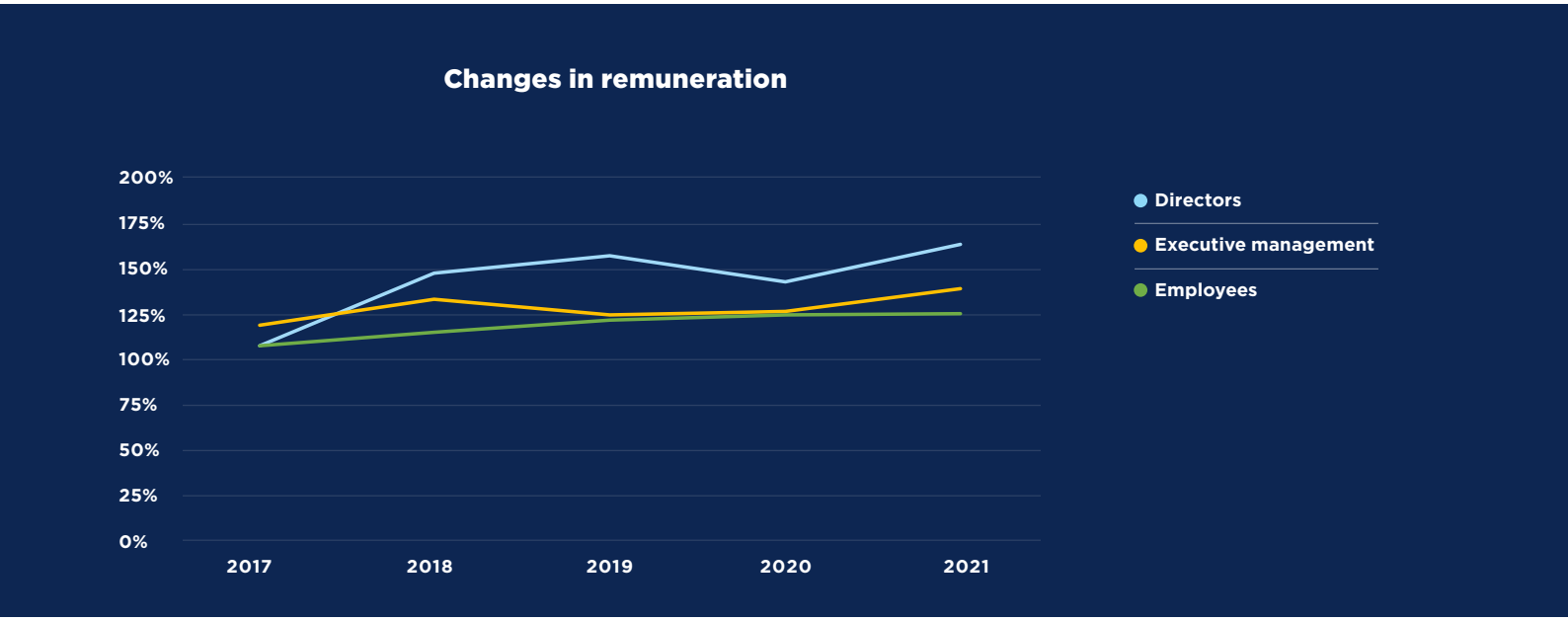
Yearly changes in remuneration and performance of Biocartis

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. 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 12-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 2021.

4.6 Share capital and shares

Issue of shares by the company in 2021

On 1 January 2021, the share capital of the Company amounted to EUR 575,456.63, represented by 57,545,663 shares. No new shares were issued in the course of 2021. An overview of the major shareholders of the Company on 31 December 2021 based on the transparency notifications received until that date can be found in the section 'Major Shareholders' under the chapter 'Creating value for our shareholders'. The Company is not aware of any shareholders' agreements with respect to the Company.

Number and form of shares of the company

Of the 57,545,663 shares of the Company outstanding at 31 December 2021, 14,018 were registered shares and 57,531,645 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 did not yet make use of such authorization in 2021.

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 sales 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 2021, 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 17.2m credit contract dated 5 January 2021 entered into between KBC Bank NV, the Company and Biocartis NV, whereby 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 EUR 150.0m senior unsecured convertible bonds due 9 May 2024 (of which a principal amount of EUR 135.0m is still outstanding), whereby (i) 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, and (ii) the conversion price of the convertible bonds shall be temporarily adjusted following the occurrence of a change of control.

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 2021, 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. In 2021, 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. In 2021, a total amount of EUR 161,415 was paid to the statutory auditor for audit fees. There were no non-audit services performed for Biocartis by the statutory auditor in 2021. Other non-audit services performed by Deloitte for Biocartis in 2021 amounted to EUR 90,800.

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 2021 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. Biocartis is organized around four key activities (research & development, manufacturing, commercial and G&A) and for all functions clear areas of responsibility are defined, as well as horizontal communication processes ensuring involvement of different functions in more complex and multilayered issues.

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:

a) 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
b) 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.

HERMAN VERRELST
CHIEF EXECUTIVE OFFICER

CHRISTIAN REINAUDO
CHAIRMAN OF THE BOARD OF DIRECTORS

1. CONSOLIDATED ANNUAL ACCOUNTS 2021

1.1. / CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED 31 DECEMBER 2021 AND 2020

1.1.1. / CONSOLIDATED INCOME STATEMENT

		Years ended 31 December,	
In EUR 000	**Notes**	**2021**	**2020**
Collaboration revenue	1.2.4	6,053	9,989
Product sales revenue	1.2.4	40,486	31,893
Service revenue	1.2.4	1,730	1,246
Total revenue		**48,269**	**43,128**
Other operating income			
Grants and other income	1.2.5	6,629	12,431
Total operating income		**54,898**	**55,559**
Cost of sales	1.2.6	-33,922	-26,284
Research and development expenses	1.2.7	-48,054	-45,783
Sales and marketing expenses	1.2.8	-16,763	-15,736
General and administrative expenses	1.2.9	-15,560	-14,618
Other expenses	1.2.9	-3,244	0
Total operating expenses		**-117,543**	**-102,421**
Operating loss for the year		**-62,645**	**-46,862**
Financial expense	1.2.11	-9,488	-14,569
Other financial results	1.2.11	1,077	-1,199
Financial result, net		**-8,411**	**-15,768**
Share in the result of joint venture		-659	-532
Loss for the year before taxes		**-71,715**	**-63,162**
Income taxes	1.2.28	243	228
Loss for the year after taxes		-71,472	-62,934
Attributable to owners of the Group		-71,472	-62,934
Earnings per share			
Basic and diluted loss per share	1.2.12	-1.24	-1.11

1.1.2. / CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In EUR 000	Notes	Years ended 31 December, 2021	2020
Loss for the year		**-71,472**	**-62,934**
Other comprehensive income (loss), not to be reclassified to profit or loss:			
Re-measurement gains and losses on defined benefit plan	1.2.24	-595	197
Income taxes on items of other comprehensive income		176	-58
Other comprehensive income (loss), that may be reclassified to profit and loss:			
Exchange differences on translation of foreign operations		410	-150
Total comprehensive loss for the year		**-71,481**	**-62,945**
Attributable to owners of the Group		-71,481	-62,945

1.1.3. / CONSOLIDATED STATEMENT OF FINANCIAL POSITION

In EUR 000	Notes	As of 31 December, 2021	2020
Assets			
Non-current assets			
Intangible assets	1.2.13	5,067	5,645
Property, plant and equipment	1.2.14	37,192	40,098
Financial assets	1.2.15	1,140	0
Investment in joint ventures	1.2.16	2,344	2,893
Other non-current assets	1.2.24	16	426
Deferred tax assets and R&D Investment tax credit	1.2.17	1,595	1,472
		47,354	**50,534**
Current assets			
Inventories	1.2.18	16,106	15,712
Trade receivables	1.2.19	16,206	13,488
Other receivables	1.2.19	6,556	3,960
Other current assets	1.2.20	2,736	3,155
Cash and cash equivalents*	1.2.21	53,522	123,668
		95,126	159,983
Total assets		**142,480**	**210,517**
Equity and liabilities			
Capital and reserves			
Share capital	1.2.22	-220,657	-220,657
Share premium	1.2.22	711,874	711,874
Share based payment reserve	1.2.22	6,862	6,102
Accumulated deficit	1.2.22	-526,405	-455,343
Other comprehensive income	1.2.22	-5,571	-5,152
Total equity attributable to owners of the Group		**-33,897**	**36,824**
Non-current liabilities			
Provisions	1.2.24	75	0
Borrowings and lease liabilities	1.2.25	14,133	18,625
Convertible debt	1.2.25	128,151	125,260
Deferred income	1.2.27	313	363
		142,672	144,248
Current liabilities			
Borrowings and lease liabilities	1.2.25	11,878	6,673
Trade payables	1.2.26	11,560	13,907
Deferred income	1.2.27	1,822	1,278
Other current liabilities	1.2.26	8,445	7,587
		33,705	29,445
Total equity and liabilities		**142,480**	**210,517**

*Cash and cash equivalents for 31 December 2020 and 2021 include EUR 1.2 million restricted cash related to KBC Lease financing

1.1.4. / CONSOLIDATED CASH FLOW STATEMENT

In EUR 000	Notes	Years ended 31 December, 2021	2020
Operating activities			
Loss for the year		-71,472	-62,934
Adjustments for			
Depreciation and amortization	1.2.13/1.2.14	9,845	9,748
Impairment losses	1.2.7/1.2.14	1,362	1,698
Income taxes in profit and loss	1.2.29	-243	-228
Financial result, net	1.2.11	8,411	15,768
Unrealized exchange gains/ losses		1,134	-1,030
Net movement in defined benefit obligation	1.2.24	69	-323
Share of net profit of associate and joint venture	1.2.16	659	532
Share based payment expense	1.2.23	760	1,432
Other		-162	-80
Changes in working capital			
Net movement in inventories	1.2.18	-2,737	-4,042
Net movement in trade and other receivables and other current assets	1.2.19/1.2.17	-5,916	1,449
Net movement in trade payables & other current liabilities	1.2.26	-1,489	6,333
Net movement in deferred income	1.2.27	494	-415
Cash flow from operating activities before interest and taxes paid		**-59,285**	**-32,092**
Interest paid		-6,429	-7,172
Taxes paid	1.2.29	-2	-3
Cash flow used in operating activities		**-65,716**	**-39,267**
Investing activities			
Interest received		7	13
Acquisition of property, plant & equipment	1.2.14	-3,686	-3,005
Acquisition of intangible assets	1.2.13	-69	-15
investment in joint venture	1.2.16	0	-1,000
Cash flow used in investing activities		**-3,748**	**-4,007**
Financing activities			
Proceeds from borrowings	1.2.25	6,000	0
Convertible bond - incentivized conversion	1.2.25	0	-4,306
Repayment of borrowings	1.2.25	-7,089	-7,167
Bank charges		-115	-50
Cash flow used in financing activities		**-1,204**	**-11,523**
Net decrease in cash and cash equivalents		**-70,668**	**-54,797**
Cash and cash equivalents at the beginning of the period		123,668	178,725
Effects of exchange rate changes on the balance of cash held in foreign currencies		522	-260
Cash and cash equivalents at the end of the period*		**53,522**	**123,668**

1.1.5. / 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 2020		**-220,668**	**698,027**	**4,670**	**-5,291**	**-392,259**	**84,480**	**84,480**
Loss for the period						-62,934	-62,934	-62,934
Re-measurement gains and losses on defined benefit plan	1.2.24				139		139	139
Consolidation translation difference						-150	-150	-150
Total comprehensive income					**139**	**-63,084**	**-62,945**	**-62,945**
Share-based payment expense	1.2.23			1,432			1,432	1,432
Convertible bond - incentivized conversion	1.2.22	11	13,847				13,858	13,858
Balance as at 31 December 2020		**-220,657**	**711,874**	**6,102**	**-5,153**	**-455,343**	**36,824**	**36,824**
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	1.2.24				-419		-419	-419
Consolidation translation difference						410	410	410
Total comprehensive income					**-419**	**-71,062**	**-71,481**	**-71,481**
Share-based payment expense	1.2.23			760			760	760
Balance as at 31 December 2021		**-220,657**	**711,874**	**6,862**	**-5,572**	**-526,405**	**-33,897**	**-33,897**

1.2. / NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1.2.1. / 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 30 March 2022 by the board of directors of the Company (the 'board of directors').

1.2.2. / SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1.2.2.1. / STATEMENT OF COMPLIANCE

The consolidated financial statements of the Group for the year ended 31 December 2021 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.

1.2.2.2. / 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 2021:

- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform – Phase 2
- Amendments to IFRS 16 Leases: COVID-19-Related Rent Concessions beyond 30 June 2021 (applicable for annual periods beginning on or after 1 April 2021 but not yet endorsed in the EU).

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 2021, are listed in note 1.2.34.

1.2.2.3. / CONSOLIDATION PRINCIPLES

The consolidated financial statements comprise the financial statements of the Company and entities controlled by the Company as at 31 December 2021.

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.

1.2.2.4. / 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.

1.2.2.5. / 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.

1.2.2.6. / 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.

1.2.2.7. / 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.

1.2.2.8. / 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.

1.2.2.9. / 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.

1.2.2.10. / 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 fair value 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.

1.2.2.11. / 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.

1.2.2.12. / 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 2021, EUR 0.3m of the Group's tax credit on research and development has become a short-term receivable.

1.2.2.13. / 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.

1.2.2.14. / 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.

1.2.2.15. / 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.

1.2.2.16. / 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.

1.2.2.17. / 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 1.2.2.8.

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.

1.2.2.18. / 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.

1.2.3. / CRITICAL ACCOUNTING ESTIMATES, ASSUMPTIONS AND JUDGMENTS

1.2.3.1. / 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 2021, commercial cartridge volumes have grown at a compound annual growth rate of 67%. Biocartis' technology is widely validated, and the global installed base is nearing 2,000 Idylla™ instruments. Revenue and gross profit from product sales and instrument servicing have grown at a compound annual growth rate of 44% and 49%, respectively between 2016 and 2021. 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 and scalable manufacturing and is committed to further grow revenues, improve gross margins, and reduce its cash burn in 2022 and beyond.

On 31 December 2021, cash and cash equivalents amounted to EUR 53 million and EUR 9 million from available credit facilities remained undrawn. Based on the projected operating cash burn for 2022 of between 43 and 47 million EUR and the anticipated cash needs for financing and investing activities, Biocartis is anticipating a need for additional funding to cover part of its cash needs until the annual general meeting of the Company in 2023, which is the applicable horizon for the going concern assessment. The board of directors acknowledges that there is inherent uncertainty in projecting future cashflows, particularly in the current economic climate. Biocartis is currently actively engaged in discussions with potential investors to secure the necessary funding to continue operating as a going concern. The board of directors believes that Biocartis will be able to attract such financing based on the established track record of strong growth and on the Group's long-term financial projections. In the event that the Group cannot timely attract additional funding, it has the ability to extend the cash runway to continue to operate at least until the annual general meeting of the Company in 2023 by reducing its operating expenses and cut back on planned investments in various areas of the business. 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.

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

No critical accounting estimates and assumptions have been made during the preparation of the 2021 consolidated financial statements.

1.2.3.2. / COVID-19

Since its outbreak in 2020, the pandemic impacted the Group's business in various respects. Initially, the pandemic deprioritized and disrupted cancer care globally. Patient access to hospitals was significantly restricted throughout almost the entire first half of 2020 and customer prospection was severely hampered. Throughout the second half of 2020, testing volumes started to recover and gradually normalized to pre-pandemic levels. In 2021, patient access to hospitals was more sporadically restricted in specific regions with a high surge of COVID-19 cases, which resulted in an overburdened healthcare system and required cancer diagnosis and treatment to be delayed. The pandemic also brought an opportunity to strengthen the Group's offering in infectious diseases. In order to respond to our customers' need for COVID-19 testing, and to bridge the shortfall in oncology testing, it 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, Biocartis 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 RSV13 nucleic acids. The growing and worldwide need for COVID-19 PCR testing also caused a shortage of reagent supply that constrained the Group's 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.

For more detailed information related to the current and expected impact of the COVID-19 situation on the financial position and performance of the Group, we refer to Part 1 'At a glance', 'Impact of COVID-19'.

1.2.3.3. / 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 2021.

1.2.4. / REVENUE

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

In EUR 000	Years ended 31 December,			
	2021		2021	2020
	At a point in time	Over time		
Collaboration revenue				
R&D services	0	5,868	5,868	8,176
License revenue	85	100	185	1,813
Milestones	0	0	0	0
	85	**5,968**	**6,053**	**9,989**
Product related revenue				
Idylla™ System Sales revenue	5,045	0	5,045	4,386
Idylla™ System Rental revenue	3,824	0	3,824	2,700
Cartridge revenue	31,618	0	31,618	24,808
	40,486	0	40,486	31,894
Service revenue				
Idylla™ System Service revenue	1,496	234	1,730	1,246
	1,496	**234**	**1,730**	**1,246**
Total	**42,067**	**6,202**	**48,269**	**43,128**

For details related to the movements in accrued and deferred income related to collaboration agreements, we respectively refer to notes 1.2.20 and 1.2.27.

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	Deferred income	
	Years ended 31 December,	
	2021	2020
2021	0	616
2022	535	0
2023	80	0
2024	0	0
2025	0	0
2026	0	0
After 2026	0	0
Total	**615**	**616**

The aggregate amount of the transaction price allocated to collaboration arrangements that are partially or fully unsatisfied as at 31 December 2021 is EUR 0.6m.

1.2.4.1. / SUMMARY OF COLLABORATION REVENUES

Below is a description of the main collaboration arrangements from which the Group generates revenue, for more details on the accounting policy of collaboration revenue we refer to note 1.2.2.15.

AMGEN

Biocartis and Amgen have several collaborations that aim at amongst others the evaluation of Idylla™ RAS testing as a tool for rapid decentralized testing and/or to accelerate access to RAS biomarker information using Biocartis' Idylla™ platform and RAS tests. Product revenue recognized under this agreement is shown under product related revenue as it relates to the placement of Idylla™ systems and cartridges.

Biocartis and Amgen also collaborate on companion diagnostics (CDx) such as the development agreement with Amgen for the Idylla™ RAS biomarker tests aimed at the registration of these test with the US Food and Drug Administration (FDA) as a CDx test for Amgen's drug Vectibix® (panitumumab). The elements included in the CDx collaboration consist of milestone payments and R&D services.

Based on the contractual dispositions, we assessed the following:

- The first stage (i.e. the clinical trial development) of the arrangement consists of one initial performance obligation and the renewal options are considered to be separate performance obligations as Amgen can terminate the contract without significant penalty and these options are treated as material rights for Amgen.
- The transaction price is currently composed of a fixed part, being an upfront fee and cost reimbursements for R&D activities delivered and a variable part, being milestone payments. Milestone payments are included in the transaction price of the arrangement only when achieved.

Given that the separate performance obligations are related to the same services, we can combine these performance obligations and hence, the transaction price does not need to be allocated over multiple performance obligations. The transaction price has therefore been allocated to a single performance obligation and revenues have been recognized over the estimated service period based on a pattern that reflects the transfer of the development activities a rato of the services performed (i.e. percentage of completion method). The milestone payments will be treated as a change in transaction price as soon as the revenue constraint assessment is resolved. The milestone payment will be allocated to the performance obligation (based on the percentage of completion of the development work).

In relation to the collaboration agreements with Amgen, the Group recognized R&D service revenue over time a rato to the services performed in 2021.

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.

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 2021, 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.

1.2.4.2. / REVENUES BY MAJOR COUNTRIES AND CUSTOMERS

	Years ended 31 December,	
In EUR 000	**2021**	**2020**
Country of domicile	618	481
Belgium	618	481
Total all foreign countries, of which	47,651	42,647
United States of America	10,966	15,604
China	1,491	1,993
Spain	3,452	2,866
France	4,320	3,497
Great Britain	7,938	3,972
Germany	3,625	2,946
Rest of the world	15,859	11,769
Total	**48,269**	**43,128**

Revenue in the above table are assigned according to the location of the Group or parent company of the customer.

In 2021 there was one customer representing 10% of the total recognized revenue, the 5 largest clients together represent 22% of the revenue.

1.2.5. / OTHER OPERATING INCOME

	Years ended 31 December,	
In EUR 000	**2021**	**2020**
R&D project support (VLAIO & IWT grants)	2,054	1,158
Other project grants (EU)	-	56
Other income	4,576	11,217
Total	**6,630**	**12,431**

The other operating income consist out of grants that were awarded to support R&D activities. In 2021, the Group was awarded a new grant from VLAIO, for the development of Idylla™ FLEX.

The final approval for the settlement related to the fire incident was obtained from the insurance company, EUR 4.6m, of which EUR 0.9m already received, is recorded as other income.

In 2020, the collaboration with Genomic Health, a subsidiary of Exact Sciences Corporation, for the development of the Ecotype DX Breast Recurrence Score® test on Idylla™ was initially delayed and ultimately terminated because of the pandemic and a decision by Exact Sciences Corporation to shift priorities to other initiatives. Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation) paid a settlement fee of EUR 10.3m, which was recorded as other income in 2020.

1.2.6. / COST OF SALES

The cost of goods sold in relation to the product sales is as follows:

	Years ended 31 December,	
In EUR 000	**2021**	**2020**
Employee benefit expenses	-9,510	-6,118
Material, lab consumables & small equipment	-16,282	-13,187
Depreciation and amortization	-4,243	-3,378
Royalty expense	-1,728	-1,486
Facilities, office and other	-2,159	-2,115
Total	**-33,922**	**-26,284**

Cost of goods sold increased to EUR 33.9m, 29% higher than in 2020, driven by 40% higher commercial cartridge volumes. Despite higher cartridge volumes, the gross margin on product sales amounted to 16% in 2021 compared to 18% in 2020. The utilization of the high-throughput automated manufacturing line ML2 was significantly lower than planned as a direct result of the fire and constrained supply of certain reagents. During the forced two-month production stop of the ML2 line, the production of certain assays was transferred to the ML1 line to preserve customer supply as much as possible. The manufacturing capacity on the ML1 line is however significantly lower and the manufacturing cost significantly higher than on the ML2 line. However, even with low production volumes on the ML2 line throughout 2021, the gross margin on assays produced on the ML2 line already reached 33%, clearly demonstrating the Company's ability to scale with unhindered and increasing production on the ML2 line. Additionally, the gross margin also slightly decreased because of lower pricing of the Idylla™ SARS-CoV-2 test products in 2021. Both tests are being transferred to the ML2 line in the first half of 2022 and will generate a contribution to the absorption of fixed manufacturing costs awaiting full capacity utilization of the ML2 line that can produce up to 1m tests annually.

1.2.7. / RESEARCH & DEVELOPMENT EXPENSES

	Years ended 31 December,	
In EUR 000	2021	2020
Employee benefit expenses	-26,585	-24,912
R&D consultancy & subcontracting	-10,383	-9,206
Laboratory and cartridge expenses	-2,955	-2,817
Quality, regulatory and intellectual property	-669	-693
Facilities, office & other	-2,835	-2,801
ICT	-380	-332
Travel, training & conferences	-139	-166
Depreciation and amortization	-4,108	-4,856
Total	**-48,054**	**-45,783**

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.

R&D expenses amounted to EUR 48.1m, an increase of EUR 2.3m compared to 2020. In 2020, several projects were delayed and carried over to 2021. Furthermore, the Company invested in further menu expansion and diversification. These investments included the preparatory work to apply for conformity of our CE-IVD assays under the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) that establishes a new regulatory framework for in vitro diagnostic medical devices. In addition to ongoing projects to broaden the core oncology test menu on Idylla™ and upgrading the functionality of the Idylla™ platform, the Company also developed and launched its Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD) which detects, in one single cartridge, SARS-CoV-2, Flu A/B and RSV nucleic acids. Finally, R&D included the continued investment in the transfer of assays from the ML1 line to the ML2 line as well as continuous improvement projects with a view to optimize the manufacturing output.

1.2.8. / SALES & MARKETING EXPENSES

	Years ended 31 December,	
In EUR 000	2021	2020
Employee benefit expenses	-11,971	-10,369
S&M consultancy & subcontracting	-662	-929
Sales and promotional expenses	-591	-658
Business development	-572	-932
Facilities, office & Other	-955	-998
Travel, training & conferences	-964	-791
Depreciation and amortization	-702	-579
Impairment of receivables	-346	-480
Total	**-16,763**	**-15,736**

Sales and promotional expenses relate to costs of external market research, advertisement, and promotional activities related to the Group's products.

S&M expenses increased by EUR 1.0m reflecting inflation and the restructuring of the US commercial team.

1.2.9. / GENERAL & ADMINISTRATIVE EXPENSES

	Years ended 31 December,	
In EUR 000	2021	2020
Employee benefit expenses	-10,994	-10,783
External advice	-785	-683
Facilities, office & other	-1,814	-1,388
Human resources	-1,306	-1,030
Travel, training & conferences	-60	-162
Depreciation and amortization	-601	-572
Total	**-15,560**	**-14,618**

	Years ended 31 December,	
In EUR 000	2021	2020
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 0.9m, reflecting inflation and increased facility costs. Other expenses entirely relate to the write-off of materials and finished products lost in the 2021 fire.

1.2.10. / EMPLOYEE BENEFIT EXPENSES

	Years ended 31 December,	
In EUR 000	2021	2020
Short term employee benefits	-57,254	-50,194
Post-employee benefit expense	-678	-485
Termination benefits	-367	-71
Share-based payments	-760	-1,432
Total	**-59,059**	**-52,182**

Employee benefit expenses include payroll expenses of fixed employees, interim staff and consultants in a permanent position. The employee benefit expenses amounted to EUR 59.1m in 2021 compared to EUR 52.2m in 2020, a year-over-year increase of 13%. This increase is predominantly a consequence of the increase in headcount, as can be seen in the table below.

The headcount can be presented as follows:

	As of 31 December	
	2021	2020
Operations staff	227	143
Research and development staff	218	185
Marketing and sales staff	91	86
General and administrative staff	83	70
Total headcount	**619**	**484**
Average full-time equivalents	579	526

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 407 for 2021.

1.2.11. / FINANCIAL INCOME AND EXPENSE

	Years ended 31 December,	
In EUR 000	**2021**	**2020**
Interest expense	-9,320	-10,184
Other financial expense	-168	-4,385
Total	**-9,488**	**-14,569**
Other financial result	1,077	-1,199
Total	**1,077**	**-1,199**
Financial result, net	**-8,411**	**-15,768**

Net financial expenses decreased to EUR 8.4m in 2021 compared to EUR 15.8m in 2020 and included financial expenses in relation to the Company's convertible bond of EUR 8.3m coupon payment in 2021 (consisting of EUR 5.4m coupon payment and EUR 2.9m of debt appreciation), compared to 9.0m in 2020. The bond was issued in May 2019. In 2021, no incentivized conversion was issued resulting in a decrease of the other financial expense of EUR 4.3m compared to 2020.

The other financial result mainly consists of non-realized foreign exchange gains and losses of EUR 1.0m in 2021 compared to EUR -1.0m in 2020, due to a higher amount of dollars on our bank account and fluctuations in the exchange rates of foreign currencies.

1.2.12. / LOSS PER SHARE

The Group has stock option plans 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,	
	2021	**2020**
Profit/loss for the period attributable to the owners of the Group (in EUR 000)	-71,472	-62,934
Weighted average number of ordinary shares for basic loss per share (in number of shares)	57,545,663	56,610,506
Basic loss per share (EUR)	**-1.24**	**-1.11**

1.2.13. / INTANGIBLE ASSETS

The Group's intangible assets comprise acquired patents, licenses and software. The carrying amounts for the periods presented can be analyzed as follows:

In EUR 000	Patents and licenses	ICT software	Total
Year ended 31 December 2020			
Opening net carrying value	6,151	143	6,294
Additions	0	15	15
Disposals	0	0	0
Disposal depreciations	0	0	0
Amortization expense	-577	-87	-664
	0	0	0
Closing net carrying value	**5,574**	**71**	**5,645**
As at 31 December 2020			
Cost	12,292	1,737	14,029
Accumulated amortization	-6,717	-1,667	-8,384
Net carrying value	**5,574**	**71**	**5,645**
Year ended 31 December 2021			
Opening net carrying value	5,574	71	5,645
Additions	0	68	68
Disposals	0	0	0
Disposal amortizations	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**

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 2021 is EUR 4.0 (2020: EUR 4.5m). The remaining useful life is 7 years.

Amortization expense on intangible assets is shown in the income statement under research and development expenses.

1.2.14. / 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 can be analyzed 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	**527**	**750**	**2,390**	**1,936**	**380**	**373**	**0**	**22**	**0**	**5,967**	**31,076**	**43,421**
Additions	30	439	1,021	427	9	5	0	108	0	3,436	2,081	**7,556**
Disposals	0	-217	-102	-686	-28	0	0	0	0	-1,386	-642	**-3,060**
Disposal depreciation	0	101	0	506	0	0	0	0	0	490	265	**1,362**
Depreciation charge of the period	-181	-269	-546	-757	-75	-225	0	0	0	-1,790	-5,239	**-9,082**
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	-17	0	-85	-5	0	0	0	0	0	-62	**-169**
Currency translation depreciations	0	4	0	43	0	0	0	0	0	0	22	**69**
Closing carrying amount	**377**	**791**	**2,763**	**1,384**	**281**	**153**	**0**	**130**	**0**	**6,718**	**27,502**	**40,098**
As at 31 December 2020												
Cost	2,025	3,063	10,315	5,938	808	2,786	29	130	0	10,245	45,096	**80,435**
Accumulated depreciation	-1,649	-2,272	-7,552	-4,554	-527	-2,633	-29	0	0	-3,527	-17,594	**-40,338**
Carrying amount	**377**	**791**	**2,763**	**1,384**	**281**	**153**	**0**	**130**	**0**	**6,718**	**27,502**	**40,098**

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**

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:

	As of 31 December	
In EUR 000	**2021**	**2020**
Non-current assets		
Right-of-use assets - buildings	9,789	10,919
Right-of-use assets - manufacturing equipment	12,075	14,541
Right-of-use assets - cars	2,432	2,007
Right-of-use assets - office furniture	20	35
Right-of-use assets - other	58	0
Total right-of-use assets	**24,374**	**27,502**

The table below provides a split of the depreciation charges by asset class:

	Years ended 31 December,	
In EUR 000	**2021**	**2020**
Depreciation expense per type right-of-use assets		
Buildings	1,573	1,786
Manufacturing equipment	2,476	2,489
Cars	1040	949
Office furniture	15	15
Other	12	0
Total depreciation expense	**5,116**	**5,239**

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.

1.2.15. / 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'.

1.2.16. / 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**	
			2021	2020
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 decreases to EUR 2.3m in 2021. 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 1.2.2.5.

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, 2021
Non-current assets	4,098
Current assets	5,131
Total assets	**9,229**
Non-current liabilities	7
Current liabilities	574
Total liabilities	**581**

Summarized statement of comprehensive income:

In EUR 000	Year ended 31 December, 2021
Operating income	1,115
Operating expenses	-2,248
Financial result, net	-186
Income taxes	0
Result of the year	**-1,318**
Other comprehensive income	0
Total comprehensive income	**-1,318**
Share in total comprehensive income	**-659**

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 2020	**2,893**
Investments of the year	0
Share of the result of the year	-659
Share of the other comprehensive income	0
Dividends received	0
Elimination of unrealized gains and losses	110
Foreign exchange differences	0
As per 31 December 2021	**2,344**

As of the date of this report, there are no material contingent liabilities related to the joint venture. Following the establishment of the joint venture, both shareholders made initial capital contributions to the joint venture. Besides these contributions, each shareholder made an extra capital contribution of EUR 1.0m in 2020.

1.2.17. / DEFERRED TAX ASSETS AND R&D INVESTMENT TAX CREDIT

Deferred taxes relate to the long-term portion of investment tax credit on research and development and amount to EUR 1.6m per 31 December 2021 (2020: EUR 1.4m). 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 2021, EUR 0.3m of the Group's tax credit on research and development has become a short-term receivable, see note 1.2.19.

	As of 31 December,	
In EUR 000	**2021**	**2020**
Tax credit research and development	1,572	1,593
Other	23	-121
Total	**1,595**	**1,472**

1.2.18. / INVENTORIES

The inventory can be analyzed as follows:

	Per 31 December,	
In EUR 000	**2021**	**2020**
Inventory		
Raw materials	5,870	4,950
Semi-finished products	465	746
Finished products	9,771	10,015
Total	**16,106**	**15,712**
Amount recognized as an expense	**-33,922**	**-26,284**

Finished products include 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 2021, EUR 2.0 m of the total inventory value was older than 12 months (2020: EUR 0.5m) for which EUR 0.5m impairment was recognized (2020: EUR 0.1m). It is the expectation that a significant part of the current inventory will be sold within the next 12 months.

1.2.19. / TRADE AND OTHER RECEIVABLES

Trade and other receivables can be analyzed as follows:

	As of 31 December,	
In EUR 000	**2021**	**2020**
Trade receivables	17,032	13,968
Allowance for doubtful receivables	-826	-480
Total	**16,206**	**13,488**

	As of 31 December,	
	2021	**2020**
VAT receivables	2,448	2,133
Tax credit research and development	330	310
Other receivables	3,777	1,518
Total	**6,555**	**3,960**

Trade receivables have increased from EUR 13.5m per 31 December 2020 to EUR 16.2m per 31 December 2021.

At the reporting date, the Group has approximately EUR 13.2m (2020: EUR 5.1m) trade and other receivables that were past due but were not impaired. In 2021 an allowance for doubtful receivables was recorded for EUR 0.8m (2020: EUR 0.5m) 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 (2020: 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 include 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.

1.2.20. / OTHER CURRENT ASSETS

Other current assets can be analyzed as follows:

	As of 31 December,	
In EUR 000	**2021**	**2020**
Accrued grant income	486	223
Accrued collaboration income	75	1,209
Other accrued income	29	29
Deferred charges	2,146	1,693
Total	**2,736**	**3,154**

Other current assets include accrued income mainly related to Flemish government grants for EUR 0.5 m (2020: EUR 0.2m). 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 1.2.4. Accrued collaboration income includes upfront payments from collaboration partners in relation to amongst others strategic licensing, development and/or commercialization collaborations.

	Accrued collaboration income
As per 31 December 2019	**627**
Invoiced	-1,115
Recognized in profit or loss	1,697
As per 31 December 2020	1209
Invoiced	-1,129
Recognized in profit or loss	-5
As per 31 December 2021	**75**

1.2.21. / CASH AND CASH EQUIVALENTS

The cash and cash equivalents can be analyzed as follows:

	Per 31 December,	
In EUR 000	2021	2020
Cash and cash equivalents		
Cash at bank and on hand	52,322	122,468
Total cash and cash equivalents	**52,322**	**122,468**
Total restricted cash	1,200	1,200
Total cash and cash equivalents for cash flow purposes	**53,522**	**123,668**

The restricted cash relates to a deposit on a debt service reserve account as a security for the lease of the Idylla™ cartridge manufacturing lines.

1.2.22. / 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 2020 and 31 December 2021. The shares are fully paid-up shares.

The number of shares issued and outstanding and the share capital is:

	Biocartis Group NV			
	Number of common shares issued and outstanding	Legal share capital in EUR000	Historical share capital adjustment EUR 000	Total share capital in EUR 000
At 31 December 2019	**56,382,088**	**564**	**-221,232**	**-220,668**
Convertible bond - incentivized conversion	1,163,575	11	0	11
At 31 December 2020	**57,545,663**	**575**	**-221,232**	**-220,657**
	0	0	0	0
At 31 December 2021	**57,545,663**	**575**	**-221,232**	**-220,657**

No capital transactions took place at the Company from 1 January 2021 until 31 December 2021:

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.

1.2.23. / SHARE BASED PAYMENTS

The table below provides an overview of the movement in stock options since 31 December 2019:

	2013 Plan	2015 Plan	2017 Plan	2018 Plan	2020 Plan	2020B Plan	Total
Total outstanding at 31 December 2019	**482,539**	**209,618**	**1,340,000**	**526,449**	**0**	**0**	**2,558,606**
Options granted	0	0	0	82,125	227,300	450,000	759,425
Remaining pool*	12,160	434	0	0	469,676	410,000	892,270
Options exercised	0	0	0	0	0	0	0
Options forfeited	-201,324	0	-127,635	-37,639	-1,500	0	-368,098
Options cancelled	0	0	0	0	0	0	0
Total outstanding at 31 December 2020	**293,375**	**210,052**	**1,212,365**	**570,935**	**695,476**	**860,000**	**3,842,203**
Options granted from remaining pool of prior year	0	0	0	0	145,000	90,000	235,000
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**
Of which remaining pool*	12,160	434	0	0	324,676	320,000	657,270

*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 2021. In 2021 119,375 options were forfeited. A total of 174,000 options are still outstanding per 31 December 2021 of which:

- 0 options have an exercise price of EUR 8.1309
- 23,104 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 31/12/2021	0	0	0	0	0	93,750
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 2021, no options were granted, no options were exercised and no options were forfeited. A total of 210,052 options are still outstanding per 31 December 2021 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 31/12/2021	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 2021 no warrants were exercised and 60,467 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 31/12/2021	167,500
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 2021, no warrants were granted, no warrants were exercised and 39,066 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 31/12/2021	8,466	35,158	116,050	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 2021, 145,000 warrants were granted for the 2020 plan and 90,000 warrants were granted for the 2020B plan. No warrants were exercised, and 12,875 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
Number of warrants granted	450,000	90,000	50,000	110,800	65,000	145,000
Number of warrants not vested at 31/12/2021	450,000	90,000	50,000	110,800	65,000	145,000
Exercise price	EUR 4.18	EUR 4.45	EUR 4.81	EUR 4.81	EUR 4.53	EUR 4.45
Expected dividend yield	0	0	0	0	0	0
Expected stock price volatility	43%	43%	43%	43%	44%	44%
Risk-free interest rate	-0.5%	-0.6%	-0.5%	-0.7%	-0.7%	-0.6%
Expected duration	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%
Fair value	EUR 1.74	EUR 1.39	EUR 1.49	EUR 1.46	EUR 1.51	EUR 1.39

ACCOUNTING FOR SHARE-BASED PAYMENT

The shared-based compensation expense recognized in the income statement as such is given below:

In EUR 000	Years ended 31 December, 2021	2020
Share based compensation	760	1,432
Total	**760**	**1,432**

1.2.24. / DEFINED BENEFIT PLANS

The Defined Benefit plans are 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 2021, the Defined Benefit plans are a net liability and are therefore reported under 'Provisions' in the consolidated statement of financial position.

In EUR 000	Years ended 31 December, 2021	2020
Defined benefit obligation	8,693	6,559
Plan assets	-8,618	-6,973
Total	**75**	**-413**

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**

The principal assumptions used for the purpose of the actuarial valuation are as follows:

	2021
Discount rate	1.26%
Minimum guaranteed interest rate	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:

	2021
Discount rate +0,5%	5
Discount rate -0,5%	-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.

1.2.25. / FINANCIAL LIABILITIES

The financial liabilities can be analyzed as follows:

	Years ended 31 December,	
In EUR 000	**2021**	**2020**
Lease liability	14,133	18,625
Bank borrowings	0	0
Convertible debt	128,151	125,260
Total non-current	**142,284**	**143,885**
Lease liability	5,878	6,615
Bank borrowings	6,000	58
Total current	**11,878**	**6,673**
Total Financial liabilities	**154,163**	**150,558**

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 2021 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 2021 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 2021 EUR 5.9m 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 2021 EUR 0.4m 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). The liability amounts to EUR 128.2m per 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. A straight loan amount of EUR 6.0m has been withdrawn as per 31 December 2021.

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	2015	3,372	S	1.77%	1/12/2021
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, 2021 Minimum lease payments	2021 Present value of minimum lease payments	2020 Minimum lease payments	2020 Present value of minimum lease payments
Lease				
< 1 year	6,490	5,878	7,255	6,615
> 1 and < 5 years	12,755	11,578	15,682	14,171
> 5 years	2,857	2,555	4,842	4,454
Total	**22,103**	**20,012**	**27,779**	**25,239**
Less interests	2,091	0	-2,537	0
Present value	**24,194**	**20,012**	**25,241**	**25,239**

The changes in liabilities from financing activities are summarized in the table below:

In EUR 000	Lease liabilities	Convertible debt	Bank
As per 31 December 2020	**25,240**	**125,260**	**58**
Changes from financial cash flows	-7,031	0	-58
Changes arising from obtaining or losing control of subsidiaries or other business	0	0	0
Changes due to the effect of changes in FX rates	0	0	0
Changes in fair value			
Capitalized interest	0	2,891	0
Additions	1,803	0	6,000
As per 31 December 2021	**20,012**	**128,151**	**6,000**

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.

In EUR 000	Years ended 31 December, 2021	2020
Depreciation expense of right-of-use assets	-5,284	-5,395
Interest expense on lease liabilities	-577	-624
Rent expense - short-term & low value leases	-83	-197
Rent expense - variable lease payments	0	0
Total amounts recognized in profit or loss	**-5,944**	**-6,215**

1.2.26. / TRADE PAYABLES AND OTHER CURRENT LIABILITIES

In EUR 000	As of 31 December, 2021	2020
Trade payables	11,560	13,907
Total trade payables	**11,560**	**13,907**

In EUR 000	As of 31 December, 2021	2020
Provision vacation pay and end-of-year premium & other social debt	8,109	7,394
VAT payable	293	152
Other	43	40
Other current liabilities	**8,445**	**7,587**

The decrease in trade payables is associated with timing of payments made to suppliers.

1.2.27. / DEFERRED INCOME

In EUR 000	Years ended 31 December, 2021	2020
Grants	-	658
Partner income	2,135	983
Total	**2,135**	**1,641**
Current	1,822	1,278
Non-current	313	363

For more details on the contract liabilities, we refer to note 1.2.4. Deferred partner income includes upfront payments from collaboration partners in relation to the strategic licensing, development and commercialization collaborations. The deferred revenue per 31 December 2020 was EUR 1.0m, of which EUR 0.4m was recognized in revenue in 2021 and the remaining balance of EUR 0.6m is still outstanding and included in the deferred revenue balance of 31 December 2021.

	Deferred partner income
As per 31 December 2019	**1,197**
Invoiced	3,369
Recognized in profit or loss	-3,583
As per 31 December 2020	**983**
Invoiced	1,894
Recognized in profit or loss	-742
As per 31 December 2021	**2,135**

1.2.28. / INCOME TAXES

1.2.28.1. / COMPOSITION OF TAX EXPENSE

In EUR 000	Years ended 31 December, 2021	2020
Current income tax	-275	-307
Deferred income tax	32	79
Total	**-243**	**-228**

1.2.28.2. / TAX RECONCILIATION

Tax expenses for the year can be reconciled to the accounting loss as follows:

	Years ended 31 December,	
In EUR 000	2021	2020
Loss before taxes	**-71,715**	**-63,162**
Income tax credit calculated at 25%	-19,685	-15,791
Effect of different tax rates	0	0
Effect of income that is exempt from taxation	-2,367	-2,077
Effect of expenses that are non-deductible in determining tax profit	746	426
Effect of unused tax losses and tax offsets not recognized as deferred tax assets	21,307	17,441
effect of tax credit for research and development	-277	-309
Other	33	82
	-243	**-228**
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	**-243**	**-228**

1.2.28.3. / 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 483.3m (2020: EUR 408.2m). The tax losses of Biocartis NV for EUR 447.4m per 31 December 2021 (2020: EUR 369.8m) in Belgium will not expire as they can be carried forward indefinitely.

1.2.28.4. / RECOGNIZED DEFERRED TAX ASSETS

The Group has R&D tax credit carryforwards in Belgium for a total amount of EUR 1.9m (2020: EUR 1.9m) for which a deferred tax asset of EUR 1.9m (2020: EUR 1.9m) has been recognized as the recognition criteria have been met as from 2014. Per 2021, EUR 0.3m of the total R&D tax credit has been classified as a current asset under 'other receivables'.

1.2.29. / FINANCIAL RISK MANAGEMENT

1.2.29.1. / 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.

1.2.29.2. / 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.

1.2.29.3. / 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 2021 and 2020.

Financial assets include current bank accounts and petty cash. Financial liabilities include trade payables and accruals in foreign currency.

	Years ended 31 December,	
In EUR 000	2021	2020
Liabilities		
USD - United States	2,573	2,762
GBP - Great Britain	3	12
Assets		
USD - United States	99,169	4,416
GBP - Great Britain	2,690	934

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 is not material. On December 31, 2021, if the USD/EUR exchange rate would have increased/decreased by 10%, this would have had a negative/positive impact of EUR 9.0m.

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 2021 there is one customer 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 1.2.25. In addition, the Group also has access to a bank guarantee line of EUR 1.5m of which EUR 1m has been taken up as per 31 December 2021. 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,					
	2021			2020		
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	11,560	11,878	8,445	13,907	6,668	7,587
1-3 years		8,068			10,453	0
3-5 years		138,510			138,718	0
5+ years		2,555			4,460	0
Total	**11,560**	**161,011**	**8,445**	**13,907**	**160,299**	**7,587**

1.2.30. / 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 2021 and 2020.
- 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 2021 and 2020.

Except for the borrowings (financial liabilities, see note 1.2.25), the carrying amount of the financial assets and liabilities approximate their fair values. The borrowings with a carrying amount of EUR 154.2m (2020: EUR 150.6m) have a fair value of EUR 154.2m (2020: EUR 150.6m).

1.2.31. / 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.

1.2.32. / COMMITMENTS

1.2.32.1. / 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 (2021: EUR 1.4m; 2020: EUR 1.0m). The Group had no other material commitments to capital expenditures on 31 December 2021.

1.2.32.2. / OPERATING COMMITMENTS

The Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 11.9m (2020: EUR 8.6m). It is expected that the majority of the commitments will be fulfilled in 2022.

1.2.32.3. / 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.

1.2.32.3.1. / 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', 'Remuneration report'.

1.2.32.3.2. / JOINT VENTURES

In EUR 000	Sales of goods and services	Purchase of good and services	Interest cost	Trade receivables	Trade payables	Financial Debt
31 December 2020	674	154	0	527	154	0
31 December 2019	2789	0	0	646	0	0

Transactions with related parties are made at arm's length. The main transactions relate to product sales towards the Group's joint venture.

1.2.32.3.3. / SUBSIDIARIES

Details of the Company's subsidiaries at 31 December 2021 are as follows:

Name of subsidiary	Principal activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2021	2020
Biocartis NV	Develop and market diagnostic platforms	Generaal de Wittelaan 11 B - 2800 Mechelen (Belgium)	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.

1.2.33. / EVENTS AFTER THE BALANCE SHEET DATE

The below important events occurred after the reporting date:

- *Achievement 2021 key business objectives* – On 10 January 2022, Biocartis announced to have achieved its most recent key business objectives for 2021.
- *Large UK study EGFR testing* – On 25 January 2022, Biocartis announced the publication of a large new study comparing the difference in turnaround time between in-house automated rapid PCR -based EGFR analysis and Next-Generation Sequencing (NGS) by an external laboratory, with a focus on patient health outcome. The study concluded that a dual PCR and NGS testing strategy for stage IV non-squamous, non-small cell lung cancer (NSCLC) patients has the potential to improve care and survival outcomes by providing access to the right test at the right time.
- *Partnership with Ophiomics* – On 8 February 2022, Biocartis announced it had signed an agreement with Ophiomics, a Lisbon (Portugal) based biotech company developing a precision medicine portfolio focused on liver cancer. The collaboration will initially focus on the commercialization of HepatoPredict™, a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation. HepatoPredict™ will be 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.

There were no further important events between 31 December 20201 and the approval date of this annual report.

1.2.34. / RELEVANT STANDARDS AND INTERPRETATIONS PUBLISHED, BUT NOT YET APPLICABLE FOR THE ANNUAL PERIOD BEGINNING ON 1 JANUARY 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)
- FRS 17 Insurance Contracts (applicable for annual periods beginning on or after 1 January 2023, but not yet endorsed in the EU)
- Amendments to IFRS 4 Insurance Contracts – Extension of the Temporary Exemption from Applying IFRS 9 (applicable for annual periods beginning on or after 1 January 2023, but not yet endorsed in the EU)
- Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current (applicable for annual periods beginning on or after 1 January 2023, 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, but not yet endorsed in the EU)
- 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, but not yet endorsed in the EU)
- 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, 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.

2. STATUTORY ANNUAL ACCOUNTS

2.1. / 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).

2.2. / 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.

2.3. / INCOME STATEMENT AND BALANCE SHEET BIOCARTIS GROUP NV

2.3.1. / INCOME STATEMENT

	Years ended 31 December,	
In EUR 000	**2021**	**2020**
Revenues	6,584	6,063
Other operating income	354	308
Total operating income	**6,938**	**6,371**
Services and other goods	-2,651	-2,253
Salaries, social security contributions and pensions	-4,031	-3,562
Other operating expenses	-3	-3
Operating expenses	**-6,685**	**-5,818**
Financial income	776	330
Financial expenses	-35,159	-10,719
Result from continuing operations	**-34,130**	**-9,836**
Income taxes	-3	-7
Net result	**-34,133**	**-9,843**

2.3.2. / BALANCE SHEET

In EUR 000	As of 31 December 2021	2020
Financial fixed assets	422,003	451,216
Non-current assets	**422,003**	**451,216**
Trade receivables	0	0
Other receivables	108,492	61,361
Cash and cash equivalents	9,665	61,731
Transitory accounts	44	67
Current assets	**118,201**	**123,160**
Total assets	**540,204**	**574,376**
Legal share capital	575	575
Share premium	550,289	550,289
Accumulated deficit	-148,045	-113,912
Total equity	**402,819**	**436,952**
Financial debt	135,000	135,000
Non-current liabilities	**135,000**	**135,000**
Financial debt	0	0
Trade payables	562	872
Provision taxes	113	0
Salaries, social security contributions and pensions	924	748
Accrued charges	786	803
Current liabilities	**2,385**	**2,423**
Total equity and liabilities	**540,204**	**574,375**

2.4. / DISCUSSION OF STATUTORY ACCOUNTS

2.4.1. / INCOME STATEMENT

Total operating income in 2021 amounted to EUR 6.9m (2020: EUR 6.4m) and consists mainly of expense recharges to the Biocartis Group NV subsidiaries. Operating expenses recorded in the period under review amounted to EUR 6.7m (2020 EUR 5.8m) and consist of salaries, social security contributions and pensions expenses for EUR 4.0m (2020: EUR 3.6m) and of expenses for services and other goods of EUR 2.6m (2020: EUR 2.3m). Services and other goods mainly consist of recurring general and administrative expenses.

Financial income amounted to EUR 0.8m (2020: EUR 0.3m) 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. On the other hand, financial expenses amounted to EUR 35.2m (2020: EUR 10.7m) and contains an impairment of the investment in the company's subsidiaries and participating interest of EUR 29.7m (see note 2.4.2.1) and interest expenses related to the convertible bond of EUR 5.4 compared to EUR 6.0m in 2020. The financial expenses of 2020 also include a cash payment of EUR 4.3 in connection with the incentivized exercise of conversion rights in relation to EUR 15.0m aggregate principal amount of Bonds.

The net result after taxes for the period ended 31 December 2021 amounts to EUR -34.1m (2020: EUR -9.8m).

2.4.2. / BALANCE SHEET

2.4.2.1. / ASSETS

The financial fixed assets consist of shares in the Biocartis Group NV subsidiaries (Biocartis NV, Biocartis US Inc. and Biocartis S.r.l.) and of the China joint venture and amounts to EUR 422.0m (2020: EUR 451.2m). The decrease in the value of the financial fixed asset is the result of an impairment of the investment in the company's subsidiaries and participating interest of EUR 29.7m.

Other receivables amounted to EUR 108.5m (2020: EUR 61.4m) and mainly relate to receivables on the Biocartis Group NV subsidiaries, mainly related to financial advances. Cash and equivalents amounted to EUR 9.7m per 31 December 2021 (2020: EUR 61.7m). Deferred charges relate to prepaid expenses.

2.4.2.2. / EQUITY

Total equity per 31 December 2021 amounted to EUR 402.8m (2020: EUR 437.0m) and the legal share capital and share premium amount to respectively EUR 0.6m (2020: EUR 0.6m) and EUR 550.3m (2020: EUR 550.3m).

2.4.2.3. / FINANCIAL LIABILITIES

The financial liabilities are related to the convertible bond and amount to EUR 135.0m in 2021 and in 2020.

2.4.2.4. / OTHER LIABILITIES

As per 31 December 2021, trade payables amounted to EUR 0.6m (2020: EUR 0.9m), payables for salaries, social security contributions and pensions to EUR 0.9m (2020: EUR 0.7m) and transitory accounts to EUR 0.8m which mainly includes accrued interests for the interest coupon payment of the convertible bond.

2.4.2.5. / TOTAL ASSETS AND LIABILITIES

Total assets and on the other hand total liabilities amounted per 31 December 2021 to EUR 540.2m (2020: EUR 574.4m).

2.5. / APPROPRIATION OF RESULTS

The statutory accounts of the Company reported a net loss of EUR 34.1m for the year 2020. The Board of Directors proposes to carry forward the statutory net loss of EUR 34.1m of 2021 to the following financial year.

2.6. / GOING CONCERN VALUATION RULES

For the going concern valuation rules, we refer to section 1.2.3.1.

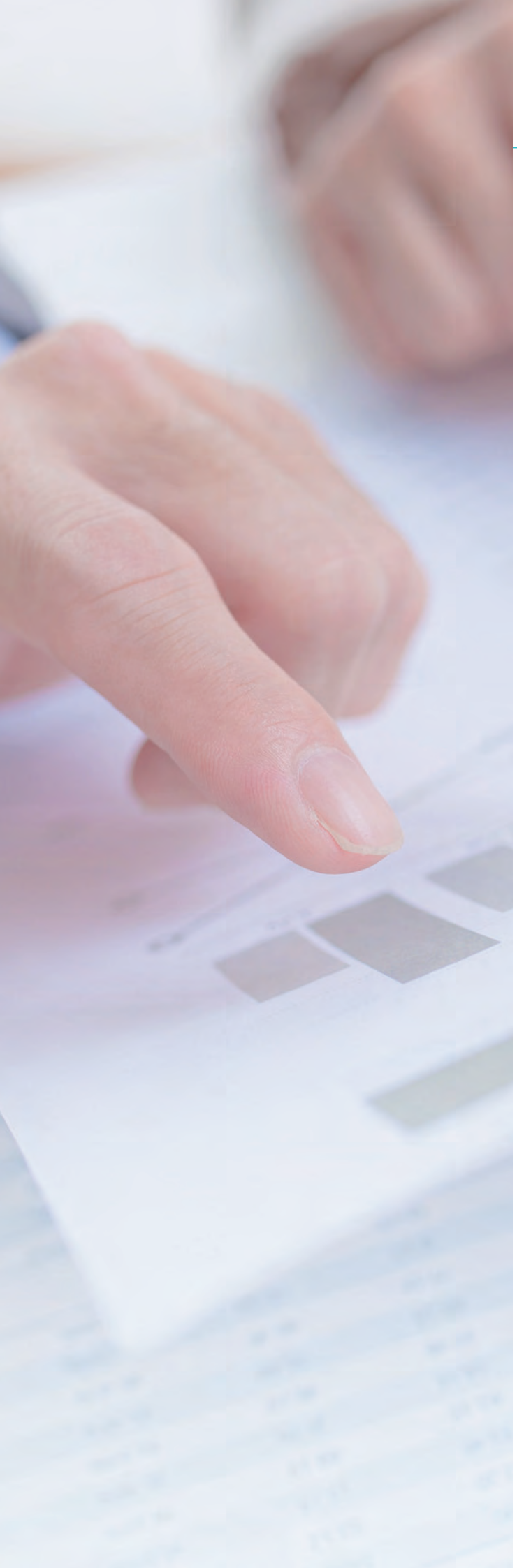
Biocartis Group NV

Statutory auditor's report to the shareholders' meeting for the year ended 31 December 2021 – 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 7 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 2021, 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 142 480 (000) EUR and the consolidated income shows a loss for the year then ended of 71 472 (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 2021 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.

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.

Key audit matters	How our audit addressed the key audit matters
Revenue recognition	
Revenue for the year 2021 amounts to 48 269 (000) EUR and includes:: ▪ Product related revenues (40 486 (000) EUR) including various combinations of instruments and cartridges in stand-alone and multiple element sales agreements, operational reagent rental agreements and rental agreements; and ▪ Collaboration revenues (6 053 (000) EUR) for research and development (R&D) collaboration agreements including simultaneous transactions and multiple element arrangements such as licenses and R&D services which are remunerated via combinations of upfront payments, milestone payments and royalties. The determination of revenue recognition for some of these contracts is complex and requires significant management judgment to determine the nature of the contractual obligations, identify the performance obligations and allocate the transaction price to the performance obligations in accordance with the transfer of the instruments, cartridges, licenses and/or R&D service activities identified in the contract. Furthermore, revenue transactions may be subject to manual adjustments. The company's disclosures about revenue are included in part 5, note 1.2.2.15 'Revenue recognition' and part 5 note 1.2.4 'Revenue' of the consolidated financial statements.	We considered the appropriateness of the Group's revenue recognition principles in accordance with the applicable IFRS standard. We obtained an understanding of the underlying processes and preventive and detective internal controls. We read the relevant agreements to assess whether the company correctly applied the Group's revenue recognition principles and we challenged the reasonableness of the judgements made by management in determining the relevant assumptions utilized in calculating recognized revenue. We tested a sample of transactions of revenue recognized in the income statement for accuracy and appropriate recognition based on the agreements, recognition principles and managements estimates and judgements. We inquired with management and read relevant meeting minutes to ensure completeness of the reported collaboration agreements. We have tested a sample of revenue transactions related to product sales. We have reviewed the manual entries to revenue for accuracy and validity.

Going concern	
In the current period, the group has continued to incur losses that have affected its financial position. The directors of the group need to make a judgment as to whether the group will be able to continue to operate for a period of 12 months after the approval of the current consolidated accounts and assess whether there are material uncertainties related to drafting the consolidated financial statements under going concern. The group's financial position is strongly linked to its revenue and gross margin generation, its access to additional liquidity from current or new investors, the continued availability of its credit lines and its ability to reduce operating expenses and cut back on planned investments in case the prior items are not (timely) realized. Significant judgments and estimates from management are required in order to predict future cash flows and the group's potential to meet all its commitments over the 12-month period following the approval of the current consolidated accounts. The company's disclosure in relation to going concern is in part 5, note 1.2.3.1 Critical accounting estimates, assumptions and judgments.	We have regularly interacted with management and the board on the various initiatives around financing and liquidity and have read relevant minutes to assess completeness of the information. We compared the forecast incorporated in the going concern model with the board approved budget to ensure consistency. We have critically evaluated the assumptions in the going concern model, by comparing projected evolutions to past performance, assessing the year-to-date results and the past forecasting accuracy of management. We have tested the arithmetic integrity of the calculations in the going concern model and have performed sensitivities on management's forecast model to understand its robustness against adverse deviations. We critically assessed the adequacy of the company's disclosures on going concern.

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 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 and other information disclosed in the annual report on the consolidated financial statements, are free of material misstatements, either by information that is incorrectly stated or otherwise misleading. In the context of the procedures performed, we are not aware of such a 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 version of the digital consolidated financial statements included in the annual financial report of Biocartis Group NV as of 31 December 2021 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

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)

CDx is a bio-analytical method designed to assess: (i) whether or not a patient will respond favorably to a specific medical treatment; (ii) what the optimal dose is for a patient; and (iii) whether the patient can expect certain side effects from a medical treatment. Any prescription of a drug with a CDx is based on the outcome of the CDx. CDx tests are also used in the drug development process.

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.

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[64].

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 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.

White Paper

Customer documentation that explains a specific issue and presents Biocartis standpoint on the matter.

Bibliography

(1) The 17 SDG's were developed by the United Nations Development Programme with the objective to produce a set of universal goals that meet the urgent environmental, political and economic challenges facing our world. They came into effect in January 2016 and are considered to be the guiding universal sustainability framework. Source: http://www.undp.org/content/undp/en/home/sustainable-development-goals/background/

(2) See www.globalreporting.org

(3) Average FTE or workforce equals the sum of the day-to-day FTE divided by the number of days. This average FTE or workforce is calculated on calendar year basis (January-December) and includes all fixed employees, excluding temporary staffing and consultants

(4) During Q1 2021, the Idylla™ platform, the Idylla™ BRAF Mutation Test (CE-IVD) and the Idylla™ EGFR Mutation Test (CE-IVD) completed registration in Russia, and the Idylla™ MSI Test (CE-IVD) completed registration in Taiwan, as such expanding the commercial footprint for Biocartis' IVD medical devices. Post the reporting period, additional registrations were also completed in Taiwan

(5) SeptiCyte® RAPID is 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 a local Biocartis representative

(6) The Idylla™ Instrument and Idylla™ Console have been exempted by the US FDA since 12 July 2017 and as such are not subject to 510(k) notification requirements prior to being placed on the US market for in vitro diagnostic use with US FDA approved or cleared assays

(7) Immunexpress Pty Ltd ('Immunexpress') is a Seattle-based molecular diagnostic company focused on improving outcomes for suspected sepsis patients

(8) 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

(9) EGFR or 'Epidermal growth factor receptor' mutations are the second most common oncogenic driver in non-small cell lung cancer (NSCLC)

(10) Arcila ME, Yang S-R, Momeni A, Mata DA, Salazar P, Chan R, Elezovic D, Benayed R, Zehir A, Buonocore DJ, Rekhtman N, Lin O, Ladanyi M, Nafa K, Ultra-Rapid EGFR Mutation Screening Followed by Comprehensive Next-Generation Sequencing: A Feasible, Informative Approach for Lung Carcinoma Cytology Specimens with a High Success Rate., JTO Clinical and Research Reports (2020), doi: https://doi.org/10.1016/j.jtocrr.2020.100077., available online 18 July 2020; Arcila ME et al., Rapid EGFR Mutation Detection Using the Single-Institution Experience of 1200 Cases Analyzed by an In-House Developed Pipeline and Comparison with Concurrent Next-Generation Sequencing Results Idylla™ Platform, J Mol Diagn 2020, Published on 23 December 2020, 1-12; https://doi.org/10.1016/j.jmoldx.2020.11.009

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(17) Accès aux tests moléculaires EGFR, RAS et BRAF /Résultats d'une enquête dans 5 régions françaises, appui à la décision, INCa, janvier 2016

(18) CAGR = Compound Annual Growth Rate. Source: MarketsandMarkets, Molecular Diagnostics Market worth $31.8 billion by 2026

(19) Source : IMARC Group, Oncology Molecular Diagnostics Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2021-2026

[20] Company sources on Total Addressable Market (TAM) calculations.

[21] 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

[22] Markets and Markets 2 Paoli et al. Crit Care Med (2018): 46: 1889-1897 and https://journals.lww.com/ccmjournal/Fulltext/2020/03000/Sepsis_Among_Medicare_Beneficiaries__3__The.4.aspx

[23] 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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(43) Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey

(44) 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

(45) Based on RTqPCR analysis, combined with an advanced machine learning algorithm

(46) 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

(47) NPV (Negative Predictive Value) > 95%

(48) And some European countries

(49) Arcila ME, Yang S-R, Momeni A, Mata DA, Salazar P, Chan R, Elezovic D, Benayed R, Zehir A, Buonocore DJ, Rekhtman N, Lin O, Ladanyi M, Nafa K, Ultra-Rapid EGFR Mutation Screening Followed by Comprehensive Next-Generation Sequencing: A Feasible, Informative Approach for Lung Carcinoma Cytology Specimens with a High Success Rate., JTO Clinical and Research Reports (2020), doi: https://doi.org/10.1016/j.jtocrr.2020.100077., available online 18 July 2020; Arcila ME et al., Rapid EGFR Mutation Detection Using the Single-Institution Experience of 1200 Cases Analyzed by an In-House Developed Pipeline and Comparison with Concurrent Next-Generation Sequencing Results Idylla™ Platform, J Mol Diagn 2020, Published on 23 December 2020, 1-12; https://doi.org/10.1016/j.jmoldx.2020.11.009

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(52) On 5 April 2017, two new EU regulations on medical devices were adopted: the regulation on medical devices and the regulation on IVD medical devices, both entering into force on 25 May 2017 with a transition period of three years for the regulation on medical devices (May 2020) and five years for the regulation on IVD medical devices (May 2022)

(53) US FDA, https://www.fda.gov/

(54) On 11 July 2017, the US FDA published a final list of devices exempted from 510(k) premarket notification requirements, which included the product code applicable to the Biocartis Idylla™ Instrument and Idylla™ Console. Consequently, Biocartis' Idylla™ Instrument and Idylla™ Console were no longer subject to 510(k) notification requirements prior to being placed on the US market for in vitro diagnostic use with FDA approved or cleared assays. All other US 510(k) requirements, including current Good Manufacturing Practices (cGMP) and vigilance reporting, remain in effect

(55) Source: MedTech Europe, https://www.medtecheurope.org/news-and-events/default/funding-and-reimbursement/

(56) Source: NILA USA, https://www.nila-usa.org/nila/PAMA.asp

(57) Source: Pacific Bridge Medical, https://www.pacificbridgemedical.com/publication/ivd-registration-reimbursement-china/

(58) Source: Europe, https://ec.europa.eu/info/policies/justice-and-fundamental-rights/gender-equality/equal-pay/gender-pay-gap-situation-eu_en and https://www.pewresearch.org/fact-tank/2021/05/25/gender-pay-gap-facts/ , last consulted on 6 January 2022

(59) Employee with direct reports

(60) 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

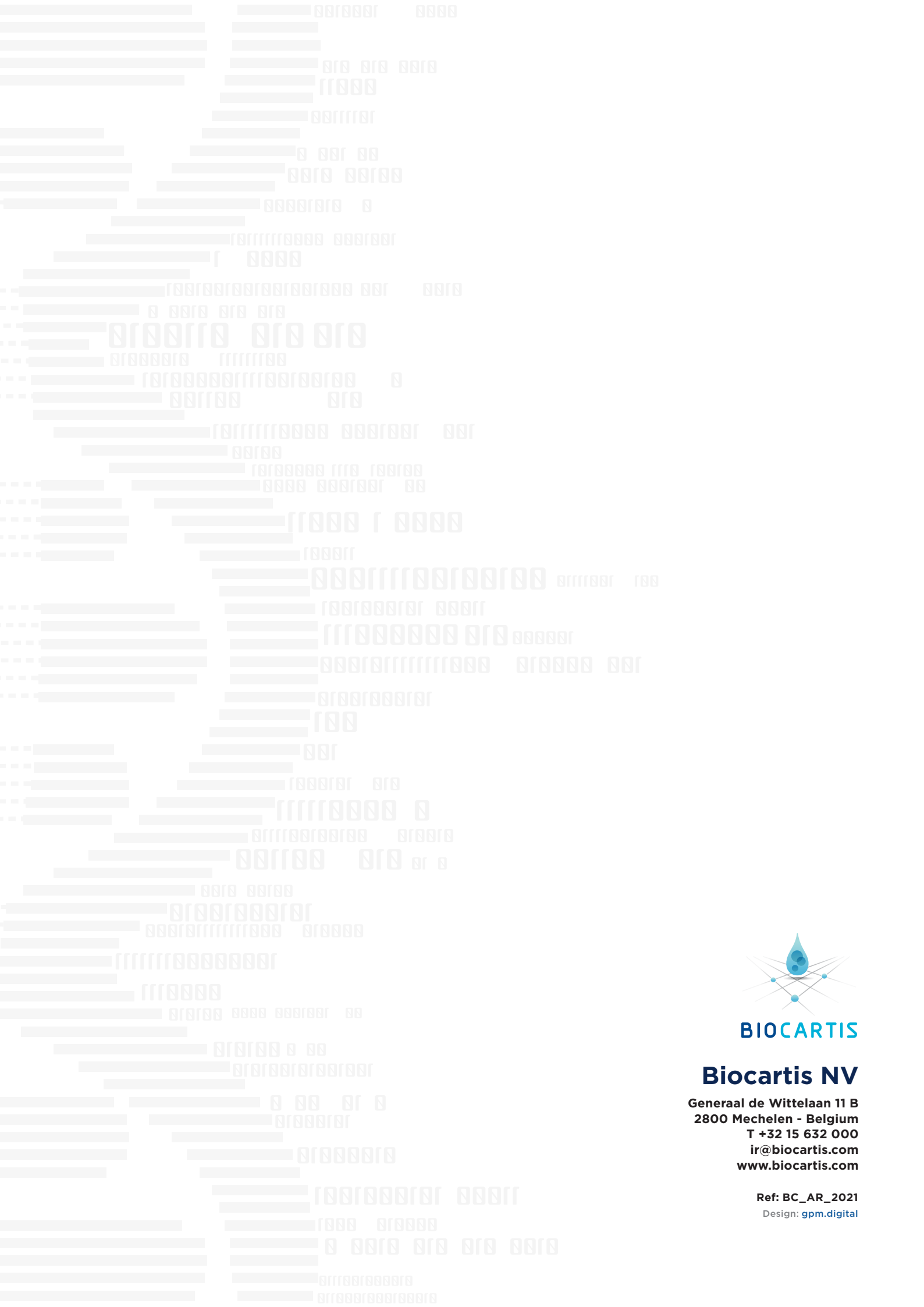
in electrical and electronic products (known as EEE). Source: www.rohsguide.com

(61) 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

(62) REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and is a European Union regulation dated 18 December 2006

(63) This pilot project, which runs until the end of 2022, is being carried out in consultation with the Flemish Energy Regulator and is supported by Flanders Innovation and Entrepreneurship Agency (VLAIO) and the Flemish energy cluster FLUX50. The first pilot measurements were started in 2020 in order to be able to proceed to the installation of, among other things, the 1,2 MWp photovoltaic installation, EV charging and energy storage

(64) 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



BIOCARTIS

Biocartis NV

Generaal de Wittelaan 11 B
2800 Mechelen - Belgium
T +32 15 632 000
ir@biocartis.com
www.biocartis.com

Ref: BC_AR_2021
Design: gpm.digital