BIOCARTIS

# ANNUAL REPORT 2020

# PART 1/ INTRODUCTION



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# PART 1/ INTRODUCTION

BIOCARTIS' MISSION IS TO OFFER

# RAPID & EASY

MOLECULAR DIAGNOSTICS SOLUTIONS AIMED AT ENABLING **FASTER & MORE ACCURATE** TREATMENT DECISIONS FOR PATIENTS ACROSS THE GLOBE


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

## ABOUT THIS REPORT

The board of directors of Biocartis Group NV (the 'Company') is responsible for the contents of this document and declares that, having taken all reasonable care to ensure that such is the case, the information contained in this Biocartis annual report 2020 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.

In defining its initial sustainability disclosures, Biocartis has taken into account the Sustainable Development Goals[1] (SDG) and the Global Reporting Initiative (GRI) guidelines[2]. The SDG framework includes 17 goals which were developed by the United Nations Development Program in January 2016 and are considered to be the guiding universal sustainability framework. The GRI guidelines represent the global reference for sustainability reporting[3]. The SDG framework places more emphasis on how corporations organize and *manage* their activities to contribute to a more sustainable world, whereas the GRI framework focuses mainly on how to *report* on a company's impact. The chapter 'sustainability' in this report provides information on how sustainability is embedded in Biocartis' core activities, as well as how Biocartis acts responsibly as a company with the social and environmental resources it uses.

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 2020 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 2020 and 31 December 2020. An overview of the securities legislation and listed company reporting requirements can be found on the Belgian Financial Authorities' website, www.fsma.be.

## ABOUT BIOCARTIS

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

## FORWARD-LOOKING STATEMENT

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

## USE OF THE IDYLLA™ TRADEMARK, LOGO AND PRODUCT 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.

## 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
CEO

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Herman Verrelst
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Christian Reinaudo
Chairman of the Board of Directors

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# 1.1. MESSAGE FROM THE CHAIRMAN AND THE CEO

*"2020 was an extraordinary year, to say the least. The pandemic deprioritized and disrupted cancer care globally. Patient access to hospitals was significantly restricted throughout almost the entire year and customer prospection was severely hampered. Nevertheless, we showed resilience and delivered on our pre-pandemic outlook. Oncology volumes continued to grow, mostly in the US, but also in Europe, and the versatility of Idylla™ allowed the rapid rollout of a pandemic response test menu that alleviated the pressure on oncology testing volumes. Furthermore, we continued to expand our global Idylla™ ecosystem, attracted new partners and made significant operational progress on our path towards continued growth.*

*We look ahead with confidence and start 2021 with a better than expected cash position that we plan to put at work to accelerate test menu expansion and diversification in a year that will again be marked by continued impact of the pandemic. We are determined to serve and build on the undebated need for rapid response testing in an overburdened healthcare system, convinced that we are very well equipped to deliver on our customers' needs in oncology as well as in infectious diseases."*

## CONTINUED GROWTH THROUGH AGILITY AND RESILIENCE IN PANDEMIC TIMES

Despite the global pandemic, we grew commercial cartridge volumes by 31% and placed 335 new Idylla™ instruments. We delivered on our pre-pandemic outlook in unprecedented market circumstances: global lock-down measures significantly restricted access to hospitals throughout almost the entire year and severely hampered our sales activities. Nevertheless, oncology volumes continued to grow and our newly developed Idylla™ SARS-CoV-2 Test kept us on track. In the US, we tripled commercial cartridge volumes compared to 2019. In Europe, sales volumes remained very resilient throughout the entire year. In distributor markets, that were particularly hit by the pandemic, we also managed to grow cartridge volumes, except in those countries where the pandemic impact was compounded by a significant weakening of the local currency versus the euro. Overall, we came out of this pandemic year in a position of strength thanks to our agility and resilience as an organization, and as a team.

## STRATEGIC EXPANSION INTO INFECTIOUS DISEASES WITH A PANDEMIC RAPID RESPONSE MENU ON IDYLLA™

More than ever, the pandemic has demonstrated that the pressing need for rapid and easy diagnostic testing. We helped find solutions to our customers' high testing demand during this pandemic with the development of a pandemic rapid response test menu on Idylla™. The Idylla™ SARS-CoV-2 Test yielded strong demand especially in the US but also in Europe, where the CE-IVD version of the Idylla™ SARS-CoV-2 Test was launched on 10 November 2020. Together with SeptiCyte® RAPID on Idylla™, released as CE-IVD on European markets on 6 October 2020, the Idylla™ pandemic test menu was ideally positioned to alleviate the pressure on intensive care units (ICUs) , and is expected to drive further growth in 2021.

## GROWING THE PARTNER BUSINESS MODEL

Numerous new partners strengthened the Idylla™ ecosystem last year. On the oncology side, we were particularly proud to expand the partnership with lung cancer targeted therapy leader AstraZeneca to, amongst others, the area of liquid biopsy testing. The FACILITATE[4] study[5], performed under the framework agreement with AstraZeneca, was selected for presentation at the renowned ESMO Virtual Congress in September 2020 and concluded that Idylla™ reduced turnaround time by more than a week versus reference methods, allowing earlier patient management decisions. Another great milestone was the expansion of our partnership with BMS to now also pursue the registration of the Idylla™ MSI test as a CDx test in metastatic colorectal cancer in China. Early November, we also marked our entry in the domain of thyroid cancer with GeneproDx, a Chile-based MDx company with who we joined forces to develop an Idylla™ version of their novel genomic test ThyroidPrint®. This test helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant. Together we aim to make this test available to laboratories and hospitals around the world, to help address this high clinical unmet need in thyroid patients. On the infectious diseases side, we strengthened our partnership with LifeArc and also with Immunexpress who now also rely on us to commercialize SeptiCyte® RAPID on Idylla™ in Europe. 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 ICUs.

## IDYLLA™ AS THE UNIQUE PLATFORM FOR DUAL USE

Focused on the specific needs of sepsis and COVID-19 testing in acute settings, the pandemic test menu we put together again demonstrated Idylla™'s uniqueness and versatility, providing speed and simplicity on one single platform to address the customers' needs in both oncology and infectious disease testing. Thanks to the Idylla™ pandemic test menu, we managed to get a first foothold of infectious disease testing customers in Europe and the US. In November, this set the tone for a strategy update during our Capital Markets Day event. In infectious diseases, we will build a menu focused on rapid triage and therapy selection of critically ill patients in acute settings. This menu will be based on the further development of the existing Idylla™ SARS-CoV-2 Test and the SeptiCyte® RAPID on Idylla™ as well new tests such as the Idylla™ Endpoint Test and the development of syndromic panels, one of the fastest growing MDx segments, on Idylla™. In oncology, which remains our core business, we reaffirmed our mission to help revolutionize the lung cancer testing workflow bringing numerous advantages of Idylla™ first-line testing versus traditional workflows that line up multiple testing methods, including NGS, all of which are slow and require large quantities of tissue that is often scarce. We also gear up to provide further evidence of the pan-cancer applicability of our oncology menu, for example for MSI testing, and we expressed the intent to develop new tests in endometrium, brain and thyroid cancer.. We will innovate the development process of new tests through our new Idylla™ FLEX technology. Without compromising the ease-of-use of Idylla™, it is designed to deliver tests at reduced costs and lead times, while offering the customer the potential to customize and even personalize future oncology assays, which will give us an avenue into the vast market of molecular surveillance monitoring. As such, Idylla™' will cover a broad need for molecular testing supporting clinical decisions in diagnosis, therapy selection, on-therapy monitoring and post-therapy recurrence monitoring.

## TOWARDS THE LARGEST MENU IN RAPID ONCOLOGY MDx TESTING

Today, we already have an outstanding menu in rapid oncology MDx testing, and our pipeline of new Idylla™ tests is expected to grow our total addressable market from 4m to over 10m tests per year. The unique combination on Idylla™ of fast time- to-result, ease of use, high and stable performance and sample versatility offers an opportunity to expand in other areas such as infectious diseases and will culminate in an unrivaled menu.

The year 2020 was undeniably challenging, but we came out more agile and more resilient and are ready to make 2021 a success. Together with our trusted customers, partners, employees, shareholders and other stakeholders, we look forward to making a difference for patients across the world by establishing Idylla™ as the go-to platform for dual use in oncology and infectious diseases.

Yours sincerely,

Herman Verrelst
CEO

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Herman Verrelst
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Christian Reinaudo
Chairman of the Board of Directors

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# 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.

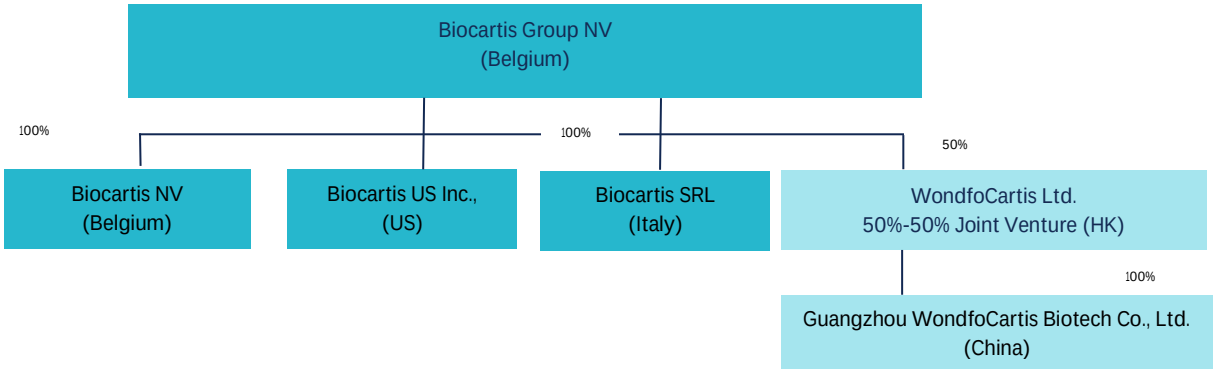
Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample, in virtually any setting, allowing fast and effective treatment selection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

LISTED ON EURONEXT BRUSSELS, TICKER BCART
HEADQUARTERED IN BELGIUM (MECHELEN)
COMMERCIALLY ACTIVE IN +70 COUNTRIES
366 EMPLOYEES[6]
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.

- 2007: Biocartis was founded in Switzerland.
- 2010: Acquisition of the 'Apollo' platform (now Idylla™) from Koninklijke Philips NV.
- 2011: R&D activities moved to Mechelen (Belgium).
- 2012: Awarded '2012 Technology Pioneer Award' by the World Economic Forum.
- 2013: Biocartis' MDx platform is named Idylla™.
- 2014: Commercial launch of the Idylla™ platform (CE-IVD) and its first Idylla™ BRAF Mutation Test (CE-IVD). Establishment of Biocartis Group NV as the group's new holding company and move of most of the company activities to Belgium.
- 2015: Biocartis listed on Euronext Brussels through an IPO in April 2015.
- 2016: First pharma partnership agreements signed with Merck KGaA (Darmstadt, Germany) and Amgen.
- 2017: Biocartis US, Inc. established in the US. Content partnership agreements signed with LifeArc (a medical research charity) and ETPL (the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research). Biocartis signs its first CDx agreement for Amgen's drug Vectibix® (panitumumab).
- 2018: Partnership agreement signed with Immunexpress for the development and commercialization of Immunexpress' SeptiCypte© RAPID on Idylla™. Partnership agreement signed with AstraZeneca. Establishment of a joint venture with Wondfo[7], a fast growing diagnostics leader in China.
- 2019: New direct go-to-market strategy for the US market. Distribution partnership agreement signed with Nichirei Biosciences for Japan. Entry into immuno-oncology with two new partnerships, with Bristol-Myers Squibb Company (NYSE: BMY) and Kite Pharma, Inc., a Gilead Company (NASDAQ: GILD)

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 2020 is as follows:




The headquarters of Biocartis Group NV are located in Mechelen, Belgium. The Company was incorporated on 24 November 2014 and is registered in Belgium under enterprise number 0505.640.808 (register of legal entities Antwerp, division Mechelen). 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 operates a US office grouping commercial, regulatory and clinical activities in Jersey City (New Jersey, US). 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. STRATEGY

## 1.3.1. THE MARKET OF 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[8] 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 them out to specialized centers, where samples are batched in order to optimize costs[9]. 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[10]. 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[11]. 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.

The worldwide COVID-19 pandemic has created an increased demand for molecular diagnostic testing. The global molecular diagnostics market is now expected to grow and reach USD 19.9 bn by the year 2027, reflecting a post COVID-19 CAGR[12] of 9.8% over the analysis period 2020 through 2027[13].
The high prevalence of infectious diseases primarily drives growth in this market, as well as other factors such as various types of cancers, increasing awareness and acceptance of personalized medicine, the use of companion diagnostics, growth in the biomarker identification market and advancements in molecular techniques.

## 1.3.2. METHODS AND TECHNOLOGIES IN MOLECULAR DIAGNOSTICS

Over the years, a variety of molecular diagnostic testing methods have been utilized in clinical diagnostic laboratories in the analysis of patient samples. Polymerase Chain Reaction or PCR, the technology on which Idylla™ is based, remains the most commonly used technique. It's a fast and inexpensive technique, replicating DNA molecules into millions of copies, thereby amplifying an attached label such that it becomes visible and allows scientists to study it in detail.

Furthermore, Biocartis is increasingly porting RNA based tests on its Idylla™ platform, such as the Idylla™ SARS-CoV-2 Test. RNA expression or gene signature tests are based on the differential mRNA expression levels that are calculated into a clinically meaningful score, namely the 'signature' that guides patient management decisions. The technology, including the complex sample preparation yielding RNA that is prone to degradation, has now been validated in Idylla™ and can be applied to hundreds of potential applications.

Another increasingly popular technique the past years is next-generation sequencing or **NGS**, which is a technique that uses a single format where a wide range of biological phenomena can be tested, such as, mRNA expression and methylation status. With NGS, the time between tumor sampling and the availability of results for all markers can easily run into multiple weeks. As the full genome is sequenced, NGS requires the use of different systems and many laboratories do not have these. As a consequence, samples are often shipped to external service providers, which also takes precious time of an anxious patient in desperate need of timely treatment. For many laboratories, the implementation and validation of an NGS workflow is technically too challenging. Additionally, the need for bioinformatics to generate reliable results and to interpret the massive amount of data is a big hurdle to routine use. Finally, another complexity is the fact that NGS, often in combination with other techniques consumes a significant amount of the tumor sample, which is rather scarce in certain types of cancer, such as non-small cell lung cancer. Most biopsies are small and heterogeneous and the lack of sample quality and quantity may lead to invalid results for a significant portion of the samples.

With Idylla™, customers get access to actionable markers in a comprehensive results format, offering speed, simplicity and reliable performance. Furthermore, Idylla™ only requires minimal amounts of sample so that first-line testing on Idylla™ for fast actionable results does not exclude more comprehensive NGS to maximize a patient's options and explore eligibility for clinical trials or experimental therapy. Memorial Sloan Kettering Cancer Center in New York, one of the largest NGS centers in the world, has performed several studies comparing EGFR testing on Idylla™ and NGS, demonstrating that Idylla™ allows rapid first assessment of the most common EGFR mutations preceding NGS.

## 1.3.3. OUR STRATEGY

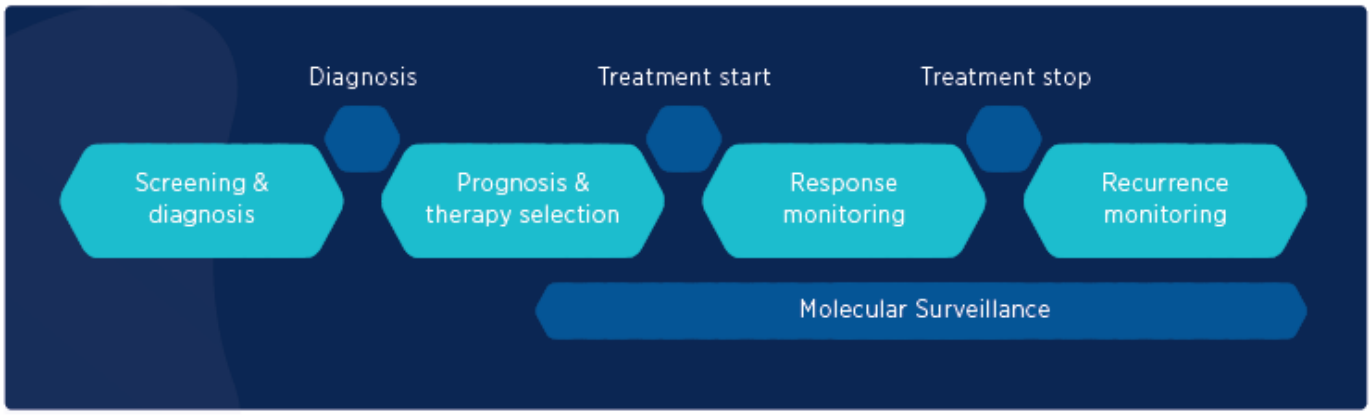
Biocartis is focused on executing a profitable growth strategy that builds value in the MDx market by making personalized medicine an everyday reality.
The worldwide COVID-19 pandemic in 2020 clearly showed the undebated value of high quality, rapid and easily accessible diagnostic testing. Unfortunately, it also showed that MDx testing today still suffers from many inefficiencies, which delay results and impact patients. The Idylla™ platform provides a unique solution in this context: 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 one single unique and versatile platform that can be used both in oncology and infectious diseases.
Since 2017, Biocartis has mainly focused its efforts on developing and commercializing oncology tests, which resulted in a solid on-market menu of proprietary Idylla™ oncology tests in colorectal cancer, lung cancer and melanoma, and ongoing developments in breast and thyroid cancer. The Idylla™ platform offers unique features in oncology allowing to accelerate in this field. Next to ongoing efforts to have a complete lung cancer menu, we see opportunities in pan-cancer applications of our tests and expansion opportunities in new areas including endometrium, brain and hematological cancers.
The current pandemic market conditions now also bring opportunities to grow in infectious diseases and as such accelerate the expansion of our installed base, offering this market the advantage of Idylla™'s speed and simplicity, together with the dual use for oncology testing.

### ONCOLOGY STRATEGY

The oncology MDx market continues to grow rapidly due to a rise in global incidence of cancer, an increased decentralization of testing and an increased need for molecular testing as more and more targeted therapies become available. Within oncology, the Idylla™ platform is uniquely positioned in this market:

1. Idylla™ enables to combine the performance of lab reference testing with the benefits of point-of-care testing, allowing molecular testing in virtually any lab setting
2. Idylla™ enables the reduction of time-to-results from weeks to hours
3. Idylla™ offers fully automated sample-to-result capabilities for both solid and liquid biopsies

Positioned within the patients' cancer treatment continuum, the cancer patient gets confronted with cancer diagnostic testing at several moments. First, at potential screening before diagnosis, second, during diagnosis and staging itself, third, after diagnosis to determine the right therapy, and fourth, to follow up on the efficiency of the therapy. Also when monitoring potential tumor residue in the body and, if needed, to start up therapy again.




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; partnerships where an already validated, proprietary, high-value oncology gene signature test is 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.

The diversity of Biocartis' oncology strategic roadmap is further supported by Biocartis' ambition to enter new high-growth oncology segments, both in its existing as well as new oncology areas.

- Existing oncology areas: development of additional Idylla™ tests in lung cancer and maximize the use of its existing products through the expansion of the intended use of the current Idylla™ oncology product portfolio. An example here is the potential use of the Idylla™ MSI Assay beyond colorectal cancer, based on the clinical value of MSI testing for endometrial cancer, gastric cancer, ovarian cancer and pancreatic cancer[14]
- New oncology areas: development of new Idylla™ tests in the domains of brain, breast and endometrium cancer and in the field of hematology.

Supported by the above-mentioned diversification strategy in oncology, in combination with geographical expansion, Biocartis aims to build the largest menu in rapid oncology molecular diagnostic testing in the years to come. More information on the Idylla™ test menu can be found in the Biocartis corporate presentation on the Biocartis investor website.

## INFECTIOUS DISEASE STRATEGY

The pandemic context in 2020 brought about a higher need for decentralized molecular diagnostic testing, which matches Biocartis' ambition to more rapidly build an installed base in acute settings such as the intensive care unit (ICU). The current Idylla™ pandemic menu is geared towards:

- COVID-19: The Idylla™ SARS-CoV-2 Test (CE-IVD) is targeted to help healthcare providers manage the pandemic through rapid and easy testing of individuals with flu-like symptoms;
- Sepsis: Sepsis is a field with high unmet needs and where current markers such as blood cultures are not rapid or are non-specific and there is an increased risk in pandemic times. The SeptiCyte® RAPID on Idylla™ is a host-response test that distinguishes sepsis from non-infectious systemic inflammation in patients. When used together, this combined testing solution on Idylla™ has the unique potential to identify patients with severe disease, as recent data[15] indicate that sepsis is the most frequently observed complication in COVID-19[16].

As such, this 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 platform capabilities can bring clear unique benefits in the area of syndromic panel testing, one of the fastest growing MDx segments.

## LEVERAGING THROUGH PARTNERSHIPS

A key strategic element for Biocartis is to accelerate its menu expansion through partnerships:

- Partnerships with pharmaceutical and biotech companies: Focusing on the (joint) development and registration of CDx tests on the Idylla™ platform. This is expected to allow Biocartis to reach faster commercial adoption as well as high market shares. Biocartis' partners are expected to benefit from an increased number of eligible patients for their targeted therapies driven by the key benefits of the Idylla™ platform: fast turnaround times, thereby reducing competition with therapies not requiring a biomarker and higher penetration of the potential market due to higher access to testing with Idylla™.
- Partnerships with diagnostic test content partners: Aiming at transfer of proprietary biomarker panels of partners, in most cases already developed and clinically validated, to the Idylla™ platform. By doing so, Biocartis adds proprietary content to its menu that will further increase the attractiveness of the Idylla™ test menu. Driven by its unique features, partners are expected to benefit from an accelerated global roll-out of their content, cost efficiencies and faster customer adoption since no platform education is needed.
- Partnerships with diagnostic test development partners: Targeting the development of Idylla™ tests, predominantly in collaboration with IVD developers. This allows Biocartis to reduce initial test menu development costs while benefiting from the collective knowledge of its development partner. Through such collaborations, partners can further contribute to medical innovation as well as benefit from knowledge sharing and building.

More information on the Idylla™ test menu can be found in the Biocartis corporate presentation on the Biocartis investor website.

# PART 2/ PERFORMANCE 2020

# 1. KEY ACHIEVEMENTS IN 2020

- Installed base of 1,581 Idylla™ instruments and 230k cartridges sold in 2020, +31% versus 2019
- EUR 31.9m product revenues (+32% compared to 2019)
- Operating income increased with 47% to EUR 55.6m
- Strengthening the oncology business through the expansion of the partnerships with AstraZeneca and Bristol-Myers Squibb and a new partnership with GeneproDx[17]
- Partner funded expansion of the Idylla™ infectious diseases test menu, together with Immunexpress, LifeArc and Endpoint Health[18]
- Infectious diseases strategy sparked by the launch of the first pandemic Idylla™ test menu, consisting of the market release of the SeptiCyte© RAPID test on Idylla™ (CE-IVD)[19] and the Idylla™ SARS-CoV-2 Test[20] (CE-IVD)
- US FDA 510(k) submission, led by Immunexpress, of the SeptiCyte® RAPID test on Idylla™ completed in December 2020
- 366 employees[6], 33 nationalities & balanced gender diversity 51% men and 49% women

# 2. BUSINESS REVIEW 2020

## COMMERCIAL HIGHLIGHTS

- *Global* – Despite the global pandemic, the number of commercial cartridges sold in 2020 grew by 31% to 230k, from 175k in 2019. After a strong first quarter of 2020, commercial cartridge volumes in oncology were significantly impacted by the disruption and de-prioritization of global cancer care. Restricted access to hospitals also hampered new customer prospection and slowed down new Idylla™ instrument placements in the first half of the year. Testing volumes in oncology started to recover towards the end of Q2, but the global surge of COVID-19 cases in Q4 ultimately tempered the year-over-year growth in oncology. To bridge the shortfall in oncology and to respond to its customers' need for COVID-19 testing, Biocartis developed the Idylla™ SARS-CoV-2 Test. Strong demand for this test in Q4, especially in the US, enabled the Company to meet its pre-pandemic guidance with 31% growth in commercial cartridge volumes and the placement of 335 new Idylla™ instruments. As per year-end, the total Idylla™ installed base amounted to 1,581 Idylla™ instruments[21].
- *Europe* – Sales in Europe proved to be very resilient throughout 2020. After the slow-down in Q2 2020, both cartridge volumes and instrument sales were rapidly tracking pre-pandemic expectations. When growth slowed down again in Q4 as a direct result of renewed lock-down measures across large parts of Europe, lagging sales in oncology were supplemented by demand for the Idylla™ SARS-CoV-2 Test, CE-IVD marked since 10 November 2020. Together with SeptiCyte® RAPID[19] on Idylla™, released as CE-IVD in European markets on 6 October 2020, the Idylla™ SARS-CoV-2 Test is ideally positioned to alleviate the pressure on intensive care units (ICUs) and is expected to drive further growth in 2021.
- *US* – After strong growth in Q1 2020, demonstrating the continued success of the direct US sales strategy, sales in the US slowed down due to the global pandemic. Cartridge volumes in oncology nevertheless grew by 20% year-over-year. Thanks to additional strong demand for the Idylla™ SARS-CoV-2 Test, US commercial cartridge volumes tripled compared to 2019. New Idylla™ instrument placements in the US also increased year-over-year and accounted for one third of total placements.
- *Distributor markets*[22] – In 2020, several countries that are served through distributors were hit specifically hard by the pandemic, often compounded by a significant weakening of local currency versus the Euro. As a result, declining volumes in amongst others Latin-America, India, Pakistan and Turkey outweighed continued growth in other parts of the world. New market authorizations were obtained for the Idylla™ MSI Test in Colombia, Canada, Malaysia and Singapore, and for the Idylla™ EGFR Mutation Test in Argentina during H1 2020. End of October 2020, medical device registration certificates were issued for the Idylla™ platform and the Idylla™ EGFR Mutation Test by the Taiwan FDA. Post the reporting period, in February 2021, the Idylla™ platform, the Idylla™ BRAF Mutation Test (CE-IVD) and the Idylla™ EGFR Mutation Test (CE-IVD) completed registration in Russia, as such expanding the distribution network for Biocartis' IVD medical devices.
- *China commercialization* – In 2020, Wondfo-Cartis, the joint venture with Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, took further steps towards establishing local manufacturing capabilities. Concerning the registration of products, a CDx[23] partnership was announced on 5 March 2020 with Bristol Myers Squibb Company (BMS), aimed at pursuing the registration in China of the Idylla™ MSI Test as a CDx test in metastatic colorectal cancer (mCRC). First product registrations in China are to be expected earliest by 2022. Compliance testing of the Idylla™ Instrument and Console with the China NMPA was successfully completed in January 2021.
- *Japan commercialization* – Continued progress in the in vitro diagnostic ('IVD') registration preparations for the Idylla™ assays, paving the way to commercialization with Nichirei Biosciences in Japan. First Idylla™ assays registrations in Japan are expected in the course of 2022.

## TEST MENU AND PARTNERSHIP HIGHLIGHTS

- *Oncology:* In 2020, Biocartis further strengthened its footprint in oncology activities through progress in its test menu and the launch of several new and expanded partnerships:
  - Partnership AstraZeneca – On 22 January 2020, Biocartis announced a master collaboration agreement with lung cancer targeted

therapy leader AstraZeneca aimed at rapid and easy testing and expanded its partnership to, amongst others, the area of liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay.

- Partnership Bristol-Myers Squibb in China – On 5 March 2020, Biocartis announced the expansion of its partnership with Bristol-Myers Squibb Company, to now also pursue, after the US, the registration of the Idylla™ MSI test as a CDx test in mCRC[24] in China.
- Idylla™ GeneFusion Assay – Biocartis made progress in its oncology test menu, more specifically in the lung cancer domain with the development of the Idylla™ GeneFusion Assay, for which a EUR 1.2m grant from VLAIO was announced on 30 September 2020.
- Partnership Exact Sciences – On 29 October 2020, Biocartis and Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation) announced to have agreed to terminate their collaboration[25]. As part of a termination settlement, Genomic Health, Inc. agreed to pay USD 12m to Biocartis and licensed certain rights and transferred certain assets to Biocartis.
- Partnership GeneproDx – On 3 November 2020, Biocartis announced to have signed 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. 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[26].
- Partnership Amgen – Motivated by a strong demand from partners and customers, Biocartis gave priority to the development of the Idylla™ SARS-CoV-2 Test and re-allocated resources accordingly. Consequently, Biocartis delayed the US FDA submission of the PMA (Pre-Market Approval) application for the Idylla™ RAS tests.

- *Infectious diseases:* Against the backdrop of the pandemic, in 2020, Biocartis paved the way to the gradual build-out of its infectious disease test menu on Idylla™:
  - Partnership Immunexpress – In March 2020, the agreement with Immunexpress was expanded with a co-commercialization agreement for the SeptiCyte® RAPID test for use on the Idylla™ platform. End of December 2020, the 510(k) submission with the US FDA of the SeptiCyte® RAPID on Idylla™, led by Immunexpress, was completed.
  - Idylla™ SARS-CoV-2 Test – In August 2020, Biocartis submitted a notification of intent to distribute and request for 'Emergency Use Authorization' (EUA) from the US FDA for the Idylla™ SARS-CoV-2 Test.
  - Partnership LifeArc – In September 2020, Biocartis announced that the agreement with LifeArc[27] was expanded to now also include the development of highly innovative prototype assays in the field of infectious and immune related diseases on the Idylla™ platform.
  - COVID-19 Testing Industry Consortium – In October 2020, Biocartis announced to have joined the COVID-19 Testing Industry Consortium, led by Bristol-Myers Squibb Company which is aimed at improving, innovating and accelerating all aspects of COVID-19 testing[28]. A first Whitepaper on 'COVID-19 Back-to-Work' was published by the COVID-19 Testing Industry Consortium in January 2021.
  - SeptiCyte® RAPID on Idylla™ – Also in October 2020, Biocartis announced the market release of the SeptiCyte® RAPID test on Idylla™ (CE-IVD).
  - Idylla™ SARS-CoV-2 Test – In November 2020, Biocartis announced the CE-IVD launch of its Idylla™ SARS-CoV-2 Test.
  - Partnership Endpoint Health – Also in November 2020, Biocartis announced the signing of a new partnership with Endpoint Health aimed at the development and commercialization of a novel CDx test on Idylla™ for critical illnesses.
- *Idylla™ performance data:* During 2020, 29 new Idylla™ papers were published, bringing the total number of Idylla™ papers end of 2020 to 84. Next to the Idylla™ papers, also several dozens of abstracts and posters were published in 2020 at large scientific conferences, including ASCO, AMP, ESMO and ECP[29]. Some highlights:
  - In June 2020, Biocartis announced the publication of a new US multicenter study[30] published in the 'American Journal of Clinical Pathology' which showed that, compared to current standard-of-care testing methods, the Idylla™ platform can substantially improve turnaround time of the results of mutation testing, independent of the size of the laboratory. The study was one of the largest studies performed involving Idylla™, with 20 laboratories of different types and sizes included throughout the US and Puerto Rico, and data from almost 800 colorectal cancer samples.
  - In August 2020, during the virtual annual ASCO, five Idylla™ abstracts and posters were published by key oncology opinion leaders, including first Idylla™ data from China where amongst others the Idylla™ EGFR Mutation Assay (RUO) showed excellent concordance with other methods.
  - In September 2020, the FACILITATE study, launched as part of the agreement between Biocartis and AstraZeneca, was selected for presentation at the renowned European Society for Medical Oncology ('ESMO') Virtual Congress. The study concluded that Idylla™ reduced turnaround time by more than a week versus reference methods, allowing earlier patient management decisions.
  - In November 2020, at the annual meeting of the 'Association for Molecular Pathology' (AMP), ten Idylla™ studies were published which highlighted the strengths of the Idylla™ platform and assays[31] in terms of performance, ease of use and turnaround time, as well as Idylla™'s capacity to overcome the obstacles of working with small amounts of sample[32].

- Also in November 2020, a global multi-center real world study[33] with the Idylla™ MSI Assay was published and demonstrated excellent performance of the Idylla™ MSI Assay (RUO) with a very low failure rate. The study was the largest so far published for Biocartis.

## ORGANIZATIONAL AND OPERATIONAL HIGHLIGHTS

- *Management team* – Following the departure of former CFO Ewoud Welten as announced on 27 January 2020, Biocartis announced on 23 April 2020 the appointment of Jean-Marc Roelandt, a senior executive with an established track record of more than 25 years as CFO in globally active publicly listed companies, as the new CFO of the Company.
- *Cartridge manufacturing* – In 2020, further progress was made in the transfer of Idylla™ assays to the second cartridge manufacturing line ('ML2'). After the transfer of the Idylla™ KRAS Mutation Test (CE-IVD) during H1 2020, the Idylla™ NRAS-BRAF Mutation Test (CE-IVD) and the Idylla™ MSI Test (CE-IVD) were successfully transferred to ML2. The transfer of the Idylla™ EGFR Mutation Test (CE-IVD) is near completion. Transferring the production of key Idylla™ assays to this line is driving cost optimizations within the Company's cartridge manufacturing activities.
- *Ordinary and Extraordinary General Shareholders' Meeting* – During the ordinary shareholders' meeting held on 8 May 2020, the shareholders of the Company approved all agenda items, including the re-appointment of Ann-Christine Sundell, Luc Gijsens BV, represented by Luc Gijsens, and Roald Borré, as independent directors of the Company. Christine Kuslich, PhD was appointed as new independent director of the Company. During the extraordinary general shareholders' meeting held on 25 September 2020, 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 20% of the then current amount of the share capital, during a period of one year.
- *Convertible bonds* – On 7 December 2020, Biocartis announced its agreement with a holder of part of its outstanding EUR 150m 4% Senior Unsecured Convertible Bonds due 2024 (the 'Bonds') regarding the exercise of conversion rights in relation to EUR 15m aggregate principal amount of Bonds[34]. Biocartis agreed to this incentivized conversion of the Bonds, as it allowed to reduce its debt at attractive market conditions while strengthening the Company's shareholders' equity at a premium to the then current share price.

## FINANCIAL HIGHLIGHTS

- *Product sales revenues* – Total product sales increased year-over-year by 32% to EUR 31.9m in 2020 from EUR 24.2m in 2019.
  - Income from cartridge sales of EUR 24.8m grew 38% year-over-year for total cartridge volume of 243k cartridges, of which 230k were commercial cartridges and 13k R&D cartridges. In addition to 31% growth of commercial cartridge volumes, good progress was made on the average selling price ('ASP') of commercial cartridges, which increased by 7% in 2020.
  - Idylla™ platform sales increased by 14% for a similar level of new Idylla™ instrument placements as in 2019 (335 in 2020, compared to 337 in 2019).
- *Total operating income* – Total operating income amounted to EUR 55.6m in 2020, representing a year-over-year growth of 47% and included a settlement payment of EUR 10.3m (USD 12m) 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™.
- *Cost of goods sold* – Cost of goods sold increased to EUR 26.3m, 23% higher than in 2019 on the back of 31% higher commercial cartridge volumes and leading to an improved gross margin on products of 18% (2019: 12%).
- *OPEX* – Total operating expenses (excluding cost of sales) amounted to EUR 76.1m, an increase of 6% compared to EUR 72m in 2019. Cautious cost management triggered by the pandemic and prioritizing the development of the Idylla™ SARS-CoV-2 Test, led to the delay and carry-over of certain projects to 2021.
- *Operational cash flow* – Revenue growth, gross margin improvement and lower than planned operating expenses reduced the total cash flow used in operating and investing activities from EUR 59.7m in 2019 to EUR 43.3m in 2020.
- *Convertible bond* – Biocartis' debt was reduced by EUR 13.6m following the incentivized conversion of 10% of total outstanding Bonds. Biocartis paid a cash incentive of EUR 4.3m to the relevant bondholder as part of the transaction.
- *Cash position* - Biocartis' cash position as per 31 December 2020 amounted to EUR 123.7m compared to EUR 178.7m as per 31 December 2019.
- *Additional details* – See key figures 2020 below for more details on the 2020 financials.

## KEY FIGURES 2020

The tables below show an overview of the key figures and a breakdown of operating income for 2020. A consolidated income statement, balance sheet, cash flow statement and statement of changes in shareholder equity of Biocartis Group NV is presented in Part 4, Financial report 2020.

| Key figures *(EUR 1,000)* | 2020 | 2019 | % Change |
|---|---|---|---|
| **Total operating income** | **55,559** | **37,732** | **47%** |
| Cost of sales | -26,284 | -21,328 | 23% |
| Research and development expenses | -45,783 | -39,844 | 15% |

| | | | |
|---|---|---|---|
| Sales and marketing expenses | -15,736 | -18,011 | -13% |
| General and administrative expenses | -14,618 | -14,151 | 3% |
| **Operating expenses** | **-102,421** | **-93,334** | **10%** |
| **Operational result** | **-46,862** | **-55,602** | **-16%** |
| Net financial result | -15,768 | -7,934 | 99% |
| Share in the result of associated companies | -532 | -631 | -16% |
| Income tax | 228 | 99 | 130% |
| **Net result** | **-62,934** | **-64,068** | **-2%** |
| Cash flow from operating activities | -39,267 | -54,254 | -28% |
| Cash flow from investing activities | -4,007 | -5,496 | -27% |
| Cash flow from financing activities | -11,523 | 175,023 | -107% |
| **Net cash flow** | **-54,797** | **115,273** | **-148%** |
| **Cash and cash equivalents**[1] | **123,668** | **178,725** | **-31%** |
| Financial debt | 150,558 | 166,578 | -10% |

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

| Operating income *(EUR 1,000)* | 2020 | 2019 | % Change |
|---|---|---|---|
| **Collaboration revenue** | **9,989** | **12,451** | **-20%** |
| Idylla™ system sales | 7,085 | 6,220 | 14% |
| Idylla™ cartridge sales | 24,808 | 18,004 | 38% |
| **Product sales revenue** | **31,893** | **24,224** | **32%** |
| Service revenue | 1,246 | 769 | 62% |
| **Total revenue** | **43,128** | **37,444** | 15% |
| Grants and other income | 12,431 | 288 | 4216% |
| **Total operating income** | **55,559** | **37,732** | 47% |

| Product sales revenue *(EUR 1,000)* | 2020 | 2019 | % Change |
|---|---|---|---|
| Commercial revenue | 30,709 | 22,862 | 34% |
| Research & Development revenue | 1,184 | 1,362 | -13% |
| **Total product sales revenue** | **31,893** | **24,224** | **32%** |

### Income statement

Total operating income increased by EUR 17.8m or 47% to EUR 55.6m in 2020. Collaboration revenue amounted to EUR 10m, a decrease of 20% from 2019. R&D service revenue decreased by EUR 0.9m, license fees by EUR 0.7m and milestone revenue by EUR 0.9m. The collaboration with Genomic Health, Inc., a subsidiary of Exact Sciences Corporation, for the development of the Oncotype 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. paid a settlement fee of EUR 10.3m, which is recorded as other income.

Revenue from product sales increased by 32% from EUR 24.2m in 2019 to EUR 31.9m in 2020, and included Idylla™ cartridge sales of EUR 24.8m (EUR 18.0m in 2019) and Idylla™ system revenues of EUR 7.1m (EUR 6.2m in 2019). Idylla™ cartridge sales included revenue from the sale of 230k commercial cartridges and of 13k R&D cartridges.

Services revenue amounted to EUR 1.2m in 2020 versus EUR 0.8m in 2019. Grant income increased to EUR 1.2m and related to the recognition of subsidies awarded in relation to the establishment of a second cartridge manufacturing line, and to the development of the Idylla™ SARS-CoV-2 Test and the Idylla™ GeneFusion Assay (RUO). In addition to the aforementioned settlement fee paid by Genomic

Health, Inc. other income included the proceeds of a USD 1.0m loan received under the US Paycheck Protection Program ('PPP'), established as part of the Coronavirus Aid, Relief and Economic Security Act ('CARES Act'). On October 29, 2020 Biocartis 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'). While no response has yet been received from the SBA, the Company believes its use of the loan proceeds met the conditions for forgiveness of the loan.

Total operating expenses amounted to EUR 102.4m in 2020, compared to EUR 93.3m in 2019. The increase was primarily driven by the cost of goods sold that increased by EUR 5m or 23% to EUR 26.3m. The increased cost of goods sold reflected the increase in commercial cartridge volume of 31%, partly offset by a reduction in the cartridge manufacturing cost, leading to an improvement of the gross margin on products to 18% (2019: 12%).

Total operating expenses, excluding the cost of goods sold, amounted to EUR 76.1m in 2020, compared to EUR 72.0m in 2019. The increase of EUR 4.1m resulted from increased R&D expenses, offset by lower spending in sales and marketing. The increase in R&D expenses was largely driven by the development of the Idylla™ SARS-CoV-2 Test. Sales and marketing expenses decreased by EUR 2.3m, in part because the pandemic significantly hampered normal commercial activities for a good part of the year. Travel was restricted and numerous conferences and events were cancelled due to global lockdown measures.

The operating loss for 2020 amounted to EUR 46.9m, an improvement of EUR 8.7m or 16% compared to 2019.

Net financial expenses amounted to EUR 15.8m in 2020 compared to EUR 7.9m, and included expenses associated with the Company's convertible bond, and commitment fees for the multiple purpose credit. In 2020, the interest expense on the convertible bond increased to EUR 6.0m compared to EUR 3.0m in 2019. The bond was issued in May 2019 and last year therefore only included one coupon. Similarly, the debt appreciation expense amounted to EUR 2.7m, compared to EUR 2.2m in 2019. The financial expenses also included 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 Bonds (see details in the section balance sheet).

### Balance sheet

In 2020, total assets reduced from EUR 268.3m in 2019 to EUR 210.5m. Non-current assets amounted to EUR 50.5m compared to EUR 53.7m, mostly because of the depreciation of intangible assets and property, plant and equipment (EUR 9.7m) and an impairment charge of EUR 1.6m, offset by investments of EUR 3.0m in new equipment. Financial assets amounted to EUR 2.9m (2019: EUR 2,4m) and included the investment in the China joint venture Wondfo-Cartis. In 2020, the Company invested an additional EUR 1.0m in the joint venture and recorded its share of EUR 0.5m in Wondfo-Cartis' net loss for the year.

End 2020, current assets amounted to EUR 160.0m, or EUR 54.4m less than in 2019. Cash and cash equivalents of EUR 123.7m reduced by EUR 55.1m. Accounts receivable increased by EUR 2.8m as a direct result of higher levels of cartridge sales towards the end of the year. Inventory increased by EUR 1.6m, mostly finished cartridges in order to meet increased demand. Other receivables decreased by EUR 4.7m from EUR 8.6m in 2019, to EUR 4.0m in 2020, following the collection of a tax credit on research and development. Other current assets increased by EUR 0.7m.

End 2020, total financial debt amounted to EUR 150.6m compared to EUR 166.6m end of 2019. The reduction resulted from the incentivized conversion (EUR 13.6m) of part of the convertible bond and the net reduction of EUR 5.1m of lease obligations, offset by the appreciation of EUR 2.7m of the convertible bond. The incentivized conversion resulted from an agreement with a holder of part of the Company's EUR 150m 4% senior unsecured convertible Bonds regarding the exercise of conversion rights in relation to EUR 15 million aggregate principal amount of Bonds. The Company agreed to the incentivized conversion of the Bonds, as it allowed the Company to reduce the reported debt at attractive market conditions and to strengthen the shareholders' equity at a premium to the share price. The amount of the debt reduction in exchange for the new ordinary shares amounts to EUR 9.3m or EUR 8 per share, 70% higher than the closing price on 4 December 2020. The total debt reduction amounts to EUR 13.6m and was recorded as a credit to the share premium in the equity attributable to the owners of the Company.

Current liabilities end of 2020 amounted to EUR 29.4m, compared to EUR 23.2m end of 2019. Trade accounts payable increased by EUR 4.8m to EUR 13.9m. Other current liabilities included payroll related provisions and amounted to EUR 7.6m, representing an increase of EUR 1.5m compared to end 2019.

### Cash flow statement

The cash flow from operating activities in 2020 amounted to EUR -39.3m, a decrease of EUR 15m from EUR -54.3m in 2019. The improvement resulted from reduced operating losses and a net reduction in working capital, partly offset by increased financial expenses.

The cash flow from investing activities in 2020 amounted to EUR –4.0m, EUR 1.5m less than in 2019, and included the capital contribution made to the China joint venture, capitalized Idylla™ systems as well as investments in laboratory and manufacturing equipment.

Financing activities used EUR 11.5m cash for the incentivized conversion of part of the convertible bond (EUR 4.3m), interest on the convertible bond (EUR 6.0m) and the scheduled repayment of lease and other obligations.

The total cash flow for 2020 amounted to EUR -54.8m compared to EUR 115.3m in 2019, which included EUR 198.8m net proceeds from the issuance of new ordinary shares (EUR 53.4m) and the convertible bond (EUR 145.5m).

# 3. IMPACT OF COVID-19

## BUSINESS IMPACT

The pandemic deprioritized and disrupted cancer care globally. Patient access to hospitals was significantly restricted throughout almost the entire year and customer prospection was severely hampered. Despite the global pandemic, the number of commercial cartridges sold in 2020 grew by 31% to 230k, from 175k in 2019. After a strong first quarter of 2020, commercial cartridge volumes in oncology were significantly impacted by the disruption and de-prioritization of global cancer care. Restricted access to hospitals also hampered new customer prospection and slowed down new Idylla™ instrument placements in the first half of the year. Testing volumes in oncology started to recover towards the end of Q2, but the global surge of COVID-19 cases in Q4 ultimately tempered the year-on-year growth in oncology. To bridge the shortfall in oncology and to respond to its customers' need for COVID-19 testing, Biocartis developed the Idylla™ SARS-CoV-2 Test. Strong demand for this test in Q4, especially in the US, enabled Biocartis to meet its pre-pandemic guidance with 31% growth in commercial cartridge volumes and the placement of 335 new Idylla™ instruments. As per year-end, the total Idylla™ installed base amounted to 1,581 Idylla™ instruments[21].

While being disruptive, the COVID-19 pandemic also created an increased demand for molecular diagnostic testing. Since 2017, Biocartis has mainly focused its efforts on developing and commercializing oncology tests, which resulted in a solid on-market menu of proprietary Idylla™ oncology tests in colorectal cancer, lung cancer and melanoma, and ongoing developments in breast and thyroid cancer.
The current pandemic market conditions now also bring opportunities to grow in infectious diseases and as such accelerate the expansion of our installed base, offering this market the advantage of Idylla™'s speed and simplicity, together with the dual use for oncology testing.

## PARTNER AND BUSINESS PROJECT IMPACT

On 29 October 2020, Biocartis and Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation) announced to have agreed to terminate their collaboration which was focused on the development of the Oncotype DX Breast Recurrence Score® Test and the Oncotype DX Genomic Prostate Score® (GPS™) Test on the Idylla™ platform. As a result of COVID-19, the project had been suspended earlier during 2020, with the project plan and timing under evaluation. The decision to terminate the agreement was driven by the uncertain timing of a product market release because of the pandemic and a decision by Exact Sciences to shift priorities to other initiatives. As part of a termination settlement, Genomic Health, Inc. agreed to pay USD 12m to Biocartis and licensed certain rights and transferred certain assets to Biocartis.
Motivated by a strong demand from partners and customers, Biocartis gave priority to the development of the Idylla™ SARS-CoV-2 Test and re-allocated resources accordingly. Consequently, Biocartis delayed the US FDA submission of the PMA (Pre-Market Approval) application for the Idylla™ RAS tests.

## SUPPLIER IMPACT

During 2020, Biocartis worked more closely than ever with its suppliers to assess and monitor the risks related to the impact of the pandemic on the supply of goods directly related to the production of our cartridges:

- Supplies were monitored closely and discussed in a COVID-19 Steering Committee on a daily basis. There were no shortfalls of supply related to the pandemic, but the pandemic has led to a more proactive supplier strategy including the allocation of volumes per supplier, a closer follow-up communication and the listing and activation of additional suppliers for core materials.
- Biocartis performed additional risk assessments encompassing any COVID-19 related risks.

## ENVIRONMENTAL IMPACT

The main environmental impact of COVID-19 on Biocartis' 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 general, the more established culture of virtual meetings is expected to have a lasting impact on the need to travel. The pandemic crisis equally put a strain on our co-workers having to adopt new ways of working. Biocartis supported its employees through the development of processes to improve office and home working and is carefully analyzing the needs of its employees in terms of a balanced office and home working regime, evaluating certain permanent changes to the working environment post-pandemic. It is therefore expected that Biocartis will continue to decrease its commuting and office floor space related emissions post the pandemic (see below).
Our staff in production continued to work 100% on site during the pandemic, leading to an increase in the use of COVID-19 safety equipment, which increased the amount of healthcare waste (non-measured).

## SOCIAL IMPACT

Since the start of the pandemic mid-March 2020, Biocartis assumed responsibility in meeting the high need for diagnostic testing and set up several actions to ensure business continuity while supporting its employees during these challenging times. These measures that contributed to business continuity and helped avoid any pandemic related unemployment, included:

- The set-up of a COVID-19 Crisis Team that gathered daily to ensure amongst others:
  - 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
  - All safety and travel guidelines remained up to date
  - Supply chain and production continuity
- The set-up of internal communications channels to disseminate specific COVID-19 related information such as an updated travel policy and strict rules on social distancing, cleaning and hygienic rules at the workplace
- Weekly staff meetings led by the CEO, COO and HR in the period between March-June, and monthly updates as from Summer, with the focus to keep everyone committed and fully updated
- IT program tools were updated and renewed for virtual working
- A COVID-19 communications campaign was set up, including topics such as wellbeing webinars to guide employees and people managers through these challenging times. Attention was also given to ergonomic tips for home working and tips and tricks for COVID-19 hygienic rules
- Switch to a fully virtual HR recruitment, onboarding and training program
- Supporting the leadership team to keep a virtual connection with their teams through virtual tool manuals and trainings
- Close collaboration with the external company doctor
- Employee survey in September 2020 showed, amongst others, that most employees are proud to be working for a company that helps to deliver a (diagnostic) solution, but attention was needed to improve the work-life balance, especially mental wellbeing.

In terms of wellbeing, Biocartis saw the pandemic as an opportunity to further develop its wellbeing strategy in 2020 and beyond. This strategy is aimed at increasing our agility and resilience as an organization. Several actions were already rolled out in 2020 to reinforce the mental 'muscle' of our employees, including webinars and virtual wellbeing sessions on mental resilience. Additionally, a renewed Wellbeing Action Plan will be rolled out in 2021, with a focus on Workplace Transformation combining the best of both office and home working, and the introduction of mental wellbeing tools such as regular webinars and articles, practical tips and tricks and e-learning modules.

# PART 3/ NON-FINANCIAL REPORT

# 1. SUSTAINABILITY

## 1.1. SUSTAINABILITY FOR BIOCARTIS

### SUSTAINABLE PRODUCTS

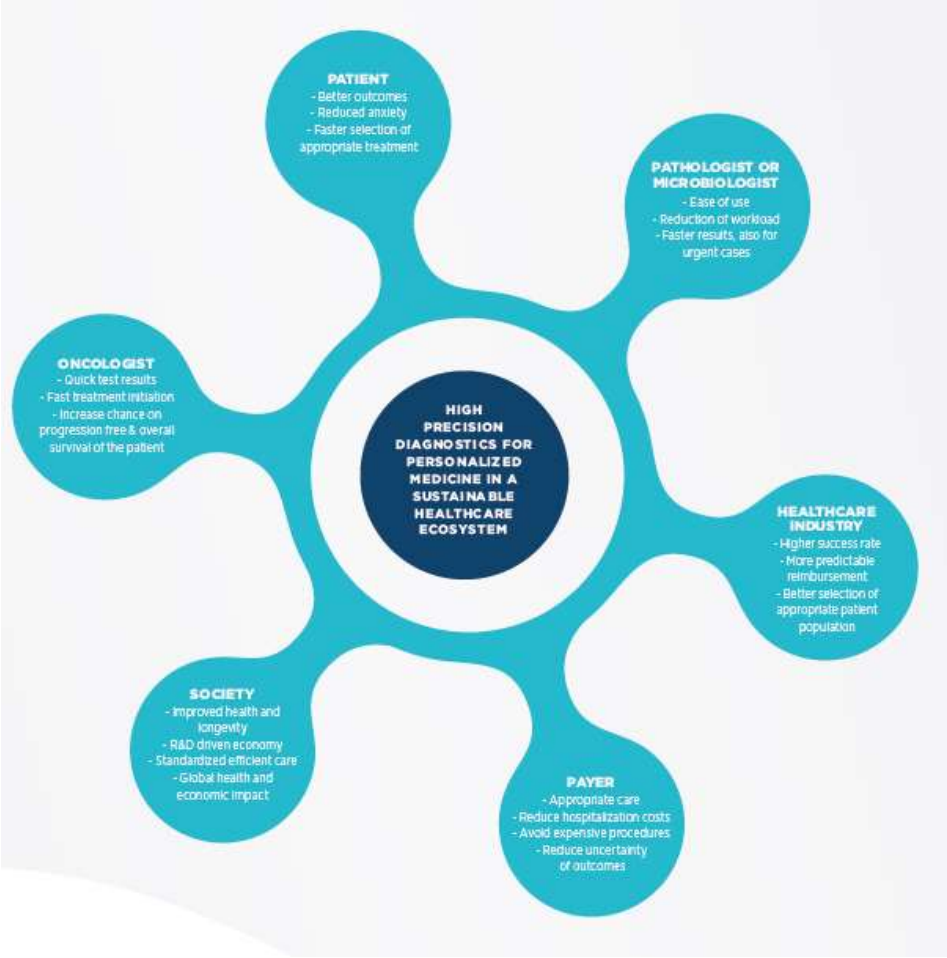
Sustainability is in the DNA of Biocartis. The Idylla™ products focus on improving the lives of patients across the globe by enabling easy and rapid access to MDx testing and as such could support more optimal treatments. This has the potential to positively impact the overall healthcare cost for society. One Idylla™ test can bring one patient one step closer towards getting the right treatment, with the best possible health outcome.

*"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***

We believe that the characteristic of Biocartis' products (i.e. fast, easy and highly accurate) contribute to a more sustainable healthcare model:

- For the patient, this could mean faster decision on therapy with the potential to better treatment outcomes
- For the care provider, such as the clinician or hospital, it could mean faster and cost effective access to accurate molecular information to better guide treatment selection with potentially less adverse effects
- For the payer, it could mean reduced healthcare costs as unnecessary costs could be avoided thanks to more certainty that the treatment will work efficiently for the patient
- For the healthcare industry, it could mean a higher success rate and adoption of targeted treatments, an improved selection of the right patient population and a more predictable reimbursement related to more predictable healthcare outcomes



In 2020, Biocartis made specific contributions to seven out of the 17 sustainable development goals which were developed universally to meet the urgent environmental, political and economic challenges our world faces. Specific actions taken in the context of the COVID-19 pandemic are indicated with a star* reference.

| | |
|---|---|
|  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**<br><br>In 2020:<br>- Installed base of 1,581 Idylla™ instructments<br>- Commercial cartridge volume of 230k cartridges sold<br>- *Development of a pandemic test menu on Idylla™: the SeptiCyte® RAPID on Idylla™ (developed in collaboration with Immunexpress) and the Idylla™ SARS-CoV-2 Test |
|  SDG 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all | **A safe & healthy workplace**<br><br>In 2020:<br>- Providing a safe & healthy workplace for all employees, *also in pandemic times<br>- No lethal accidents or accidents causing disability on the workplace<br>- 21,520 training hours |
|  SDG 5: Achieve gender equality and empower all women and girls | **A balanced gender diversity**<br><br>In 2020:<br>- 366 employees[6] across 33 nationalities<br>- 51% men - 49% women balanced gender diversity |
|  SDG 8: Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all<br>SDG 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation | **Delivering growth**<br>In 2020:<br>- +32% product sales revenues<br>- +31% Idylla™ cartridge volume or 230k cartridges sold<br>- + 335 Idylla™ instruments added to the installed base |
|  SDG 13: Take urgent action to combat climate change and its impacts | **Reducing our environmental impact**<br><br>In 2020:<br>- Update of the waste manual (including optimization of waste flows and revision of acceptance criteria for waste flows and chemical waste flows)<br>- Further follow-up and monitoring of energy and water consumption<br>- Preparation of permit application for the Biocartis 'BC5' building<br>- Review and update of the Health, Safety & Environment manual<br>- Investigation of biocide use in hot water baths<br>- Phasing out of the use of refrigerants |
|  SDG 17: Strengthen the means of implementation and revitalize | **Building a global Idylla™ ecosystem with partners**<br><br>In 2020:<br>- Strengthening of the oncology business through expansion of the partnerships with AstraZeneca and Bristol-Myers Squibb and new partnership with GeneproDx in the thyroid cancer domain |

| | |
|---|---|
| the global partnership for sustainable development | - Partner funded expansion of the Idylla™ test menu in infectious diseases, together with partners Immunexpress, LifeArc and Endpoint Health<br>- *Idylla™ pandemic test menu: SeptiCyte® RAPID on Idylla™ (in collaboration with Immunexpress) and Idylla™ SARS-CoV-2 Test<br>- 29 new Idylla™ papers were published, to a total of 84 end of 2020. Several abstracts and posters were published at large scientific conferences<br>- Virtual fundraising actions set up by employees supporting different non-profit organizations in the area of cancer and health |

Further information on our sustainability activities can be found below under 'Creating value for our stakeholders', section 'Partners' and 'Customers & patients'.

### CORPORATE RESPONSIBILITY: ACTING RESPONSIBLY AS A COMPANY

Biocartis strives to act responsible when using social and environmental resources. Information on this topic can be found throughout this report and covers different aspects, of which the main ones and their references in this report are listed below:

- We have integrated sustainability in the governance of our organization. Sustainability is the responsibility of our board and executive management. Since 2018, a new Code of Conduct is in place that includes several ethical business measures to avoid corruption, bribery & fraud, as well as an ethics hotline ('whistleblowing') for Biocartis employees as well as principles on diversity & inclusiveness. We refer to the Corporate Governance Report for more information.
- We integrate long term value creation in our remuneration policy. We refer to the remuneration section in the Corporate Governance Report for more information.
- We see diversity as a key talent management driver of our business. For more information we refer to the 'Non-financial report' under 'Creating value for our stakeholders', section 'Employees' and to the Corporate Governance Report for more information.
- We aim to use materials that do no harm our environment and contribute to a sustainable supply chain. We refer to the 'Non-financial report' under 'Creating value for our stakeholders', section 'Suppliers' and section 'Environment'.
- We want to create a healthy and safe working environment for our employees. We refer to the 'Non-financial report' under 'Creating value for our stakeholders', section 'Employees' for more information, as well as the section in part 1 under 'impact of COVID-19'.
- We strive to have a positive societal impact on a local level. We refer to the 'Non-financial report' under 'Creating value for our stakeholders', section 'Employees' for more information.

# 1.2. CREATING VALUE WITH OUR PRODUCTS

## 1. PRODUCT 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.

### 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 2020, Biocartis further prepared for the application of the Regulation on IVD medical devices[35] by assessing all current IVD products against the new requirements, and ensuring that new IVD products under development are meeting the new standards. An overview of Biocartis' CE-marked Idylla™ products is available under the section 'Product overview' below. 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 validation efforts 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[36].

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. An overview with Biocartis' EUA-marked Idylla™ products is available under the section 'Product overview' below. The Idylla™ instrumentation is exempt from 510(k) premarket notification requirements[37].

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.

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.

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. An overview of all RUO-labelled products can be found under the section 'Product overview' below. 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.

## 2. DATA PRIVACY

Biocartis is an ethical organization that is committed to protect the rights and freedoms of the individuals whose personal data is being processed. Therefore, the products and business activities are designed with privacy as a top priority.

Biocartis protects personal data of patients, customers and personnel by applying data protection principles. Personal data is being processed in accordance with applicable law, in a fair and transparent manner. Only the minimal set of data required is processed to achieve a pre-defined purpose. Biocartis keeps personal data secure, accurate and only for the period necessary to achieve the purpose. Furthermore, Biocartis takes responsibility for the protection of the personal data being processed, at the highest management level and throughout the organization.

In 2020, a number of actions were taken to embed data privacy more deeply in the organization:

- Setup of a privacy governance framework, supporting compliance with legal obligations, alignment with broader business objectives & goals and fully supported at all levels across the organization. This also includes the creation of the Privacy Core Team, consisting of key stakeholders of higher management levels in the organization, and a privacy maturity assessment methodology
- Creation of a legal framework supporting international transfers of personal data between Biocartis NV and Biocartis US Inc. in the US
- A review of the data breach management process including the set-up of a formal methodology to assess the severity of a personal data breach
- The training of more than 150 employees and contractors aimed to increase awareness and knowledge of data protection

### Information security

Biocartis has built and implemented an Information Security Management System (ISMS) with the aim to obtain the ISO 27001 certification in 2021. The scope of this program is the design, development, maintenance, service provision and support of Biocartis' commercially available Idylla™ platform and associated customer-facing software.
The implementation targets 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 & contractual requirements and data protection regulations
-Receive from customers a high level of confidence and trust in Biocartis information security management practices

## 3. TRANSPARENCY: THE SUNSHINE ACT

As Member of Medtech Europe, Biocartis closely follows the 'Medtech Europe Code of Ethical Business Practice Guidelines'. In that context, since 2017, Biocartis complies with the Belgian beMedtech reporting, reinforced by the 2017 Belgian Sunshine Act which requires reporting of premiums and benefits granted to healthcare professionals, healthcare organizations and/or patient organizations.

| 2018 | 2019 | 2020 |
|---|---|---|
| EUR 8.697,60 | EUR 9.035,25 | EUR -* |

**Reporting for 2020 will be completed in 2021. 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 Sunshine transparency on certain payments or other transfers of value provided to US physicians or teaching hospitals and other research entities. An overview of payments made in the US can be found below:

| 2018 | 2019 | 2020 |
|---|---|---|
| USD 1.734,99 | USD 986,99 | USD -* |

**Reporting for 2020 will be completed in 2021. 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.*

Finally, Biocartis started reporting in France in 2020, in combination with additional internal measures ensuring a correct follow-up of the new French anti-gift law.

## REIMBURSEMENT

Clinical MDx testing is increasingly important in the guidance of the right cancer therapy. IVD tests are either reimbursed by state 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.

Today, most Idylla™ assays in Biocartis' product offering contain biomarkers that are already included in the clinical guidelines, and are as such mostly already reimbursed by third-party payers. 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[38]. 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 to 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[39]. 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[40]. 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.

## 4. INTELLECTUAL PROPERTY (IP)

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 its 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 such intellectual property and relates to various aspects of the Idylla™ platform, chemistries and biomarkers. Furthermore, Biocartis also has exclusively licensed specific third-party technologies. On 31 December 2020, Biocartis' patent portfolio consisted of 29 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 2020, the value of the Idylla™ platform was protected by a group of 50 patent families (27 proprietary patent families and 23 in-licensed patent families) and two invention disclosures, 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.

## 5. PRODUCT OVERVIEW

### THE IDYLLA™ PLATFORM

*"We offer rapid & easy molecular diagnostic solutions aimed at enabling faster & more accurate treatment decisions for patients across the globe."*


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 labelling.

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, and its short turnaround time, allowing immediate access to therapy.

## MENU OF IDYLLA™ ONCOLOGY MOLECULAR DIAGNOSTIC TESTS

As per end 2020, Biocartis offered oncology tests supporting melanoma, colorectal and lung cancer.

### METASTATIC COLORECTAL CANCER (MCRC)

Colorectal cancer is the third most common cancer worldwide, with over 1.8 million new cases in 2018[41]. About 46% of all metastatic colorectal tumors harbor KRAS gene mutations and about 5% of all metastatic colorectal tumors harbor NRAS gene mutations[42]. According to ESMO[10], NCCN[43], ASCO[44] and CAP/AMP/ASCO[45] guidelines, genotyping of clinically actionable mutations[46] is now mandatory on tumor tissue (either primary or metastasis) of all metastatic colorectal cancers, since the presence of these mutations correlate with the lack of response to certain anti-EGFR antibody therapies[47]. BRAF testing is recommended in all patients with metastatic melanoma and metastatic colorectal cancer (mCRC). In mCRC, BRAF mutation status should be assessed alongside the assessment of tumor RAS mutational status for prognostic assessment (the presence of a BRAF mutation indicates poor prognosis). The prevalence of BRAF in mCRC is about 8-15%[47]. The Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test offer a complete testing for metastatic colorectal cancers (mCRC) for clinical use on Idylla™, as recommended by the most recent clinical guidelines of ASCO and ESMO[48]. The ability of Biocartis' RAS test offering to enable same-day results can now open routes towards faster treatment selection for mCRC patients. Next to using solid tumor tissue, the use of liquid biopsies for KRAS or NRAS-BRAF testing is minimally invasive, fast and easy to perform and can be used as an alternative or complement to tissue testing to determine the RAS mutation status at diagnosis.

IDYLLA™ KRAS MUTATION TEST (CE IVD, DIAGNOSTIC USE)

- 120 minutes sample-to-result
- 21 mutations, directly on FFPE tissue sections (5-10µm)
- ~ 2 minutes hands-on time

IDYLLA™ ctKRAS MUTATION TEST (CE IVD, DIAGNOSTIC USE)

- 130 minutes sample-to-result
- 21 mutations, directly on 1 ml plasma
- ~ 1 minute hands-on time

IDYLLA™ NRAS-BRAF MUTATION TEST (CE IVD, DIAGNOSTIC USE)

- 120 minutes sample-to-result
- 18 NRAS mutations and 5 BRAF mutations, directly on FFPE tissue sections (5-10µm) from mCRC
- ~ 2 minutes hands-on time

IDYLLA™ ctNRAS-BRAF MUTATION TEST (CE IVD, DIAGNOSTIC USE)

- 110 minutes sample-to-result
- 18 NRAS mutations and 5 BRAF mutations, directly on 1 ml plasma
- ~ 1 minute hands-on time

### Idylla™ MSI detection on solid biopsies

MSI stands for Microsatellite instability (MSI) and it is caused by deficiency of the DNA mismatch repair system (dMMR) resulting in a distinct accumulation of insertions and deletions in microsatellite and homopolymeric regions[49]. MSI-high (MSI-H) is detected in 15% of all colorectal cancers; 3% are associated with Lynch Syndrome (LS), the other 12% have sporadic disease[50].

Guidelines recommend assessing the MSI status for all patients with colorectal or endometrial[51] carcinomas for screening for Lynch Syndrome as well as for prognostic stratification and potential response to certain immunotherapies[52]. Research studies have shown that MSI-H patients respond favorably to immune checkpoint inhibitors, and checkpoint blockade therapy has recently been incorporated into clinical care for gastrointestinal cancers[53].

IDYLLA™ MSI TEST (CE IVD, DIAGNOSTIC USE)

- 150 minutes sample-to-result
- 7 novel tumor specific biomarkers
- ~ 2 minutes hands-on time
- No need for paired tissue
- Unbiased result reporting

*"Idylla™ allows very quick results with little hands-on time."*
*Beatriz Bellosillo Laboratori de Biologia Molecular, Hospital del Mar, Barcelona (Spain)*

### LUNG CANCER

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)[54]. EGFR mutations are mainly observed in lung cancer. EGFR mutation testing is recommended in all patients with advanced non-small cell lung cancer (NSCLC) of a non-squamous subtype. Activating mutations in the EGFR gene have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics[55].

IDYLLA™ EGFR MUTATION TEST (CE IVD, DIAGNOSTIC USE)

- 150 minutes sample-to-result
- 51 mutations, directly on 1 FFPE tissue section (5µm)
- ~2 minutes hands-on time

*"Today, EGFR testing is a cumbersome process and it often takes several weeks before results are analyzed. This may lead to the administration of anti-EGFR therapy as second-line agents, which is less efficient than their use in first-line therapy. The Idylla™ EGFR Mutation Test technology has the potential to change that: it is a cost-effective solution, ensuring reliable and fast detection of all relevant mutations."* *Prof Giancarlo Troncone, University of Napoli Federico II, Naples (Italy)*

### MELANOMA

About 50% of all metastatic melanoma patients harbor mutations in the BRAF gene, making them eligible for BRAF or BRAF/MEK inhibitor therapy[56]. BRAF testing is recommended in all patients with metastatic melanoma and mCRC. In mCRC, BRAF mutation status should be assessed alongside the assessment of tumor RAS mutational status for prognostic assessment (the presence of a BRAF mutation indicates poor prognosis).

IDYLLA™ BRAF MUTATION TEST (CE IVD, DIAGNOSTIC USE)

- 90 minutes sample-to-result

- 7 mutations, directly on FFPE tissue sections (5-10µm) from metastatic melanoma
- ~ 2 minutes hands-on time

*"The Idylla™ system has the potential to allow the start of targeted therapy within a time window of less than 24 hours following the diagnosis of metastasis, thereby saving precious time."* ***Prof. B. Neyns, M.D., Ph.D,***
***Medical Oncology, UZ Brussels, Belgium***

RESEARCH USE ONLY ASSAYS & PAN-TUMOR TESTING POTENTIAL

IDYLLA™ BRAF MUTATION ASSAY (RUO, NOT FOR DIAGNOSTIC USE)

- 90 minutes sample-to-result
- 7 mutations, directly on 1 slice of FFPE tissue
- ~ 2 minutes hands-on time

IDYLLA™ ctBRAF MUTATION ASSAY (RUO, NOT FOR DIAGNOSTIC USE)

- 85 minutes sample-to-result
- 7 mutations, directly on 1 ml plasma
- ~ 1 minute hands-on time

IDYLLA™ KRAS MUTATION ASSAY (RUO, NOT FOR DIAGNOSTIC USE)

- 120 minutes sample-to-result
- 21 mutations, directly on 1 slice of FFPE tissue
- ~ 2 minutes hands-on time

IDYLLA™ ctKRAS MUTATION ASSAY (RUO, NOT FOR DIAGNOSTIC USE)

- 130 minutes sample-to-result
- 21 mutations, directly on 1 ml plasma
- ~ 1 minute hands-on time

IDYLLA™ NRAS-BRAF-EGFR S492R MUTATION ASSAY (RUO, NOT FOR DIAGNOSTIC USE)

- 120 minutes sample-to-result
- 18 NRAS mutations, 5 BRAF mutations and 2 EGFR mutations, directly on 1 slice of FFPE tissue
- ~ 2 minutes hands-on time

IDYLLA™ ctNRAS-BRAF-EGFR S492R MUTATION ASSAY (RUO, NOT FOR DIAGNOSTIC USE)

- 110 minutes sample-to-result
- 18 NRAS mutations, 5 BRAF mutations and 2 EGFR mutations, directly on 1 ml plasma
- ~ 1 minute hands-on time

IDYLLA™ EGFR MUTATION ASSAY (RUO, NOT FOR DIAGNOSTIC USE)

- 150 minutes sample-to-result
- 51 EGFR mutations, directly on 1 slice of FFPE tissue
- ~ 2 minutes hands-on time

IDYLLA™ ctEGFR MUTATION ASSAY (RUO, NOT FOR DIAGNOSTIC USE)

- 160 minutes sample-to-result
- 49 EGFR mutations, directly from 2 ml of plasma
- ~ 2 minutes hands-on time

IDYLLA™ MSI ASSAY (RUO, NOT FOR DIAGNOSTIC USE)

- 150 minutes sample-to-result
- 7 novel tumor specific biomarkers
- ~ 2 minutes hands-on time
- No need for paired tissue
- Unbiased result reporting

Therapy selection is increasingly driven by the genetic make-up of the tumor rather than its tissue of origin within the body. This could allow for a pan-tumor application of targeted therapies, which in turn increases the demand for molecular tests. Consequently, Idylla™ assays are increasingly being assessed for pan-tumor testing, as such potentially expanding the applicability of the current Idylla™ test menu. Examples include:

- BRAF: Activating mutations in the BRAF gene are observed in about 8% of all cancers[57] and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics. Cancers in which BRAF mutations are observed include: melanoma, colorectal cancer, thyroid cancer, lung cancer, hairy cell leukemia and ovarian cancer

- RAS (KRAS and NRAS): Activating mutations in the RAS genes are observed in 9-30% of all cancers and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics[58]. Cancers in which KRAS mutations are observed include: colorectal, lung and pancreatic cancer. Cancers in which NRAS mutations are observed include colorectal, lung, thyroid cancers and melanoma
- MSI[59]: Clinical trials and pathophysiological studies indicate a wide distribution of MSI-H across tumor types[60]. In addition to CRC, high incidences are observed in endometrial cancer (20-30%), and gastric cancer (15-20%)[50]. Many MSI studies on Idylla™[61] demonstrate the importance of pan-tumor MSI testing in non-colorectal cancer types such as endometrial, gastric, ovarian, pancreatic and other cancers in the context of Lynch Syndrome and immunotherapy use.

Additionally, new sample types are the subject of recent studies, including:

- KRAS mutations detected in FFPE lung samples[62] and in pancreatic cyst fluid samples[63]
- NRAS and BRAF mutations detected in FFPE melanoma samples[49] and in thyroid Fine Needle-Aspirate (FNA) samples[64]

### THE IDYLLA™ GENEFUSION ASSAY

The Idylla™ GeneFusion Assay, launched as RUO in Q1 2021, consolidates traditional testing workflows into one streamlined, fully-automated process providing reliable, objective information on ALK, ROS1, RET, METex14 skipping and NTRK1/2/3 in about 180 minutes. It provides a simultaneous detection of strategic biomarkers on-demand from a minimum of sample thereby saving valuable samples, and provides an ultra-rapid actionable solution which can be seamlessly integrated into virtually any laboratory workflow complementing comprehensive NGS. More info on https://www.biocartis.com/en/meet-idylla/idylla-oncology-assays

## MENU OF IDYLLA™ INFECTIOUS DISEASE MOLECULAR DIAGNOSTIC TESTS

As per end 2020, Biocartis offered a first infectious disease pandemic test menu for COVID-19 and sepsis testing, aimed at use in acute settings.

### SEPSIS

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[65], with annual healthcare costs est. at over USD 60 billion in the US alone[66].
Sepsis testing represents a high unmet need, as current markers are not rapid (blood cultures) or are non-specific (PCT, CRP)[67]. 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. Biocartis offers a sepsis-oriented test portfolio consisting of:

#### SEPTICYTE® RAPID* ON IDYLLA™ (CE-IVD), DEVELOPED IN PARTNERSHIP WITH IMMUNEXPRESS

- RNA signature from blood
- 65 minutes assay turnaround time
- ~ 2 minutes hands-on time
- Result as a probability score
- Access on demand
- Highly sensitive and standardized

** SeptiCyte® RAPID is a CE-marked IVD, developed by Immunexpress Inc in collaboration with Biocartis. Biocartis has the exclusive distribution rights for the EU. The test is not available in all countries. Availability to be checked with local Biocartis representative. The SeptiCyte® RAPID uses SuperScript™ III. The SuperScript III trademark is owned by Life Technologies Corporation.*

### 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 or 'COVID-19'.

#### IDYLLA™ SARS-COV-2 TEST (CE-IVD)

- 90 minutes assay turnaround time
- ~ 2 minutes hands-on time
- 200 mL VTM (Viral Transport Medium) from nasopharyngeal swabs
- Access on demand
- Highly sensitive and standardized

# 1.3. CREATING VALUE FOR OUR STAKEHOLDERS

## PARTNERS

Partnerships are a cornerstone in Biocartis' Idylla™ expansion strategy. End of 2020, 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[68], the partnership was expanded in December 2016 to up to 10 European countries and in 2017 to the field of CDx development. The aim of the CDx agreement announced on 4 December 2017 is to register the Idylla™ RAS biomarker tests with the US FDA as a CDx test for Amgen's drug Vectibix® (panitumumab). Vectibix® is the first and only fully human monoclonal anti-epidermal growth factor receptor (EGFR) antibody indicated for certain metastatic colorectal cancer (mCRC) patients with wild-type RAS.

### ASTRAZENECA

On 29 November 2018, Biocartis and AstraZeneca, a global science-led biopharmaceutical company (LON/STO/NYSE: AZN) announced their agreement focused on demonstrating how the unique features of the Idylla™ platform can overcome the current complexity and long turnaround time of biomarker testing for lung cancer patients. The prospective study with the tissue-based Idylla™ EGFR Mutation Test (CE-IVD) under the partnership was initiated at more than a dozen sites in several European countries. On 22 January 2020, Biocartis announced to have broadened this partnership to additional countries within and outside Europe. At the same time Biocartis announced its master collaboration agreement with AstraZeneca to enable the collaborative development and commercialization of Idylla™ based molecular tests in support of AstraZeneca's pharmaceutical products. The first project under the new agreement was a study focused on evaluating if liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay (RUO) could provide further benefits to tissue-based EGFR molecular testing. The study was selected for presentation at the renowned European Society for Medical Oncology ('ESMO') congress in September 2020 and concluded that Idylla™ reduced turnaround time by more than a week versus reference methods, allowing earlier patient management decisions.

### 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 United States 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 and 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 it has entered into 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 Biocartis' CDx business and infectious disease test menu alongside its core oncology offering 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 it has signed 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 qRT-PCR[69] based mRNA-expression classifier[70] test that helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant[71]. A benign test result[72] 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, announced their partnership on 24 January 2018 aimed at 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.

### KITE/GILEAD

On 1 June 2019, Biocartis announced that it has entered into 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 is aimed at the development of 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, whilst both partners are further progressing in vitro diagnostic ('IVD') registration preparations for the Idylla™ assays.

### 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. In the first quarter of 2019, Biocartis announced the completion of the joint venture with Wondfo, aimed at the commercialization of the Idylla™ platform in China with a first focus on the establishment of local manufacturing capabilities and product registrations.

# CUSTOMERS & PATIENTS

## GO-TO-MARKET STRATEGY IN ONCOLOGY

### PATHOLOGY LABS AND HOSPITALS: THE PATHOLOGIST & ONCOLOGIST AS KEY IDYLLA™ STAKEHOLDERS

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 are key Idylla™ features for the pathologist in an increasingly complex molecular testing scene. On the other side of the spectrum, the oncologist, who is in contact with the patient, is a key user of MDx information that it receives from amongst others the molecular pathologists, to determine the best treatment plan for each individual patient. Obtaining fast test results and in the future, potentially the monitoring of treatment efficiency by means of liquid biopsy tests, is of the essence for the oncologists.

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 multiple numbers of instruments, large amounts 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.

## GO-TO-MARKET STRATEGY IN INFECTIOUS DISEASES

### MICROBIOLOGY LABS

Infectious disease 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[16].

## DIRECT AND INDIRECT SALES CHANNELS

End 2020, Biocartis was active in over 70 countries through a combination of direct sales and (distribution) partners.

- Direct sales strategy: In all key European countries, US and Canada, Biocartis has a go-to-market strategy based on a direct sales force. The Biocartis direct sales force is in direct contact with a vast network of pathology labs and hospitals for its oncology products, as well as an expanding network of microbiology labs for its infectious disease products. As such, the Biocartis sales team can leverage on Idylla™'s unique USP's as the go-to platform for rapid and easy testing both in oncology as in infectious diseases.
- Distributor sales strategy in distribution markets and Japan: In distribution market countries[73], Biocartis collaborates with a vast network of distributors. Since 2017, Biocartis focused on assisting its distribution partners in commercially supporting 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, joining 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 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.

*"Idylla™ delivers results within 2 hours instead of 2 days, with minimal hands-on time. This brings huge benefits, as it has the potential to enable faster and improved cancer treatment decisions."*
*Alexander C. Mackinnon, Jr., MD, PhD, Medical College of Wisconsin, Milwaukee, MI (USA)*

## US, THE LARGEST SINGLE MARKET FOR MDx TESTING IN THE WORLD

The North American molecular diagnostics market size was USD 3.66 billion in 2017 and is expected to register a CAGR of 10.4% between 2018-2025[74]. With a significant number of mid and smaller sized labs and hospitals not performing MDx today, there is great potential for Idylla™ in the US.

In oncology, access to timely molecular information in the US is difficult, with nearly 80% of cancer patients that do not have genetic mutation results available at their initial oncology consultation, and up to 25% of patients that begin treatment before they receive their results[75]. The first go-to-market focus in the US in this segment is on the large institutional laboratories and regional reference laboratories performing oncology MDx today and mid-sized laboratories that are currently sending out samples for testing. In a second wave, Biocartis plans to target the smaller laboratories and hospitals that do not yet perform MDx testing.

In infectious diseases, the go-to-market focus in the US is on microbiology labs that perform MDx testing for acute settings, such as sepsis and COVID-19 testing. Labs that perform both oncology and infectious disease testing are good potential customers, to position Idylla™ as the go-to platform for versatile, rapid, and easy testing in both oncology as in infectious diseases.


## CUSTOMERS

Biocartis connects with its customers through a variety of channels, including conferences, customer trainings and meetings, its website, as well as direct interactions with its dedicated Sales, Customer Service and Support teams.

Since direct contact with customers and prospects was hampered in 2020 due to the global pandemic, the Biocartis teams remained in contact with its Idylla™ users and prospects through several virtual interfaces:

- Conferences: In 2020, Biocartis participated in three large virtual conferences: the conference of the International Society of Liquid Biopsy, a virtual Biocartis Symposium at ESP (European Society of Pathology) and a Biocartis workshop and booth at the virtual AMP (Association for Molecular Pathology, US) congress. Biocartis also participated in 16 local virtual conferences
- Customer events & trainings: Marketing teams organized three virtual Idylla™ customer events on several topics including MSI and EGFR testing, welcoming participants from across the world
- Online customer portal: In 2020, the customer portal website was updated following new product releases
- Distributors: During 2020, Biocartis developed several new sales tools for our distributor network including new Idylla™ information brochures


Finally, the sales team remained up-to-date by following several virtual trainings including sales trainings on improving sales processes and virtual selling, a training on updates in the EU reimbursement system and various e-learning modules on for example MSI, EGFR, ctEGFR testing and recent non-small cell lung cancer literature in view of the launch of Biocartis' new Idylla™ GeneFusion Assay, planned to be launched as RUO in Q1 2021.

### KEY OPINION LEADERS

Biocartis is in continuous dialogue with KOLs which serve as true Idylla™ ambassadors in the market. KOLs have an important role in providing continuous feedback on the Idylla™ product offering. In 2020, oncology activities here in 2020 consisted of:

- Papers, abstracts and posters: During 2020, 29 new Idylla™ papers were published, bringing the total number of Idylla™ papers to 84. Additionally, several abstracts and posters were published in 2020 at large scientific conferences, including ASCO, AMP, ESMO and ECP[28]. Some highlights:
  - In June 2020, Biocartis announced the publication of a new US multicenter study[76] published in the 'American Journal of Clinical Pathology' which showed that, compared to current standard-of-care testing methods, the Idylla™ platform can substantially improve turnaround time of the results of mutation testing, independent of the size of the laboratory. The study was one of the largest studies performed involving Idylla™, with 20 laboratories of different types and sizes included throughout the US and Puerto Rico, and data from almost 800 colorectal cancer samples
  - In August 2020, during the virtual annual ASCO, five Idylla™ abstracts and posters[77] were published by key oncology opinion leaders, including first Idylla™ data from China where amongst others the Idylla™ EGFR Mutation Assay (RUO) showed excellent concordance with other methods
  - In September 2020, the FACILITATE study, launched as part of the agreement between Biocartis and AstraZeneca (LON: AZN), was selected for presentation at the renowned European Society for Medical Oncology ('ESMO') Virtual Congress. The study concluded that Idylla™ reduced turnaround time by more than a week versus reference methods, allowing earlier patient management decisions
  - In November 2020, at the annual meeting of the 'Association for Molecular Pathology' (AMP), ten Idylla™ studies were published which highlighted the strengths of the Idylla™ platform and assays[78] in terms of performance, ease of use and turnaround time, as well as Idylla™'s capacity to overcome the obstacles of working with small amounts of sample[79]
  - Also in November 2020, a global multi-centre real world study[33] with the Idylla™ MSI Assay was published and demonstrated excellent performance of the Idylla™ MSI Assay (RUO) with a very low failure rate. The study was the largest so far published for Biocartis
- Key Expert Meetings: In September 2020, Biocartis organized a virtual KOL meeting with oncology and pathology experts to assess current trends and market opportunities in oncology MDx testing. The meeting focused on Biocartis' new Idylla™ products in the pipeline including gene fusion testing in lung, as well as positioning of Idylla™ in new areas such as thyroid, endometrium and brain cancer. In total, 11 experts from key European countries attended to share their insights and vision on the evolution of molecular diagnostics and therapeutics in cancer care.

In terms of infectious diseases, in November 2020 during the annual meeting of the 'Association for Molecular Pathology (AMP), three out of the ten published Idylla™ studies discussed Biocartis' new rapid response Idylla™ pandemic menu tests, the Idylla™ SARS-CoV-2 Assay and the SeptiCyte® RAPID on Idylla™.

#### SCIENTIFIC ADVISORY BOARD

In order to continuously keep up with oncology MDx testing market trends, Biocartis has established a Scientific Advisory Board composed of KOLs and headed by Biocartis' Chief Scientific Officer Geert Maertens. Members of this board serve as scientific advisors to Biocartis' Idylla™ product developments. They meet regularly to discuss medical and biomarker needs for cancer patients, and provide support in Biocartis' Idylla™ pipeline priorities in an independent and unbiased manner. An overview of the members is available on www.biocartis.com.

## SUPPLIERS

More than ever, Biocartis is working closely with its suppliers to ensure that they meet Biocartis' requirements in terms of quality, safety and environmental compliance through:

- Risk assessments: Biocartis performs thorough risk assessments to get an overview of potential risks. Pro-active checks are in place to avoid or mitigate issues before entering into partnerships. This strategy has helped Biocartis to ensure supply continuity during the COVID-19 pandemic. More information can be found under the chapter 'Impact of COVID-19', supplier impact.
- Business continuity plans are established in order to avoid or mitigate potential internal and external threats, such as IT, power outage, fire
- Agreements: Biocartis is executing upon its plan to expand its agreements (such as quality, manufacturing) with its suppliers outlining a clear set of expectations in terms of technical specifications, quality, safety and environment
- Performance audits: Every year, an audit plan is established and several supplier audits are executed to ensure all materials meet expectations for technical specifications, quality, safety and environment
- Supplier performance: Biocartis actively monitors supplier performance on various topics and is continuously in dialogue with its suppliers to ensure they meet the required performance, such as product specification documents and audit action plans

Key manufacturing & supply chain focus areas in 2020 were:

- Sustaining the cartridge manufacturing output on the first manufacturing line 'ML1' while completing the transfer of its highest volume assays to the second, close to fully automated manufacturing line 'ML2'
- Continued organizational capability development through investment in talent and through the roll out of Lean Six Sigma projects

- Continue a companywide program geared at establishing readiness for anticipated US FDA audit inspections and IVDR regulations
- Completion of the re-certification of the ISO 13485:2016 standard and MDSAP regulations.

## EMPLOYEES

*"During the pandemic, our employees really stepped up to the challenge, demonstrating commitment, team work, agility and resilience."*
*Susy Spruyt, Head of People & Organization Biocartis*

### PEOPLE STRATEGY

Our employees are essential to our success. We are dedicated to building a diverse, global team of talented people that contribute to our organizational success. The foundation of our people strategy is built on the fundaments of an organizational governance framework that has been set up to be a customer-, partner- and service-oriented organization.

Our HR strategy builds on the following pillars:

1. Competency based framework with focus on our core competencies, including cross-functional teamwork, accountability, result driven, continuous improvement, quality mindset, customer centricity
2. Governance structure which fosters accountability and decision-making at the right level and provides fast escalation and issue resolution when needed
3. Project execution skills focus which includes clinical validity, regulatory compliance and quality mindset skills
4. Succession planning and talent acquisition program
5. Learning & development framework to create opportunities for employee growth

### DIVERSITY & INCLUSIVENESS

With 366 employees[6] end of 2020 across more than 70 countries, the Biocartis culture is global, diverse and innovative. Talented, committed and accountable people with diverse backgrounds are essential for successfully implementing Biocartis' strategy.

Biocartis fosters 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. End of 2020, the Biocartis workforce of 366 employees[6] counted:

- 33 different nationalities
- A balanced level of gender diversity of 51% male and 49% female, stable since 2016
- Approx. 90% of the Biocartis employees worked full-time, stable since 2016

### TRAINING & DEVELOPMENT

At the heart of its people strategy, Biocartis' learning & development program aims at ensuring a robust succession planning. Being a fast-growing technology company, Biocartis cultivates learning and career development as an integral part of the Biocartis employee experience. Training plans include:

- Individual training plan per employee based on his/her role and responsibilities
- Regular review and discussion of the employee training plan with the manager
- Follow-up of the training plan through MasterControl, the quality & compliance software

Continuous learning & development activities include:

- When starting at Biocartis, new employees attends an Induction Day to feel welcome and receive all information and tools needed to take up his or her new job. In 2020, 23 induction days were held for all new employees. As of March 2020, due to the COVID-19 pandemic, these Induction days were organized virtually
- The Biocartis Academy is composed of a number of development programs rolled out cross-functionally. These include modules on building business & financial acumen, process ownership and leadership development
- 'Open' learning formats such as quarterly staff meetings, Biocartis 'Learn & Grow sessions, or ad hoc expert speaker sessions from KOLs
- Individualized learning & development program based on goals, competence management and career plans that employees define together with their manager

In 2020, the Biocartis workforce followed 21,520 training hours.

### EMPLOYEE WELLBEING, ALSO IN PANDEMIC TIMES

Well-being at work means ensuring employees are safe, physically and mentally healthy, satisfied, engaged and working in an efficient manner. This contributes to a culture of recognition and support, as well as a healthy work-life balance where employees thrive to develop

their highest potential. Being active in a rapidly changing environment which requires agility and resilience, Biocartis has been increasingly focusing on its employee wellbeing in the past years. This included structural initiatives such as the creation of a company structure with clear roles and expectations for every employee, supportive leadership with attention for daily wellbeing and flexible working schedules, and regular company-wide celebrations of successes and events. Additionally, since 2019, Biocartis rolled out several campaigns with key note speakers on topics such as mental health & resilience, focus, digital detox and the importance of sleep.

The year 2020 was particularly challenging for employee wellbeing due to the global COVID-19 pandemic. More information on how Biocartis managed the pandemic impact for its employees can be found in the chapter 'Impact of COVID-19'.

## HEALTH & SAFETY

Biocartis is committed to invest in a safe, healthy and environmentally friendly workplace and has therefore established a Health, Safety & Environmental (HS&E) Policy for all of its employees, contractors and visitors worldwide.

The Biocartis HS&E Policy ensures Biocartis understands and complies with HS&E regulatory requirements and all relevant HS&E risks through a dynamic risk assessment. Furthermore, 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 2020:

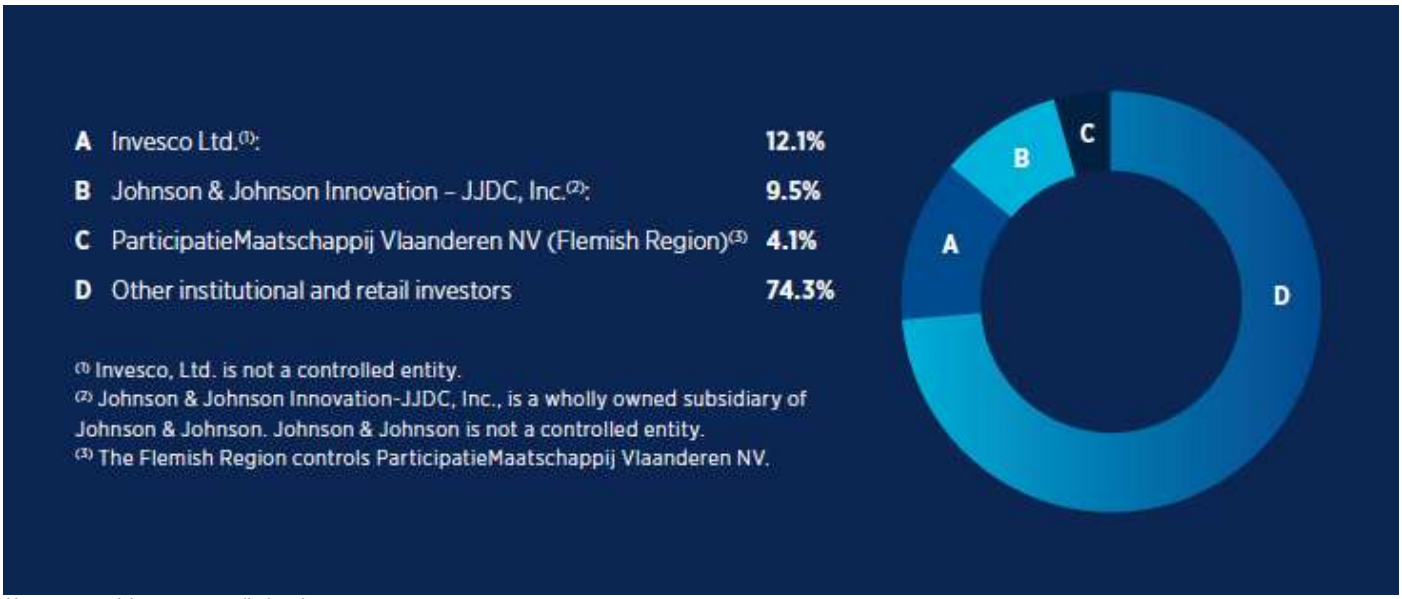
- An integrated safety management system was developed to further improve risk assessment, ensure safety and define safety improvement areas in domains such as chemical safety, machine safety, personal protective measures and ergonomics. No legal EHS regulation breaches were reported
- Biocartis employees followed several virtual H&S trainings, including basic rescue trainings, first-aid refreshment trainings, fire safety & spill training and machine & electrical safety
- No lethal accidents or working accidents causing disability occurred. Four workplace accidents occurred causing minor injuries. Each event triggered a root cause analysis and mitigation actions were taken to avoid future workplace injuries.

An overview of H&S measures taken in the context of COVID-19 can be found in the section 'Impact of COVID-19' under 'social impact' and 'environmental impact'.

# SHAREHOLDERS

## 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 2020 and the transparency notifications received until that date, the shareholder structure of the Company was as follows:



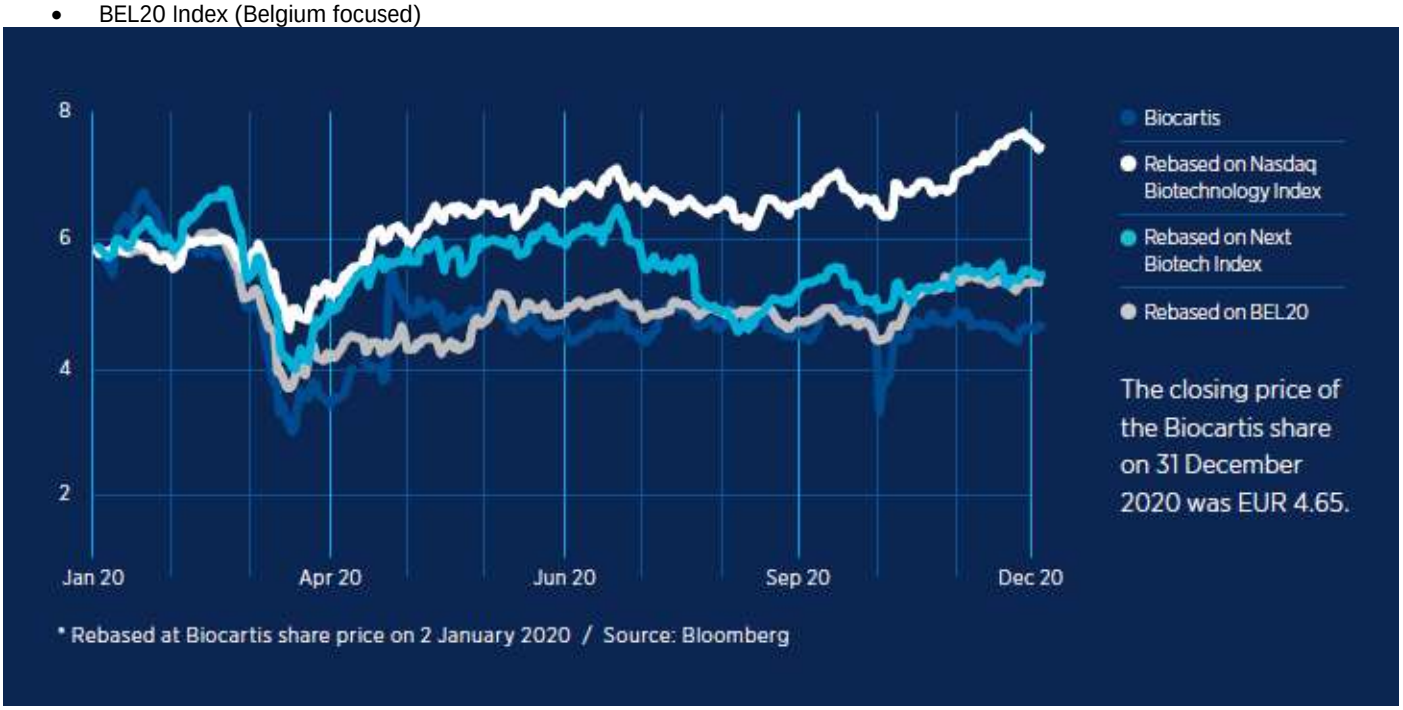

(1) Invesco, Ltd. is not a controlled entity.
(2) Johnson & Johnson Innovation-JJDC, Inc., is a wholly owned subsidiary of Johnson & Johnson. Johnson & Johnson is not a controlled entity.
(3) The Flemish Region controls ParticipatieMaatschappij Vlaanderen NV.

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)



## TRADING VOLUME

Below is a summary of the 2020 trading volumes of Biocartis' share.

| BCART | 2020 | 2019 | Change % |
|---|---|---|---|
| Average daily volume | 169,073 | 134,687 | 20% |
| Average daily value | 4.79 | 9.56 | -50% |
| Total traded volume | 43,451,721 | 34,345,170 | 21% |
| Total traded value | 208,725,342 | 606,959,025 | -66% |

Source: Bloomberg

## ANALYST COVERAGE

The Biocartis share was covered by six brokers end of 2020:

| Broker | ANALYST | RATING END 2020 |
|---|---|---|
| Berenberg | Michael Healy | Buy |
| Degroof Petercam | Thomas Guillot | Hold |
| KBC Securities | Lenny Van Steenhuyse | Buy |
| Kempen & Co | Alexandru Cogut | Buy |
| Kepler-Cheuvreux | Maja Pataki | Buy |
| Bryan-Garnier | Dylan van Haaften | Buy |

### FINANCIAL CALENDAR 2021

- 25 February 2021 Full year results 2020
- 1 April 2021 Publication Annual Report 2020
- 22 April 2021 Q1 2021 Business Update
- 14 May 2021 Annual General Meeting Biocartis Group NV
- 2 September 2021 H1 2021 results
- 10 November 2021 Q3 2021 Business Update

### INVESTOR RELATION 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. QUALITY

Quality plays a crucial role in Biocartis' ambition to enhance the healthcare outcome for patients with its unique Idylla™ products. Biocartis is committed to continuous improvement and has established a Quality Management System (QMS) compliant with the international standards and regulations which provides a framework for measuring and improving performance.

The Biocartis QMS covers all of Biocartis' products and tests. All processes needed for the QMS and their application throughout the organization are defined in a Quality Manual which describes the key processes to develop, manufacture and deliver high quality products to Biocartis' customers and to leverage customer feedback for continuous improvement. Each of the underlying key processes is described in procedures and work instructions that are deployed throughout the organization.

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 (e.g. ISO 13485 and FDA 21 CFR part 820) and internal requirements established as per the Biocartis' Quality Manual and Quality Policy. 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.

Biocartis complies with the following standards:

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on IVD medical devices
- 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)

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. Main quality related achievements in 2020 were:

- The integration of the new organizational structure in the Biocartis QMS, which required a joint effort of multiple departments and process owners to update key QMS processes and associated documents
- The recertification of the Biocartis QMS against the ISO 13485:2016 standard and full set of MDSAP regulations (Australia, Brazil, Canada, Japan, USA) and achieving issuance of new certificates for Biocartis NV

## 1.5. ENVIRONMENT

Biocartis carefully manages its environmental impact. Biocartis is therefore committed to full compliance with all applicable environmental legislation related to its products and activities.

### ENVIRONMENTAL IMPACT OF OUR PRODUCTS

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[80] directive regarding the Restriction of Hazardous Substances in electrical and electronic equipment
- The WEEE directive[81] 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[82]

## ENVIRONMENTAL IMPACT OF OUR ACTIVITIES AS A COMPANY

Biocartis also complies with the directives originating from its manufacturing and research activities:

- The Contained Use Directive aimed at limiting contact of the environment with genetically modified and infectious microorganisms
- The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) aimed at a sustainable management of biocides and reduce the risk and impact of it on the environment and human and animal health
- The Waste Directive aimed at improving the recovery and recycling of waste
- The Energy Efficiency Directive aimed at a more efficient use of energy at all stages of the energy chain, from production to final consumption

Biocartis has obtained all required environmental consents, permits and licenses related to these regulations. Furthermore:

- Environmental compliance is ensured through the Biocartis Environmental Management System
- Biocartis has appointed an external environmental coordinator to stay up-to-date with all legislative changes
- Regular update of the environmental permit (adjustments/extension of production)

In 2020, Biocartis performed a review of all applicable new environmental legislation (Europe/Belgium/Flanders) to ensure full compliance. This review included legislation relating to biocides and updates to the Flemish 'Materials Decree/VLAREMA' regulation requirements and the Flemish regulation for sustainable management of materials and waste (incl. separate collection of e.g. plastics films).

Other actions in 2020 included:

- Update of the waste manual (including optimization of waste flows and revision of acceptance criteria for waste flows and chemical waste flows)
- Further follow-up and monitoring of energy and water consumption
- Preparation of permit application for the Biocartis 'BC5' building
- Review and update of the HSE manual
- Investigation of biocide use in hot water baths
- Phasing out of the use of refrigerants

# 2. 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 MDX INDUSTRY IS HIGHLY COMPETITIVE AND SUBJECT TO RAPID TECHNOLOGICAL CHANGES. IF BIOCARTIS' CURRENT OR FUTURE COMPETITORS DEVELOP SUPERIOR, ALTERNATIVE OR MORE WIDESPREAD SOLUTIONS AND TECHNOLOGIES, OR OBTAIN REGULATORY CLEARANCE OR APPROVAL BEFORE BIOCARTIS DOES, OR OBTAIN GREATER INTELLECTUAL PROPERTY PROTECTION, BIOCARTIS' COMPETITIVE POSITION AND OPERATIONS WOULD BE NEGATIVELY IMPACTED.

The molecular diagnostics ('MDx') industry is characterized by a rapid and continuous drive for technological innovation, evolving market standards, changes in customer needs, emerging competition and new product launches that could impact the competitive positioning of Biocartis' current and future products. Biocartis may need to develop or in-license new technologies and solutions 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' 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 in the oncology field in the future or that existing random-access sample-to-result platforms that are currently deployed in other MDx markets could extend their focus to the oncology MDx market. Biocartis' 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 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-, 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, ITS MENU OF TESTS 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 tests, but so far Biocartis has only generated limited revenues. There can be no assurance that Biocartis' current products or any further products launched by Biocartis 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 the products launched by Biocartis, including:

- The speed and breadth of building an installed base of Idylla™ instruments and consoles, 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 Biocartis' menu of tests 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 payers' needs and emerging clinical and technology trends;
- The competition (for further information, see risk factor 'The MDx industry is highly competitive and subject to rapid technological changes. If Biocartis' current or future competitors develop superior, alternative or more widespread solutions and technologies, or obtain regulatory clearance or approval before Biocartis does, or obtain greater intellectual property protection, Biocartis' competitive position and operations would be negatively impacted.');
- The unavailability of Biocartis' products 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 Biocartis' products;
- 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 its products 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 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 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 Biocartis' current products, as well as any further products launched, for which Biocartis will have to spend substantial time and resources to overcome them.

### BIOCARTIS FACES UNCERTAINTIES OVER THE REIMBURSEMENT FOR ITS PRODUCTS 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/or any future products depends, in part, on the degree to which they are reimbursed by public health administrations, private health insurers, managed care organizations and other organizations ('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, at all or to a material extent, if they do not receive adequate reimbursement for the procedures used to run Biocartis' products, and potential patients may be unwilling to pay for the Idylla™ platform, the Idylla™ tests and/or any future products themselves, or only at pricing levels which are uneconomical for Biocartis.

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 Biocartis products will depend on obtaining a 'reimbursement code' for such product (or underlying procedure). 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', payers (e.g. national healthcare systems or health insurance companies) have to agree to provide coverage for the procedure(s) used to run the Idylla™ platform, the Idylla™ tests and/or any future products. Moreover, even if a 'reimbursement code' is in place for a product, governments may decide to change the reimbursement levels 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 Biocartis' products will not have any form of health insurance, and that those patients therefore 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 could be faced with significant efforts and expenses to establish, and may never succeed in establishing, widespread or systematic reimbursement arrangements for its future products.

Furthermore, reimbursement levels are set by parties outside the control of Biocartis and they may change over time. Generally, hospitals, governments and third-party payers are increasingly exerting downward pressure on pricing and reviewing the cost effectiveness of medical products, therapies 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 therapies. A reduction in reimbursement levels may affect the price that Biocartis is able to obtain for the Idylla™ platform and tests.

### 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, with Belgian and foreign companies. 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 could be substantially delayed or impaired if such partners:

- Fail to comply with their regulatory obligations;
- Do not successfully develop or commercialize the Idylla™ 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 and tests;
- 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 uses 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. Furthermore, disagreements with these partners could require or result in litigation or arbitration, which would be time-consuming, distracting and expensive. If any of these issues arise, it may delay the development and commercialization of the Idylla™ platform and tests, and may materially and adversely affect Biocartis' business, prospects, financial condition and results of operations.

## 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 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 CMOs. The assembly of the cartridge is currently performed in-house at Biocartis' facilities in Mechelen (Belgium).

Biocartis has constructed a more automated and higher volume production line for Idylla™ cartridges in its Mechelen (Belgium) facilities that, together with its first manufacturing line, should provide for sufficient manufacturing capacity to cover expected demand. Biocartis has well advanced the process of transferring its commercial volume to this new production line. However, due to the high level of complexity of the cartridge manufacturing process, there can be no assurance that it would enable Biocartis to manufacture products in sufficient quantities, to the same standards and at an economically attractive cost compared to Biocartis' competitors, or at all. The manufacturing transfer could also require new registrations or updates to registrations of existing products that could adversely impact the availability of products from the new production line in select countries and/or regions (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.'). All these factors could affect Biocartis' ability to continue supply to its customers which could result in potential financial and reputational damages.

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. There can be no assurance that the contracted CMOs will deliver products on time, or in compliance with the standards that are required by the relevant regulatory authorities, or that it 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.

To date, the Idylla™ platform has been commercialized on the basis of a limited number of tests that are approved for clinical use. 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™ instruments and consoles. 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 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 or validation 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 MAY NOT BE SUCCESSFUL IN FURTHER GROWING ITS COMMERCIALIZATION INFRASTRUCTURE.

Biocartis only initiated deploying a commercialization infrastructure in diagnostics markets in 2014 and may not succeed in hiring additional and/or retaining key personnel, or making appropriate arrangements with distributors and other parties, to execute the commercial deployment of the Idylla™ platform and tests.

Biocartis is still expanding its commercialization infrastructure for the Idylla™ platform and tests, an innovative solution that requires the development of a new go-to-market approach. Furthermore, to commercialize the Idylla™ platform and tests, Biocartis will need to further

build a maintenance and service organization in order to ensure adequate installation and servicing of its installed base. Biocartis will also need to coordinate commercialization with its partners, distributors and other third parties outside of its control.

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

Furthermore, part of Biocartis' commercial strategy is placing its diagnostic platform with clients under, among others, operational lease contracts. Under such contracts, the customers are entitled to return the platform to Biocartis under certain conditions, which could have an impact on Biocartis' installed base and could result in a loss in product revenues.

If Biocartis fails to further grow its commercialization infrastructure successfully, this will have a material 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.

### IF BIOCARTIS FAILS TO ATTRACT OR RETAIN KEY PERSONNEL, ITS ABILITY TO CONDUCT AND EXPAND ITS BUSINESS COULD BE NEGATIVELY AFFECTED.

The performance of Biocartis is dependent, to a certain extent, on the members of its management team and its technical, scientific and other key personnel. Biocartis does not maintain 'key man' insurance policies on the lives of these individuals or the lives of any other employees. The loss of any of these persons or the inability to find suitable replacements on a timely basis could potentially harm its business, financial condition, or results of operations. Biocartis relies on personnel with experience in the development, registration, manufacturing and commercialization of complex MDx products. Competition for personnel with the appropriate skill set and experience is intense and may limit Biocartis' ability to hire and retain highly qualified personnel on acceptable terms, or at all. Many of the competitors have greater financial and other resources, different risk profiles and a longer history than Biocartis. In addition, Biocartis' anticipated growth and expansion in accordance with its strategy is expected to place greater demands on its resources, requiring the addition of new skilled personnel in areas such as test development, engineering, clinical development, sales, marketing and finance. Attracting, retaining and training personnel with the requisite skills could therefore be challenging. If, at any point, Biocartis is unable to hire, train and retain a sufficient number of qualified employees to support its growth, this could have a material adverse effect on its ability to implement its business strategy, which in turn may have a material adverse impact on its business, financial condition and results of operations.

### 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 computer and 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 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 all of the data on the Idylla™ platform is designed to be de-identified ("pseudonymised") and patient details should only be available at the point of testing, 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, including patient records, 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 BREXIT

On 31 January 2020, the United Kingdom ('UK') formally left the EU (commonly referred to as 'Brexit'). The long-term effects of Brexit in general, and of the trade and cooperation agreement negotiated between the UK and the EU in particular, remain uncertain.

In particular, the manufacturing or assembly of the Idylla™ instrument and the console has been outsourced to a CMO based in Scotland. The manufacturing or assembly of the cartridges is currently performed in-house at Biocartis' facilities in Mechelen (Belgium) and only a few components are sourced or distributed from the UK. Whilst Biocartis closely monitors any Brexit related developments, closely liaises with its suppliers in this respect and has taken measures to mitigate potential delays and other customs related effects, Brexit remains an unprecedented situation with a lot of uncertainty that may have negative impacts on Biocartis' logistic streams from and to the UK and hence on the availability of its products and components.

### UNCERTAINTIES DUE TO COVID-19 OUTBREAK

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. The COVID-19 pandemic has resulted in a deprioritization of global cancer care and a significant reduction in global diagnostic testing volumes in oncology. Throughout the COVID-19 pandemic, and to this date, patient access to hospitals remains significantly restricted and customer prospection continues to be severely hampered. Testing volumes in oncology may therefore remain lower than expected until lock-down measures are eased on a global scale. Although the pandemic presented new opportunities for Biocartis in infectious diseases as a result of, among others, the significant global increased need for molecular diagnostic COVID-19 test capacity, there can be no assurance that Biocartis will continue to be able to offset the shortfall in the sales in the oncology MDx space by sales of tests of its pandemic response menu, or that it will be able to sell those tests at competitive prices or at all.

Moreover, 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 continue to run its operations without disruptions, as a prolonged impact of the pandemic 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 claims that are inherent in clinical testing and MDx. Biocartis faces the risk of liability for damages if there are deficiencies with any of its products, affecting among others product performance, due to component failures, manufacturing errors, design or labelling defects or other deficiencies and issues. Biocartis cannot be certain that it will be able to successfully defend any product 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 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 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 claims have been initiated against Biocartis. Biocartis cannot provide any assurance that it will be able to maintain sufficient insurance coverage on commercially acceptable terms in the future, 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.

### BIOCARTIS CANNOT PROVIDE ASSURANCE THAT PATIENTS, HOSPITALS, PHYSICIANS OR OTHER PARTIES WILL NOT TRY TO HOLD IT RESPONSIBLE FOR ALL, OR PART, OF THE MEDICAL DECISIONS UNDERLYING THE TREATMENT OF PATIENTS.

The existing Idylla™ products on the market are designed to detect the presence or levels of certain specific biomarkers. These products are not designed to specify the treatment necessary for each patient, which remains the responsibility of relevant medical personnel. Although Biocartis indicates in its marketing materials and in the labelling of its products (which indicates, among other things, the relevant test's accuracy rate) that its products are not designed to specify the course of treatment for patients and although Biocartis has not yet

encountered such actions to date, Biocartis cannot provide assurance that patients, hospitals, physicians or other parties will not try to hold Biocartis responsible for all or a part of the medical decisions underlying the treatment of patients, exposing Biocartis to potential litigation or civil or criminal liability. Such actions or liability could lead governmental agencies to conclude that Biocartis' products or services are no longer to be used or used improperly, all of which could significantly damage Biocartis' reputation and could materially impair the continued adoption of Biocartis' product offering in the market, which may have a material adverse impact on its business, financial condition and results of operations.

## 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 2020, Biocartis' patent portfolio consisted of 29 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 2020, the value of the Idylla™ platform was protected by a group of 50 patent families (27 proprietary patent families and 23 in-licensed patent families) and two invention disclosures, 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 of 5 October 1973 (as amended) (a 'European Patent') most third parties (other than assumed infringers) usually 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. The value of the unique Idylla™ platform is, in part, protected by a group of 50 patent families of which 23 are in-licensed families, comprising issued patents and pending patent applications worldwide, covering the platform technology and its associated biochemistry (for further information, see risk factor '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').

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 sublicensor 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 REGULATORY STANDARDS AND REQUIREMENTS, 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 other ongoing 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, limitations on reimbursement, inability to commercialize or obtain reimbursement, product liability, 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, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, 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.

### BIOCARTIS IS SUBJECT TO HEALTHCARE FRAUD AND ABUSE AND OTHER LAWS APPLICABLE TO BIOCARTIS' BUSINESS ACTIVITIES. IF BIOCARTIS IS UNABLE TO COMPLY WITH SUCH LAWS, IT COULD FACE SUBSTANTIAL PENALTIES.

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

The federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly or willfully soliciting, receiving, offering or paying any remuneration, overtly or covertly, directly or indirectly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order, arrange for, or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;

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

The federal Health Insurance Portability and Accountability Act of 1996, which established new federal crimes for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, concealing a material fact, or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

An increasing number of state 'sunshine' laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring medical device companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, and to prohibit or limit certain other sales and marketing practices; and

A US federal law known as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

Biocartis is also subject to various fraud and abuse laws in jurisdictions outside of the US. For example, pursuant to the Belgian 'Sunshine Act' of 18 December 2016 (and its implementing measures ), manufacturers of medical devices are required to document and disclose all direct or indirect premiums and benefits granted to healthcare professionals, healthcare organizations and patient organizations with a practice or a registered office in Belgium.

If Biocartis' operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of Biocartis' operations, the exclusion from participation in government healthcare programs and individual imprisonment, 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 shall 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 in the transition period leading up to the May 2022 effective date of the new regulation.

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 (which entered into force in May 2017 with a transitional period of five years), Idylla™ oncology tests are classified as high-risk, thereby requiring the services of a Notified Body for their CE-marking. 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. 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. There is also 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 its products 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.

For instance, certain policies in the US may impact the medical device industry. There have been judicial and congressional challenges to certain aspects of the Patient Protection and Affordable Care Act (the 'Affordable Care Act'), as well as recent efforts to repeal or replace certain aspects of the Affordable Care Act and such challenges and amendments may continue. These actions may adversely affect the healthcare industry in the US and around the world. Biocartis cannot predict the likelihood, nature or extent of government regulation that may arise in the US or elsewhere.

## 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 in 2007. Operating loss for the year ended 31 December 2020 was EUR 46.8m. As of 31 December 2020, Biocartis had an accumulated deficit of EUR −460.5m. These losses have resulted principally from costs incurred in the design, industrialization and commercialization of the Idylla™ platform, the development of tests, the establishment of manufacturing facilities that comply with the FDA standards, 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 OR TAKE ADVANTAGE OF NEW BUSINESS OPPORTUNITIES, 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, 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. In addition, these securities may be sold at a discount from the market price of Biocartis' common stock. 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. CORPORATE GOVERNANCE REPORT

## 3.1. INTRODUCTION

During 2020, 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 (https://www.corporategovernancecommittee.be/en). 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 (https://investors.biocartis.com/en).

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 4from the provisions of the Corporate Governance Code 2020 is justified as it is not in a position to grant shares to non-executive directors as part of their remuneration. This deviation is described below in the Remuneration Policy and Remuneration Report.

## 3.2. BOARD OF DIRECTORS

### COMPOSITION

The table below gives an overview of the members of the Company's board of directors on 31 December 2020.

| Name | Position | Start of mandate | End of term |
|---|---|---|---|
| Christian Reinaudo(1) | Chairman, independent director | 2018 | 2021 |
| Herman Verrelst | Chief executive officer, executive director | 2017 | 2021 |
| Luc Gijsens(2) | 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 CRBA Management BV. As from beginning 2021, Mr. Reinaudo performs his director mandate in personal name and no longer via CRBA Management BV (liquidated).

(2) 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 GmbH since 2016.

Herman Verrelst was appointed as chief executive officer of the Company effective as of 31 August 2017. He is a seasoned executive and serial 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 as well as founder and CEO of DATA4s.

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, 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. Previously, 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. 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 8 May 2020 reappointed Ann-Christine Sundell, Luc Gijsens BV, permanently represented by Luc Gijsens, and Roald Borré as directors of the Company for a term of two years, and appointed Christine Kuslich as director of the Company for a term of two years. The mandates of Christian Reinaudo and Herman Verrelst will end after the annual shareholders' meeting of 14 May 2021. 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(1) | • E-health & digital imaging solutions<br>• Managing companies<br>• International business | Male | 66 | France |
| Herman Verrelst | • Molecular diagnostics<br>• Software solutions<br>• Entrepreneurship | Male | 47 | Belgium |
| Luc Gijsens(2) | • Finance<br>• Capital markets<br>• Corporate and investment banking | Male | 67 | Belgium |
| Ann-Christine Sundell | • Life sciences<br>• Diagnostics<br>• Strategy and operations | Female | 56 | Finland |
| Christine Kuslich | • Molecular diagnostics<br>• Oncology & Infectious disease<br>• Strategy & investment | Female | 53 | USA |
| Roald Borré | • Corporate finance and M&A<br>• Investment funds<br>• Accounting and auditing | Male | 48 | Belgium |

Notes:
(1) As from beginning 2021, Mr. Reinaudo performs his director mandate in personal name and no longer via CRBA Management BV (liquidated);
(2) Permanently representing Luc Gijsens BV.

Belgian company law requires at least one third of the directors of a listed company to be of a different gender than the other directors. Currently, the Company has two female directors on its board of directors on a total of six directors. The board is of the opinion that there is currently sufficient diversity in terms of age. It however believes that in terms of 'functional background and expertise' it could benefit from additional profiles with board experience in internationally operating (listed) companies, experience in commercialization of molecular diagnostics products and/or corporate business development.


## ACTIVITY REPORT

In 2020, 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 2020 was 100%, save for Luc Gijsens BV, represented by Luc Gijsens, 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 the Group's strategy, operations, commercial performance, ongoing menu development and the impact of the COVID-19 pandemic on its business, discussed business development opportunities and the status of ongoing collaborations, and discussed regular updates of the implementation of the integrated quality plan. The board also discussed various corporate governance, as well as nomination and remuneration matters, such as the hiring of a new CFO, the proposed changes to board composition (and consequently, the composition of the board committees), the board evaluation, the approval of a new version of the corporate governance charter, and the approval of two new share option plans. Moreover, the board discussed the regular updates of the financial performance and the budget for financial year 2021 as well as the Company's long-term financial plan. The board also discussed and approved the full year and half year financial statements and reports, and the Q1 and Q3 business updates and related communication. In addition, the board discussed the proposal to the shareholders to renew the authorized capital, and approved the incentivized conversion of part of its outstanding convertible bonds.

## 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 2020:

| | |
|---|---|
| Christian Reinaudo | • CRBA Management BV(1)<br>• Agfa Gevaert NV<br>• Domo Chemicals GmbH |
| Herman Verrelst | • South Bay Ventures (SBV) BV<br>• Opdorp Finance BV<br>• Heran BV<br>• Icometrix<br>• FlandersBio VZW |
| Luc Gijsens | • Luc Gijsens BV<br>• Aveve NV<br>• PMV NV<br>• KMDA VZW<br>• KMDA NV<br>• Global Rental Properties NV |

| | |
|---|---|
| Ann-Christine Sundell | • Raisio Oyj<br>• Medix Biochemica Group Oy<br>• Revenio Oyj<br>• Immunovia AB<br>• Förlags Ab Sydvästkusten<br>• AConsult |
| Christine Kuslich | N/A |
| Roald Borré | • FNG Groep NV<br>• High Wind NV<br>• Capricorn Cleantech Fund NV<br>• Media Invest Vlaanderen NV<br>• Flange Holding NV<br>• Kebony AS<br>• Kebony Belgium NV<br>• Kebony Norge AS<br>• Kebony Danmark A/S<br>• Kebony Sverige AB<br>• ALZV vzw |

(1) CRBA Management BV has been liquidated in the beginning of 2021.

## 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 three times in 2020 during the meetings held on 4 March 2020, 31 March 2020 and 20 April 2020. The extract of the minutes of those meetings is as follows:

Meeting 4 March 2020

*"Prior to discussing the next item, Mr. Herman Verrelst, director and CEO of the Company, declared that he has an interest of a financial nature which is conflicting with the decisions that fall within the scope of the powers of the Board of Directors, with respect to the determination of the amount of his variable remuneration and the vesting of his performance-based share options under the share option plan 2017 regarding performance year 2019, the determination of the KPIs for his variable remuneration package regarding performance years 2020 to 2022, and the KPIs for the vesting of his performance-based share options regarding performance year 2020.*

*In accordance with Article 7:96 of the Belgian Code of Companies and Associations, Mr. Herman Verrelst will refrain from taking part in the deliberations and from voting on the matters for which he has a conflict of interest.*

*In accordance with Article 7:96 of the Belgian Code of Companies and Associations, the minutes of this Board meeting will be provided to the auditor of the Company, Deloitte Bedrijfsrevisoren CVBA, permanently represented by Mr. Gert Vanhees. Furthermore, the relevant sections of these minutes will be included in the annual report of the Board of Directors.*

*A. Following the recommendations of the Remuneration and Nomination Committee, the Board discussed the goals for the CEO relating to performance year 2019 (consisting for 75% of the 1-year targets defined in the beginning of 2019, and for 25% of the 2-year targets defined in 2018) and assessed the degree to which these goals were achieved in 2019. The Board was of the opinion that overall 40.8% of the 1-year targets was achieved and 16.8% of the 2-year targets was achieved, and resolved to approve the amount of the variable remuneration for the CEO relating to performance year 2019 on this basis (i.e., an amount of EUR 73,125).*

*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 2019. The Board considered that overall 40.8% of the KPIs were achieved. Therefore, after discussion, the Board resolved to approve that 68,340 performance-based share options under the share option plan 2017 relating to the performance year 2019 have vested. The other 99,160 performance-based share options relating to the performance year 2019 will not vest, and*

*will immediately become null and void. The non-vested 28,475 share options related to the performance year 2018 which were carried-over to the performance year 2019 will become null and void as the condition for vesting thereof (i.e., overachievement) was not met.*

*B. 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 years 2020 - 2022. For the 1-year target (for 2020), the proposal is to use 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 2-year (2021) and 3-year (2022) target, the proposal to the Board will be formulated during the next Board meeting, after further analysis by the Remuneration and Nomination Committee and the external advisor to be engaged.*

*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."*

Meeting 31 March 2020

*"Prior to discussing the next item, Mr. Herman Verrelst, director and CEO of the Company, declared that he has an interest of a financial nature which is conflicting with the decisions that fall within the scope of the powers of the Board of Directors, with respect to the determination of his remuneration for 2020 and beyond.*

*In accordance with Article 7:96 of the Belgian Code of Companies and Associations, Mr. Herman Verrelst will refrain from taking part in the deliberations and from voting on the matters for which he has a conflict of interest.*

*In accordance with Article 7:96 of the Belgian Code of Companies and Associations, the minutes of this Board meeting will be provided to the auditor of the Company, Deloitte Bedrijfsrevisoren CVBA, permanently represented by Mr. Gert Vanhees. Furthermore, the relevant sections of these minutes will be included in the annual report of the Board of Directors.*

*Following the recommendations of the Remuneration and Nomination Committee, the Board discussed the KPIs relating to the vesting of maximum 167,500 performance-based subscription rights (formerly known as warrants) under the 2017 plan for the CEO for performance year 2020. The Board determined that the same KPIs will be used as the 1-year KPIs determined by the Board on 4 March 2020 for the CEO's cash bonus.*

*Subsequently, the Chairman summarized the recommendations made by the Remuneration and Nomination Committee with respect to the remuneration of the CEO. Overall, no adjustments are proposed with respect to the fixed remuneration of the CEO. After discussion, the Board resolved however that:*

- *50% of the variable remuneration of the CEO will be linked to 1-year KPIs (which for 2020 have been determined by the Board during its meeting of 4 March 2020), 25% will be linked to a 2-year KPI and the remaining 25% will be linked to a 3-year KPI. The Board resolved that the 2-year and 3-year KPIs will be put in place in the form of a phantom stock plan linked to the evolution of the share price of the Company;*
- *the CEO would be entitled to a grant of 300,000 subscription rights (formerly known as warrants) in 2020, followed by three annual grants of 60,000 subscription rights in 2021, 2022 and 2023, all of which will be subject to a cliff vesting after three years after the relevant grant date;*
- *the CEO will be subject to the requirement to hold a number of shares in the Company which is equivalent to at least one year fixed remuneration.*

*The different aspects of the remuneration of the directors and members of the executive management will be included in the remuneration policy of the Company, which will be submitted to the shareholders' meeting after the European Directive 2017/828 as regards the encouragement of long-term shareholder engagement has been duly implemented into Belgian law."*

Meeting 20 April 2020

*"Prior to discussing the next item, Mr. Herman Verrelst, director and CEO of the Company, declared that he has an interest of a financial nature which is conflicting with the decisions that fall within the scope of the powers of the Board of Directors, with respect to the approval of the phantom stock plan 2020 and the share option plan 2020B.*

*In accordance with Article 7:96 of the Belgian Code of Companies and Associations, Mr. Herman Verrelst will refrain from taking part in the deliberations and from voting on the matters for which he has a conflict of interest.*

*In accordance with Article 7:96 of the Belgian Code of Companies and Associations, the minutes of this Board meeting will be provided to the auditor of the Company, Deloitte Bedrijfsrevisoren CVBA, permanently represented by Mr. Gert Vanhees. Furthermore, the relevant sections of these minutes will be included in the annual report of the Board of Directors.*

*Following the recommendations of the Remuneration and Nomination Committee, and in execution of previous decisions of the Board in this respect, the Board discussed the phantom stock plan 2020 which will among others be used in relation to the 2-year and 3-year KPIs for the members of the executive management. The Board noted that no pay-out will be due to the beneficiaries in case the value of the Biocartis share has decreased below 50% of the relevant reference value, and a maximum pay-out equal to 150% of the deferred bonus amount will apply. The Board requested to revise the draft plan so that every time the value of the Biocartis share is to be taken into account for the purposes of the plan (e.g., when determining the amount of phantom stock to be awarded or when determining the pay-outs to be made), such value shall be calculated over a 30-day reference period, except for the first grant under the phantom stock plan 2020 for which the closing price of the Biocartis share on Euronext Brussels on the trading day before the present Board meeting shall be taken into account.*

*After discussion, the Board resolved to approve the phantom stock plan 2020 as presented but subject to the comments made, as well as the performance of the obligations that the Company is to assume and perform in that regard. Furthermore, the Board resolved to approve the signing of all documentation and agreements to which the Company is or must become a party in the framework of the proposed issuance, offering and granting of phantom stock 2020.*

*Mr. Verrelst also informed the meeting that the agenda refers to the issuance of the Share Options 2020B in the framework of the Share Option Plan 2020B, and that he is a Beneficiary under the Share Option Plan 2020B. Mr. Verrelst informed the meeting that, as a result, he might have a conflict of interest within the meaning of Article 7:96 of the Belgian Code of Companies and Associations in relation to the resolutions to be passed by the board of directors with respect to the proposed issuance of the Share Options 2020B and the Share Option Plan 2020B. The Company's statutory auditor will also be informed of the foregoing, as far as needed and applicable, in accordance with the provisions of Article 7: 96 of the Belgian Code of Companies and Associations.*

*Despite this potential conflict, however, Mr. Verrelst stated that he believed that the proposed issuance of the Share Options 2020B in the framework of the Share Option Plan 2020B is in the Company's interest, as it will allow the Company to attract, encourage, motivate and retain the Beneficiaries and to align the interests of the Beneficiaries with the interests of the Company and its shareholders by giving them the opportunity to share in the potential increase in the value of the Company, as further specified in*

*the Board Report. Subsequently, Mr. Verrelst no longer took part in the further deliberation and resolutions of the board of directors with respect to the Share Option Plan 2020B.*

*All directors unanimously (it being understood that Mr. Verrelst did not participate in the voting) resolved to approve the issuance of the Share Options 2020B and the Share Option Plan 2020B."*

More information on the remuneration of Herman Verrelst in 2020 can be found in the Remuneration Report below.

The procedure pursuant to Article 7:97 of the Belgian Code of Companies and Associations was not applied in 2020.

## 3.3. 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 2020, the audit committee held five meetings which were attended by all members, except for Mr. Reinaudo and Mr. Borré who were each excused during one meeting. During its meetings, the audit committee among others reviewed and discussed the financial reporting process, the internal control processes and the compliance framework. It also discussed the accounting treatment of the incentivized conversion of part of the convertible bonds issued by the Company. The audit committee assessed the declarations regarding internal control and risk management in the annual report 2019. It also discussed the cooperation with the external auditor of the Company, Deloitte Bedrijfsrevisoren CVBA, represented by Nico Houthaeve (who replaced Gert Vanhees as audit partner during 2020). 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 2020 during the last meeting of the audit committee held in 2020. 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 2020, 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, determined the search process and lead the search for new members of the board and a new CFO. Furthermore, the committee discussed and approved the achievement of the 2019 company goals and related variable remuneration of the executive management, and set the 2020 company goals. It discussed the HR and operational strategy of the Company, supported an externally facilitated board evaluation, 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 2019 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.

## 3.4. EXECUTIVE MANAGEMENT

### COMPOSITION

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

| Name | Age | Function |
|---|---|---|
| Herman Verrelst | 47 | Chief executive officer (CEO) |
| Jean-Marc Roelandt(1) | 56 | Chief financial officer (CFO) |
| Piet Houwen(2) | 53 | Chief operating officer (COO) |

(1) Permanently representing Marcofin BV. Mr. Roelandt replaced Mr. Ewoud Welten as CFO, with effect as of 23 April 2020. Mr. Welten left Biocartis with effect as of the end of March 2020; (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 2020, 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. The executive management is surrounded by a diverse middle management team. More information on this can be found under Part 3, non-financial report, section 'creating value for our stakeholders', 'employees'.

## 3.5. REMUNERATION POLICY

### INTRODUCTION

This remuneration policy sets out the principles regarding the remuneration of the directors and executive management of the Company. The remuneration policy has been developed by the Company's remuneration and nomination committee. The remuneration policy is drawn up in accordance with the Belgian Code of Companies and Associations and the Corporate Governance Code 2020.

### PRINCIPLES

The objective of the Company's remuneration policy is to enable the Company to attract, retain and reward the most talented, qualified and expert individuals in order for it to achieve its strategic objectives and accomplish operational excellence. Moreover, it aims to align remuneration with individual and company performance in order to motivate people to deliver increased shareholder value through superior business results. The policy is designed to balance focus on short-term operational performance with the long-term objective of creating sustainable value, while taking into account as much as possible the interests of the different stakeholders.

The remuneration policy deals with the remuneration of the members of the board of directors and the members of the executive management. The remuneration policy has been approved by the board of directors on 10 November 2020, upon recommendation of the remuneration and nomination committee, which takes into account the overall remuneration philosophy of the Company and the general principles of the remuneration of the employees. The board of directors will submit this policy for approval to the annual shareholders' meeting of the Company to be held in May 2021.

The board of directors, with support from the remuneration and nomination committee, is responsible for compliance with this policy and for completing an annual review of the policy. This policy is submitted to the annual shareholders' meeting at least every four years and upon any proposed material change of the policy.

## DETERMINATION OF THE REMUNERATION OF DIRECTORS AND EXECUTIVE MANAGEMENT

The remuneration of the members of the board of directors and the executive management is determined by the board of directors based on proposals from the remuneration and nomination committee. It is subject to the approval of the shareholders' meeting of the Company where required by applicable law. The remuneration is reviewed against market practice at regular occasions as the case may be with the assistance of external advisors.

The Company aims to prevent any conflicts of interests with respect to the establishment and implementation of the remuneration policy and the determination of the remuneration of the directors and the members of the executive management. To this end, the remuneration and nomination committee is composed exclusively of non-executive board members and a majority of its members must qualify as independent directors. The CEO only participates to the meetings of the remuneration and nomination committee in an advisory capacity when the remuneration of another member of the executive management is discussed. He does not participate in the discussions relating to his own remuneration. The CEO also does not participate in the deliberations and voting within the board of directors with respect to his remuneration. The remuneration of the non-executive directors is subject to approval by the shareholders' meeting.

## REMUNERATION POLICY FOR DIRECTORS

The remuneration of the non-executive directors is composed of a fixed fee and an attendance fee. The amount of these fees was approved by the shareholders' meeting of the Company, and takes into account the role of the directors as chairperson of the board or a board committee, their resulting responsibilities and commitment in time. The Company also reimburses the non-executive directors for reasonable out of pocket expenses (including travel expenses) incurred in the performance of their mandate. In addition, for certain non-executive directors residing abroad, a fee for travel time per meeting of the board of directors attended in person is paid. The remuneration of the non-executive directors does not contain a variable part. As from 1 January 2020, the Company no longer grants share options to non-executive directors. The CEO, who is an executive director of the Company, is remunerated for his executive management mandate only and not for his director mandate.

The board of directors, upon recommendation of the remuneration and nomination committee, decided to deviate from provision 7.6 of the Corporate Governance Code 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.

## REMUNERATION POLICY FOR EXECUTIVE MANAGEMENT

The remuneration of the members of the executive management consists of an annual fixed cash amount and variable remuneration. The latter consists of short-term variable remuneration and long-term variable remuneration.

The remuneration of the members of the executive management is benchmarked on a regular basis against overall market trends on the basis of benchmarking studies and other relevant sources. The board also reviews the executive management's remuneration annually as part of the Company's merit cycle.

## FIXED REMUNERATION

The annual fixed cash remuneration of the members of the executive management is determined by the board of directors upon the recommendation of the remuneration and nomination committee. The Company aims to provide a fixed base remuneration which is in the range of the market median for the relevant position.

## SHORT-TERM VARIABLE REMUNERATION

The short-term variable remuneration of the members of the executive management is structured so as to link rewards to company and/or individual performance of the executive (goals and objectives). The goals and objectives are established annually by the board of directors upon recommendation of the remuneration and nomination committee. The level of achievement of these pre-determined goals and objectives is reviewed in the beginning of the first subsequent year by the remuneration and nomination committee and finally established by the board of directors.

In the beginning of each year, the board of directors, upon recommendation of the remuneration and nomination committee, establishes the key company objectives and the key performance indicators (KPIs) on the basis of the Company's strategy and long-term interests. The company goals and objectives consist of KPIs based on a range of business metrics that consist of financial and non-financial KPIs which may be grouped into different KPI categories such as financial performance (such as operational income growth, gross margin improvement and capping the net cash burn), commercial success (such as commercial cartridge volume and installed base growth, as well as growth in the partner business topline), execution and delivery on projects in support of financial and commercial growth and operating a highly performing manufacturing capability, and advancement of organizational capabilities (such as completion of organizational improvements, completion of training goals by Biocartis staff, completion of the yearly employee engagement conversations, employee wellbeing and sustainable mobility, and health and safety at work). The individual goals and objectives are tailored to the individual executive and relate to the executive's key responsibilities. The board is of the opinion that these KPIs contribute most to the realization of the Company's strategy, long-term interests and sustainable growth. For each KPI, a minimum achievement threshold, the bonus amount payable related to a certain level of achievement of the KPI, and a maximum bonus amount payable are defined.

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.

### Non-Deferred Short-Term Variable Remuneration

In accordance with applicable law, 50% of the short-term variable remuneration is linked to performance criteria measured over one performance year and is settled in cash (i.e. non-deferred short-term variable remuneration). For the CEO, these performance criteria are linked solely to company performance (100%). For the other members of the executive management, these performance criteria are linked to company performance (counting for 80%) and individual performance (counting for 20%).

### Deferred Short-Term Variable Remuneration

The remaining 50% of the short-term variable remuneration is deferred by means of a grant of phantom stock, whereby 25% is linked to performance criteria measured over two financial years and the other 25% is linked to performance criteria measured over three financial years.

Phantom stock is the conditional right to receive an amount in cash, which depends on the evolution of the share price of the Company in the period between the moment of the award of the phantom stock and the moment of vesting of the phantom stock. The phantom stock plan foresees the flexibility to enable settlement of the phantom stock by means of shares of the Company instead of a cash payout. Such settlement in shares is however currently not yet legally possible for the Company. The phantom stock plan contains a minimum share price threshold which must be obtained, as well as a cap to the maximum cash amount which is payable. In case of termination of service before the vesting date, forfeiture rules apply.

The phantom stock plan facilitates retention and aligns management with shareholders on a longer term with the aim for management to increase the value of the Company and to spread a corporate culture of value creation in all strategic and operational decision-making. Because this instrument is linked to the value of the underlying share, this provides a reward for the contribution of the executive management to the sustainable growth of the Company.

### LONG-TERM VARIABLE REMUNERATION (SHARE OPTIONS)

The members of the executive management are also eligible to obtain share options (having the form of subscription rights under Belgian law, formerly called warrants) under existing or future share option plans of the Company. The purpose of the share option plans is to attract, encourage, motivate and retain the executives and to align their interests with the interests of the Company and its shareholders by giving them the opportunity to share in the potential increase in the value of the Company.

The main characteristics of the share options are as follows:

- Each share option can be exercised for one ordinary share of the Company
- The share options are granted for free (i.e., no consideration is payable upon the grant of the share options)
- 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 share options granted before 1 January 2020 were not subject to the aforementioned vesting mechanism. In particular, the share options granted to the CEO under the 2017 plan, which was approved by the shareholders' meeting of the Company, are subject to a time-based vesting regime whereby 12.5% of the share options vest at each of the first four anniversary dates of the date of grant, while the remaining 50% of the share options is subject to performance-based vesting
- In case of termination of service before the vesting date, forfeiture rules apply

### ADJUSTMENT AND CLAW-BACK OF VARIABLE REMUNERATION

The phantom stock plan and share options plans contain bad leaver provisions that can result in the phantom stock and share options, whether vested or not, automatically and immediately becoming null and void. Moreover, contractual mechanisms are in place pursuant to which the Company may revise or refuse payments of the unpaid short-term and long-term cash bonus in the following circumstances: (i) if the Company's financial statements need to be revised and such revision has a significant negative impact on the Company, (ii) if the relevant executive violates the Company's Code of Conduct, or (iii) if the relevant executive participates in specific mechanisms with the aim or consequence of promoting fraud by the Company and/or third parties. Finally, the Company can reclaim cash bonus amounts after payment thereof in the above circumstances, subject to certain conditions.

### BENEFITS IN KIND

The members of the executive management are reimbursed for certain costs and expenses made in the performance of their function. Currently, all members of the executive management are self-employed and do not receive any other benefits in kind. However, in case any future members of the executive management would be employed through an employment contract, such persons would benefit from a pension plan, company car with fuel card and certain other elements. The pension plan is a defined contribution plan covering life (pension), decease, disability and premium relief.

## MAIN TERMS RELATING TO BOARD MANDATES AND CONTRACTS WITH MEMBERS OF EXECUTIVE MANAGEMENT

### DIRECTORS

The directors of the Company are appointed for a term of no more than four (4) years by the general shareholders' meeting. They may be re-elected for a new term. The duration of the mandates of the directors of the Company can be found in the most recent version of the Company's corporate governance statement which is part of its annual report. The general shareholders' meeting can decide at any time to terminate the mandate of a director with immediate effect and without specifying a reason, unless decided otherwise by the general shareholders' meeting. Every director can decide at any time to terminate his or her mandate by notification to the board of directors. Upon request of the Company, such director must remain in function until the Company can reasonably provide for a replacement.

### EXECUTIVE MANAGEMENT

All members of the executive management provide their services under an agreement with Biocartis Group NV that is subject to Belgian law. The main terms of these agreements are set out below.

The managing director agreement of Herman Verrelst for the performance of his services as CEO was entered into for an indefinite term, and can be terminated at any time with a prior notice of six (6) months (or, in case of termination by the Company, the payment of an equivalent indemnity equal to six months of fixed fee). In certain circumstances, the agreement can be terminated by the Company or by Herman Verrelst with immediate effect (such as in case of breach of the agreement by the other party, subject to certain conditions).

The consultancy services agreement of Marcofin BV, represented by Jean-Marc Roelandt, for the performance of its services as CFO was entered into for an indefinite term, and can be terminated at any time with a prior notice of three (3) months (or the payment of an equivalent indemnity equal to three (3) months of fixed fee). In certain circumstances, the agreement can be terminated by the Company or by Marcofin BV with immediate effect (such as in case of breach of the agreement by the other party, subject to certain conditions).
The consultancy services agreement of Scmiles BV, represented by Piet Houwen, for the performance of its services as COO was entered into for an indefinite term, and can be terminated at any time with a prior notice of three (3) months (or the payment of an equivalent indemnity equal to three (3) months of fixed fee). In certain circumstances, the agreement can be terminated by the Company or by Scmiles BV with immediate effect (such as in case of breach of the agreement by the other party, subject to certain conditions).

### MINIMUM SHARE OWNERSHIP FOR EXECUTIVE MANAGEMENT

In 2020, the board of directors set the minimum threshold of shares to be held at any time by the CEO to the number of shares equivalent to one year of the CEO's fixed remuneration. The minimum threshold of shares to be held at any time by the CFO and COO was set to the number of shares equivalent to 50% of their respective annual fixed remuneration. The minimum threshold will be re-calculated yearly. To determine the equivalent number of shares for a given calendar year, the average closing price of the Company's share on Euronext Brussels during the thirty (30) day period prior 31 December of the previous calendar year and the fixed remuneration granted for such preceding calendar year will be taken into account. The minimum share ownership thresholds must be reached before 31 December 2024 for existing executive management or within four (4) years as from the date of their appointment for future executive members.

### DEVIATIONS FROM THIS REMUNERATION POLICY

In exceptional circumstances, the board of directors may decide to deviate from any items of this remuneration policy if necessary to serve the long-term interests and sustainability of the Company, or to ensure its viability. Any such deviation must be discussed at the remuneration and nomination committee, which will provide a substantiated recommendation to the board of directors. Any deviation from this remuneration policy will be described and explained in the Company's remuneration report which is a part of the Company's annual report.

## 3.6. 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 2020.
Following a clear positive vote by Biocartis' shareholders on the remuneration report of 2019, the changes to the remuneration of the directors and members of the executive management in 2020 as compared to 2019 have been kept to a minimum. One notable change relates to the deferred short-term variable remuneration for the members of the executive management which is now structured by way of a grant of phantom stock. Other changes result from the entry into force of new legislation and the Corporate Governance Code 2020.
This remuneration report must be read together with Biocartis' remuneration policy (see above) and with the performance of Biocartis in 2020 as set out in detail in this annual report.

### REMUNERATION OF THE DIRECTORS

#### PRINCIPLES

The remuneration of the non-executive directors is composed of a fixed fee and an attendance fee. The amount of such fees was set by the annual shareholders' meeting held on 11 May 2018. The CEO, who is also a director of the Company, is remunerated for his executive management mandate only, and not for his director mandate.

Annual fixed fees:

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

Attendance fees:

In addition to the annual fixed fees mentioned above, each non-executive director receives an attendance fee of EUR 3,000 per meeting of the board of directors attended in person (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) or EUR 1,500 per meeting of the board of directors attended per conference call, EUR 1,000 per meeting of the audit committee attended by the director who is a member of such committee, and EUR 500 per meeting of the remuneration and nomination committee attended by the director who is a member of such committee.

No share based awards:

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

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

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

## REMUNERATION OF THE MEMBERS OF THE BOARD OF DIRECTORS IN 2020

Based on what is set out above, the remuneration of the directors for the performance of their director mandate in 2020 is as follows(1):

| Name of Director, Position | Fixed remuneration | | | Variable remuneration | | Extraordinary items | Pension expense | Total remuneration | Proportion of fixed and variable remuneration (4) |
|---|---|---|---|---|---|---|---|---|---|
| | Fixed fees (2) | Attendance Fees (3) | Fringe benefits | One-year variable | Multi-year variable (4) | | | | |
| CRBA Management BV, repr. by Christian Reinaudo (Chairman)(5) | 50,000 | 25,500 | 0 | 0 | 0 | 0 | 0 | 75,500 | Fixed: 100% Variable: 0% |
| Luc Gijsens BV, repr. by Luc Gijsens (independent) | 18,000 | 23,000 | 0 | 0 | 0 | 0 | 0 | 41,000 | Fixed: 100% Variable: 0% |
| Ann-Christine Sundell (independent) | 12,000 | 21,500 | 0 | 0 | 0 | 0 | 0 | 33,500 | Fixed: 100% Variable: 0% |
| Christine Kuslich (independent) | 7,770 | 10,000 | 0 | 0 | 0 | 0 | 0 | 17,770 | Fixed: 100% Variable: 0% |
| Roald Borré (non-executive)(6) | 12,000 | 24,000 | 0 | 0 | 0 | 0 | 0 | 36,000 | Fixed: 100% Variable: 0% |
| CLSCO BV, repr. by Leo Steenbergen (former director) | 4,230 | 9,500 | 0 | 0 | 0 | 0 | 0 | 13,730 | Fixed: 100% Variable: 0% |
| Scientia II LLC, repr. by Harry Glorikian (former director) | 4,230 | 7,500 | 0 | 0 | 0 | 0 | 0 | 11,730 | Fixed: 100% Variable: 0% |

Notes:

(1) Amounts mentioned are gross amounts in Euro. Amounts of base salary are pro-rated taking into account the changes to the composition of the board of directors and its committees with effect as from the annual shareholders' meeting dated 8 May 2020. As of such date, Christine Kuslich was appointed as director of the Company, and the mandates of CLSCO BV, permanently represented by Leo Steenbergen, and Scientia II LLC, permanently represented by Harry Glorikian, expired.

(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 2020 have not been taken into account. See the table below for more information on the share options of the directors as per 31 December 2020.

(5) As from beginning 2021, Mr. Reinaudo performs his director mandate in personal name and no longer via CRBA Management BV.

(6) 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.

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 2020:

| Name of Director, position | The main conditions of share option plans | | | | | | Information regarding the reported financial year | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Opening balance | During the year (2)(3) | | Closing balance |
| | Specification of plan | Award date | Vesting Date (1) | End of holding period | Exercise period | Strike price | Share options held (of which vested) | Share options awarded | Share options vested | Share options held (of which vested) |
| CRBA Management BV, repr. by 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 (5,000) | 0 | 5,000 - EUR 15,550 | 15,000 (10,000) |
| 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 (5,000) | 0 | 5,000 - EUR 15,550 | 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 (5,000) | 0 | 5,000 - EUR 15,550 | 10,000 (10,000) |
| Christine Kuslich (independent) | N/A | N/A | N/A | N/A | N/A | N/A | 0 | 0 | N/A | 0 |
| Roald Borré (non-executive) | N/A | N/A | N/A | N/A | N/A | N/A | 0 | 0 | N/A | 0 |
| CLSCO BV, repr. by Leo Steenbergen (former director) | 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 (5,000) | 0 | 5,000 - EUR 15,550 | 10,000 (10,000) |
| Scientia II LLC, repr. by Harry Glorikian (former director) | 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 (5,000) | 0 | 5,000 - EUR 15,550 | 10,000 (10,000) |

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 2020, 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 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. Although such requirement will only apply as from 31 December 2024, Mr. Verrelst already meets the aforementioned threshold of share ownership following his acquisition of 500,000 shares in the Company the course of 2020.

### REMUNERATION OF THE MEMBERS OF THE EXECUTIVE MANAGEMENT IN 2020

#### Total Remuneration

The total remuneration of the members of the executive management in 2020 is as follows(1):

| Name of Executive, Position | Fixed remuneration | | | Variable remuneration | | Extraordinary items | Pension expense(4) | Total remuneration | Proportion of fixed and variable remuneration |
|---|---|---|---|---|---|---|---|---|---|
| | Base salary | Fees | Fringe benefits | One-year variable (2) | Multi-year variable (3) | | | | |
| Herman Verrelst (CEO) | 375,000 | 0 | 0 | 93,750 | 32,813 | 0 | 0 | 501,563 | Fixed: 74.8% Variable: 25.2% |
| Other executives (CFO and COO) | 618,457 | 0 | 3,510 (5) | 103,657 | 0 | 0 | 1,008 | 726,632 | Fixed: 85.7% Variable: 14.3% |

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. For the CFO and COO no deferred variable remuneration was paid with respect to 2020 given that they only recently joined Biocartis. The deferred variable remuneration of the CFO and COO is structured by way of phantom stock under the phantom stock plan which was created in 2020. The value of any share options vested in 2020 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 2020.

(4) Amounts mentioned in this column relate to the pension plan (in the form of a defined contribution plan) for the former CFO who left Biocartis with effect as of the end of March 2020.

(5) Amount mentioned relate to the fringe benefits which include company car, mobile phone/data subscription, long term disability insurance and lump sum cost reimbursement of the former CFO who left Biocartis with effect as of the end of March 2020.

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.

### 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. This entails that the KPIs set out in the table below on deferred short-term variable remuneration will gradually be replaced by the phantom stock mechanism which links pay-out to the evolution of the Company's share price during a reference period. For more information on the phantom stock mechanism, please see the Company's remuneration policy above.

The table below provides an overview of the total non-deferred short-term variable remuneration for performance year 2020(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% | 119.3% |
| | 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%<br><br>For growth in partner business topline: 75% | For commercial cartridge volume and installed base growth: 200%<br><br>For growth in partner business topline: 125% | 105.7% |
| | Execution and delivery on projects in support of financial and commercial growth | 12.5% | N/A | 100% | 67.2% |
| | Development and running a highly | 12.5% | N/A | 100% | 98.6% |

| | | | | | |
|---|---|---|---|---|---|
| | performing manufacturing capability | | | | |
| | Advancement of organizational capabilities | 15% | N/A | 100% | 88.0% |
| | | | | | Total weighted performance: 101.3%, however capped at 100%; corresponding to EUR 93,750 |
| 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 103,657 |

The table below provides an overview of the total deferred short-term variable remuneration for 2020(1).

| Name of executive, position | Description of the performance criteria | Relative weighting of the performance criteria | Information on Performance Targets (2) | | Measured performance and total remuneration |
|---|---|---|---|---|---|
| | | | Minimum threshold performance | Maximum performance | |
| Herman Verrelst (CEO) | 2-year KPIs (set in 2019):<br><br>KPIs relating to total operating income and gross margin on product revenues | 50% each | 70% | 100% | 80% for total operating income (corresponding to 60% pay-out) and 25% for gross margin on product revenues (corresponding to 0% pay-out) |
| | | | | | Total weighted pay-out: 30% corresponding to EUR 14,063 |
| | 3-year KPIs (set in 2018):<br><br>KPIs relating to total operating income and gross margin on product revenues | 50% each | 75% | 100% | 80% for total operating income (corresponding to 80% pay-out)and 25% for gross margin on product revenues (corresponding to 0% pay-out) |
| | | | | | Total weighted pay-out: 40% corresponding to EUR 18,750 |
| Other executives (COO)(3) | N/A | | | | N/A |

(1) Amounts mentioned are gross amounts in Euro.

For the two-year and three-year KPIs, a minimum and maximum performance threshold have been identified. For the two-year KPIs, each level of performance above the minimum threshold corresponds to a certain pay-out level whereby 70% achievement corresponds to 40% pay-out, with each one percent incremental achievement giving right to an additional 2% pay-out. For the three-year KPIs, no such accelerator applies (linear).(3)For the CFO and COO no multi-year variable remuneration was paid with respect to 2020 given that they only recently joined Biocartis. The deferred variable remuneration of the CFO and COO is structured by way of phantom stock under the phantom stock plan which was created in 2020.

### 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 2020:

| 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 | 11-09-2017 | 2018-2021 (4) | N/A | 1/1/2021 – 11/9/2022 | EUR 9.92 | 1,212,365 (542,365) | 0 | 167,500 time-based + 167,500 performance-based (EUR 716,900) | 1,212,365 (877,365) |
| | 2020B Plan | 30/4/2020 | 1/1/2024 | N/A | 1/1/2024 - 29/4/2027 | EUR 4.18 | 0 | 300,000 | 0 | 300,000 (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 | 0 | 100,000 | 0 | 100,000 (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 (0) | 0 | 28,437 (EUR 66,543) | 65,000 (28,437) |
| | 2020B Plan | 30/4/2020 | 1/1/2024 | N/A | 1/1/2024 - 29/4/2027 | EUR 4.18 | 0 | 50,000 | 0 | 50,000 (0) |
| Ewoud Welten (former CFO) | 2015 Plan | 3/8/2015 | 2015-2019 | N/A | 1/1/2019 – 3/8/2022 | EUR 13.28 | 62,500 (62,500) | 0 | 0 | 62,500 (62,500) |
| | 2018 Plan | 9/5/2019 | 2020-2023 (6) | N/A | 1/1/2023 - 8/5/2026 | EUR 11.93 | 10,000 (0) | 0 | 2,500 (EUR 5,850) | 2,500 (2,500) (2) |
| | 2018 Plan | 7/10/2019 | 1/1/2024 (6) | N/A | 1/1/2023 - 6/10/2026 | EUR 6.48 | 10,000 (0) | 0 | 2,500 (EUR 3,650) | 2,500 (2,500) (2) |

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 2020, no share options were exercised by any members of the executive management. There were no performance-based share options held by Mr. Verrelst that became null and void. Following the departure of Mr. Welten as CFO in the course of 2020, 15.000 share options held by him under the 2018 Plan 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 2020.

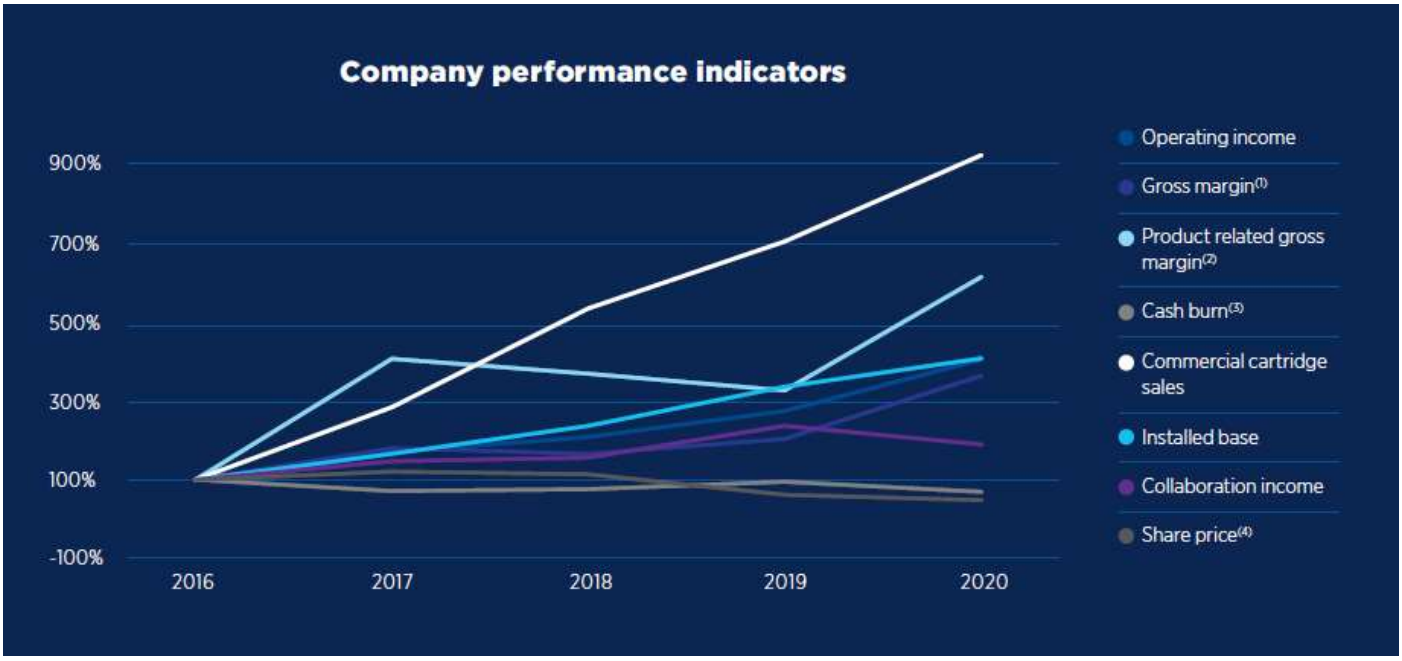
(4) The share options held by Herman Verrelst under the 2017 plan vest as follows: (i) 12.5% of the share options vests on each of the first four anniversary dates of the award date (being 11 September 2017); and (ii) the other 50% of the shares will vest if and to the extent of Mr. Verrelst achieving 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.

(6) Mr. Welten left Biocartis with effect as of the end of March 2020.

## 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.




Notes:

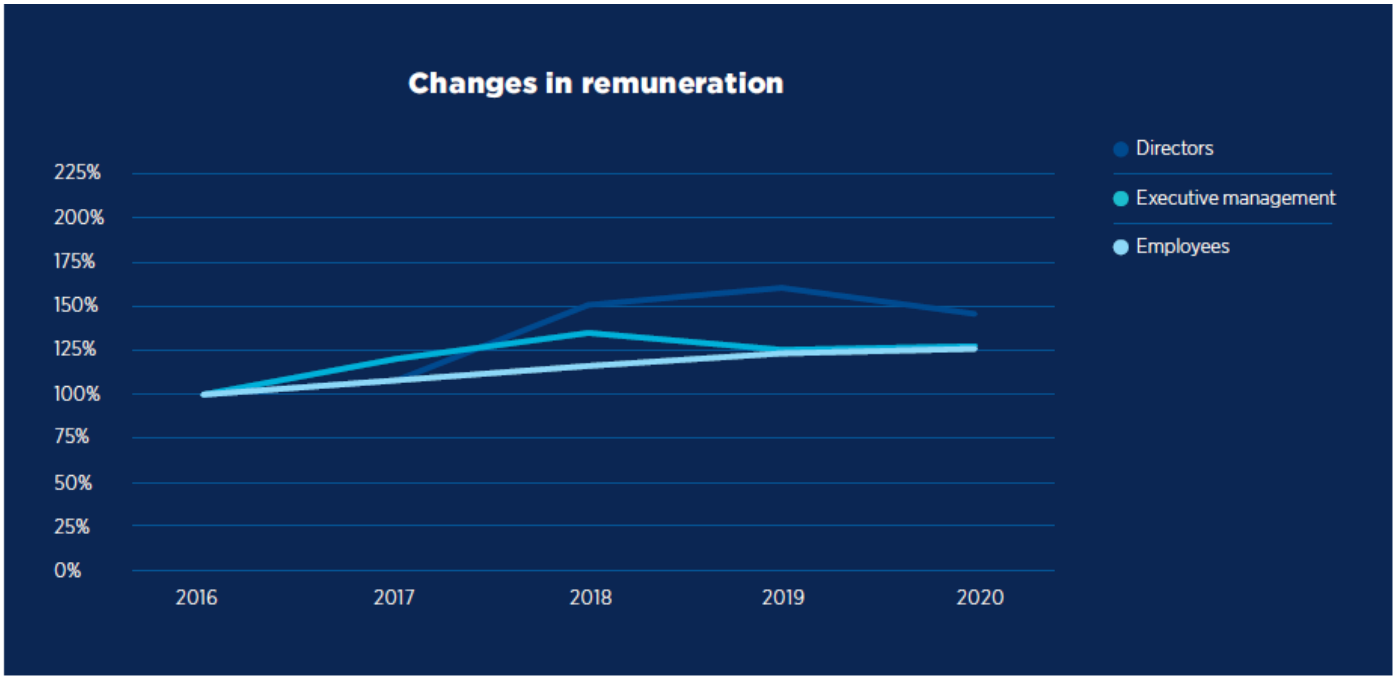
(1) Gross margin is defined as total operating income less cost of sales.

(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 2020 (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. 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 13-to-1. Share options are excluded from the calculations.

### SEVERANCE PAYMENTS FOR DEPARTING MEMBERS OF THE EXECUTIVE MANAGEMENT

In 2020, Mr. Ewoud Welten left Biocartis as CFO of the Company. No severance payment was made to Mr. Welten.

## 3.7. SHARE CAPITAL AND SHARES

### ISSUE OF SHARES BY THE COMPANY IN 2020

On 1 January 2020, the share capital of the Company amounted to EUR 563,820.88, represented by 56,382,088 shares. On 25 September 2020, the extraordinary shareholders' meeting of the Company resolved to increase the capital of the Company with an amount of EUR 104,070,594.45 without issuance of new shares and by way of incorporation of a part of the issuance premium in the capital of the Company, and immediately after the aforementioned capital increase, to decrease the capital of the Company in accordance with Article 7:210 of the Belgian Code of Companies and Associations with an amount of EUR 104,070,594.45 to bring it to EUR 563,820.88 by way of incorporation of losses incurred in the aforementioned amount of EUR 104,070,594.45. Such capital decrease took place without cancellation of existing shares of the Company. On 14 December 2020, the Company increased its share capital with an amount of EUR 11,635.75 in the framework of a conversion of convertible bonds issued by the Company, resulting in the issuance of 1,163,575 new shares. Consequently, on 31 December 2020, the total share capital of the Company amounted to EUR 575,456.63, represented by 57,545,663 shares. An overview of the major shareholders of the Company on 31 December 2020 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 2020, 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

The board of directors used its powers under the then existing authorized capital on 3 March 2020 to issue the share option plan 2020 and on 30 April 2020 to issue the share option plan 2020B. On 25 September 2020, 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 20% of the share capital at the time of the convening of the shareholders' meeting granting such authorization (i.e., EUR 112,764.18).

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 one year as from the date of the publication of the authorization in the Annexes to the Belgian State Gazette (*Belgisch Staatsblad*), i.e., until 5 October 2021. The board did not yet make use of such authorization in 2020.

## MODIFICATIONS TO THE ARTICLES OF ASSOCIATION AND SHARE CAPITAL

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

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

## PURCHASE AND SALE OF TREASURY SHARES

The Company may purchase, subject to the provisions of the Belgian company law, its own shares if authorized by a prior decision of an extraordinary shareholders' meeting approved by a majority of 75% of the votes cast, at a meeting where at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required attendance quorum is not present or represented at the first meeting, a second meeting needs to be convened. The second general shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special majority requirements, however, remain applicable. The aforementioned rules are also applicable to the acquisition of shares of the Company by its subsidiaries. The sale of treasury shares is also subject to the provisions of the Belgian Code of Companies and Associations. The board of directors is currently not authorized by an extraordinary shareholders' meeting to purchase or sell its own shares. On 31 December 2020, 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 135.0 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.

## 3.8. EXTERNAL AND INTERNAL CONTROL

### EXTERNAL CONTROL

In 2020, the Company's statutory auditor was Deloitte Bedrijfsrevisoren CVBA, represented by Nico Houthaeve (who replaced Mr. Gert Vanhees as from May 2020). 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. The reappointment of the statutory auditor will be submitted for approval by the Company's annual shareholders' meeting to be held on 14 May 2021.

In 2020, a total amount of EUR 153,263 was paid to the statutory auditor. This amount includes the following elements: EUR 142,185 for audit fees, and EUR 11,078 for work performed in relation to legal mission work (EUR 8,306) and other non-audit services (EUR 2,772) for the Company.

## 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 2020 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, 'Non-financial report'.

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.

# PART 4 / FINANCIAL REPORT

# 1. CONSOLIDATED ANNUAL ACCOUNTS

## 1.1. / CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED 31 DECEMBER 2020 AND 2019

### 1.1.1. / CONSOLIDATED INCOME STATEMENT

| | | Years ended 31 December | |
|---|---|---|---|
| In EUR 000 | Notes | 2020 | 2019 |
| Collaboration revenue | 1.2.4 | 9,989 | 12,451 |
| Product sales revenue | 1.2.4 | 31,893 | 24,224 |
| Service revenue | 1.2.4 | 1,246 | 769 |
| Total revenue | | 43,128 | 37,444 |
| Other operating income | | | |
| Grants and other income | 1.2.5 | 12,431 | 288 |
| Total operating income | | 55,559 | 37,732 |
| Cost of sales | 1.2.6 | -26,284 | -21,328 |
| Research and development expenses | 1.2.7 | -45,783 | -39,844 |
| Sales and marketing expenses | 1.2.8 | -15,736 | -18,011 |
| General and Administrative expenses | 1.2.9 | -14,618 | -14,151 |
| Total operating expenses | | -102,421 | -93,334 |
| Operating loss for the year | | -46,862 | -55,602 |
| Financial expense | 1.2.11 | -14,569 | -8,008 |
| Other financial results | 1.2.11 | -1,199 | 74 |
| Financial result, net | | -15,768 | -7,934 |
| Share in the result of joint venture | | -532 | -631 |
| Loss for the year before taxes | | -63,162 | -64,167 |
| Income taxes | 1.2.29 | 228 | 99 |
| Loss for the year after taxes | | -62,934 | -64,068 |
| | | | |
| Attributable to owners of the Group | | -62,934 | -64,068 |
| | | | |
| Earnings per share | | | |
| Basic and diluted loss per share | 1.2.12 | -1.11 | -1.14 |

# 1.1.2. / CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

| In EUR 000 | Notes | Years ended 31 December 2020 | 2019 |
|---|---|---|---|
| Loss for the year | | -62,934 | -64,068 |
| Other comprehensive income (loss), not to be reclassified to profit or loss: | | | |
| Re-measurement gains and losses on defined benefit plan | 1.2.24 | 197 | -243 |
| Income taxes on items of other comprehensive income | | -58 | 72 |
| Other comprehensive income (loss), that may be reclassified to profit and loss: | | | |
| Exchange differences on translation of foreign operations | | -150 | -113 |
| Decrease in fair value of investment in associates | | | -5,052 |
| Total comprehensive loss for the year | | -62,945 | -69,404 |
| Attributable to owners of the Group | | -62,945 | -69,404 |

# 1.1.3. / CONSOLIDATED STATEMENT OF FINANCIAL POSITION

| In EUR 000 | Notes | As of 31 December 2020 | 2019 |
|---|---|---|---|
| Assets | | | |
| Non-current assets | | | |
| Intangible assets | 1.2.13 | 5,645 | 6,294 |
| Property, plant and equipment | 1.2.14 | 40,098 | 43,421 |
| Investment in joint ventures | 1.2.16 | 2,893 | 2,358 |
| Other non-current assets | 1.2.24 | 426 | 13 |
| Deferred tax assets | 1.2.17 | 1,472 | 1,609 |
| | | 50,534 | 53,695 |
| Current assets | | | |
| Inventories | 1.2.18 | 15,712 | 14,161 |
| Trade receivables | 1.2.19 | 13,488 | 10,695 |
| Other receivables | 1.2.19 | 3,960 | 8,640 |
| Other current assets | 1.2.20 | 3,155 | 2,407 |
| Cash and cash equivalents* | 1.2.21 | 123,668 | 178,725 |
| | | 159,983 | 214,628 |
| Total assets | | 210,517 | 268,323 |
| Equity and liabilities | | | |
| Capital and reserves | | | |
| Share capital | 1.2.22 | -220,657 | -220,668 |
| Share premium | 1.2.22 | 711,874 | 698,027 |
| Share based payment reserve | 1.2.22 | 6,102 | 4,670 |
| Accumulated deficit | 1.2.22 | -455,343 | -392,259 |
| Other comprehensive income | 1.2.22 | -5,152 | -5,291 |
| Total equity attributable to owners of the Group | | 36,824 | 84,479 |
| Non-current liabilities | | | |
| Provisions | 1.2.24 | 0 | 49 |
| Borrowings and lease liabilities | 1.2.25 | 18,625 | 24,000 |
| Convertible debt | 1.2.25 | 125,260 | 136,158 |
| Deferred income | 1.2.27 | 363 | 461 |
| | | 144,248 | 160,668 |
| Current liabilities | | | |
| Borrowings and lease liabilities | 1.2.25 | 6,673 | 6,420 |
| Trade payables | 1.2.26 | 13,907 | 9,070 |
| Deferred income | 1.2.27 | 1,278 | 1,595 |
| Other current liabilities | 1.2.26 | 7,587 | 6,091 |
| | | 29,445 | 23,176 |
| Total equity and liabilities | | 210,517 | 268,323 |

*Cash and cash equivalents for 31 December 2020 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 2020 | 2019 |
|---|---|---|---|
| **Operating activities** | | | |
| Loss for the year | | -62,934 | -64,068 |
| **Adjustments for** | | | |
| Depreciation and amortization | 1.2.13/1.2.14 | 9,748 | 9,719 |
| Impairment losses | 1.2.7/1.2.14 | 1,698 | 476 |
| Income taxes in profit and loss | 1.2.29 | -228 | -99 |
| Financial result, net | 1.2.11 | 15,768 | 7,934 |
| Unrealized exchange gains/ losses | | -1,030 | 0 |
| Net movement in defined benefit obligation | 1.2.24 | -323 | -150 |
| Share of net profit of associate and joint venture | 1.2.16 | 532 | 631 |
| Share based payment expense | 1.2.23 | 1,432 | 1,225 |
| Other | | -80 | 37 |
| **Changes in working capital** | | | |
| Net movement in inventories | 1.2.18 | -4,042 | -3,858 |
| Net movement in trade and other receivables and other current assets | 1.2.19/1.2.17 | 1,449 | -1,182 |
| Net movement in trade payables & other current liabilities | 1.2.26 | 6,333 | 1,507 |
| Net movement in deferred income | 1.2.27 | -415 | -960 |
| Cash flow from operating activities before interest and taxes paid | | -32,092 | -48,788 |
| Interest paid | | -7,172 | -5,288 |
| Taxes paid | 1.2.29 | -3 | -178 |
| **Cash flow from operating activities** | | -39,267 | -54,254 |
| **Investing activities** | | | |
| Interest received | | 13 | 8 |
| Acquisition of property, plant & equipment | 1.2.14 | -3,005 | -2,121 |
| Acquisition of intangible assets | 1.2.13 | -15 | -394 |
| investment in joint venture | 1.2.16 | -1,000 | -2,989 |
| **Cash flow from investing activities** | | -4,007 | -5,496 |
| **Financing activities** | | | |
| Proceeds from the issue of a convertible bond | | 0 | 145,438 |
| Convertible bond - incentivized conversion | 1.2.25 | -4,306 | 0 |
| Net proceeds from the issue of ordinary shares, net of transaction costs | 1.2.22 | 0 | 53,360 |
| Repayment of borrowings | 1.2.25 | -7,167 | -23,738 |
| Bank charges | | -50 | -37 |
| **Cash flow from financing activities** | | -11,523 | 175,023 |
| **Net increase (decrease) in cash and cash equivalents** | | -54,797 | 115,273 |
| Cash and cash equivalents at the beginning of the period | | 178,725 | 63,539 |
| Effects of exchange rate changes on the balance of cash held in foreign currencies | | -260 | -87 |
| **Cash and cash equivalents at the end of the period*** | | 123,668 | 178,725 |

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

# 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 2019 | | -220,718 | 632,769 | 3,445 | -67 | -328,078 | 87,351 | 87,351 |
| Loss for the period | | | | | | -64,068 | -64,068 | -64,068 |
| Re-measurement gains and losses on defined benefit plan | 1.2.24 | | | | -171 | | -171 | -171 |
| Consolidation translation difference | | | | | | -113 | -113 | -113 |
| Fair value adjustment of investment in associates | | | | | -5,052 | | -5,052 | -5,052 |
| Total comprehensive income | | | | | -5,223 | -64,181 | -69,404 | -69,404 |
| Share-based payment expense | 1.2.23 | | | 1,225 | | | 1,225 | 1,225 |
| Share issue - private placement on 28 January 2019 | 1.2.22 | 50 | 55,450 | | | | 55,500 | 55,500 |
| Costs related to private placement on 28 January 2019 | 1.2.22 | | -2,311 | | | | -2,311 | -2,311 |
| Share issue - exercise of stock options on 4 April 2019 | 1.2.22 | | 171 | | | | 171 | 171 |
| Issuance of convertible bond on 9 May 2019 | | | 11,948 | | | | 11,948 | 11,948 |
| Balance as at 31 December 2019 | | -220,668 | 698,027 | 4,670 | -5,291 | -392,259 | 84,479 | 84,479 |
| Balance as at 1 January 2020 | | -220,668 | 698,027 | 4,670 | -5,291 | -392,259 | 84,479 | 84,479 |
| 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 |
| Other comprehensive income | | | | | | | | |
| 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 | -5,152 | -455,343 | 36,824 | 36,824 |

# 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 23 February 2021 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 2020 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 2020:

- Amendments to IAS 1 and IAS 8 Definition of Material
- Amendments to IFRS 3 Business Combinations: Definition of a Business
- Amendments to IFRS 9, IAS 39 and IFRS 7 Interest Rate Benchmark Reform – Phase 1
- Amendments to references to the Conceptual Framework in IFRS standards

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 2020, are listed in note 1.2.35.

## 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 2020.

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.

## 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 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 2020, 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

*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

*IDYLLA™ SYSTEMS PRESENTED ON THE BALANCE SHEET*

Idylla™ systems are both presented on the balance sheet under inventory and under property, plant and equipment (PPE). Idylla™ systems that are recorded as property, plant and equipment are used for amongst other assay research and development, platform engineering, production process optimization, quality testing purposes and marketing purposes. Furthermore, Idylla™ systems recorded as PPE include also systems that are rented by clients under the operating lease reagent rental agreements, presented as capitalized systems for rent. These systems are recorded at their acquisition cost and are depreciated over 5 years and have the same accounting treatment as other property, plant and equipment, we also refer to 1.2.2.7.

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.

### COVID-19

For more 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 2 'Performance 2020', 'Impact of COVID-19'.

### 1.2.3.2. / OPERATING SEGMENTS

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

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

In addition, substantially all non-current assets of the Group are located in the country of domicile (Belgium) per 31 December 2020.

## 1.2.4. / REVENUE

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

| In EUR 000 | Years ended 31 December | | | |
|---|---|---|---|---|
| | 2020 | | 2020 | 2019 |
| | At a point in time | Over time | | |
| **Collaboration revenue** | | | | |
| R&D services | 0 | 8,176 | 8,176 | 9,026 |
| License revenue | 1,713 | 100 | 1,813 | 2,517 |
| Milestones | 0 | 0 | 0 | 908 |
| | 1,713 | 8,276 | 9,989 | 12,451 |
| **Product related revenue** | | | | |
| Idylla™ System Sales revenue | 4,386 | 0 | 4,386 | 4,232 |
| Idylla™ System Rental revenue | 2,700 | 0 | 2,700 | 1,987 |
| Cartridge revenue | 24,808 | 0 | 24,808 | 18,004 |
| | 31,893 | 0 | 31,893 | 24,224 |
| **Service revenue** | | | | |
| Idylla™ System Service revenue | 1,041 | 205 | 1,246 | 769 |
| | 1,041 | 205 | 1,246 | 769 |
| **Total** | 34,647 | 8,481 | 43,128 | 37,443 |

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 |
|---|---|
| 2021 | 616 |
| 2022 | 0 |
| 2023 | 0 |
| 2024 | 0 |
| 2025 | 0 |
| After 2025 | 0 |
| Total | 616 |

The aggregate amount of the transaction price allocated to collaboration arrangements that are partially or fully unsatisfied as at 31 December 2020 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.

The transaction price has been allocated to the 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 2020.

### 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 2020, the Group recognized a license fee and 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 | 2020 | 2019 |
| Country of domicile | 481 | 756 |
| Belgium | 481 | 756 |
| Total all foreign countries, of which | 42,647 | 36,688 |
| United States of America | 15,604 | 14,752 |
| China | 1,993 | 3,079 |
| Spain | 2,866 | 2,809 |
| France | 3,497 | 2,199 |
| Great Britain | 3,972 | 1,782 |
| Germany | 2,946 | 1,903 |
| Rest of the world | 11,769 | 10,164 |
| Total | 43,128 | 37,444 |

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

In 2020 there are no costumers representing at least 10% of the total recognized revenues, however the 5 largest clients together represent 24% of the revenue.

## 1.2.5. / OTHER OPERATING INCOME

| | Years ended 31 December | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| R&D project support (VLAIO & IWT grants) | 1,158 | 283 |
| Other project grants (EU) | 56 | - |
| Other income | 11,217 | 5 |
| Total | 12,431 | 288 |

The collaboration with Genomic Health, a subsidiary of Exact Sciences Corporation, for the development of the Oncotype 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 is recorded as other income.

The other operating income also consist out of grants that were awarded to support R&D activities. In 2020, the Group was awarded two new grants from VLAIO, for the development of the Idylla™ SARS-CoV-2 Test and the Idylla™ GeneFusion Assay.

## 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 | 2020 | 2019 |
| Employee benefit expenses | -6,118 | -6,047 |
| Material, lab consumables & small equipment | -13,187 | -11,145 |
| Depreciation and amortization | -3,378 | -1,768 |
| Royalty expense | -1,486 | -1,290 |
| Facilities, office and other | -2,115 | -1,078 |
| Total | -26,284 | -21,328 |

For the explanation on the increase of the cost of sales we refer to Part 2, 'Performance 2020'.

## 1.2.7. / RESEARCH & DEVELOPMENT EXPENSES

| | Years ended 31 December | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Employee benefit expenses | -24,912 | -21,752 |
| R&D consultancy & subcontracting | -9,206 | -5,063 |
| Laboratory and cartridge expenses | -2,817 | -2,355 |
| Quality, regulatory and intellectual property | -693 | -444 |
| Facilities, office & other | -2,801 | -1,509 |
| ICT | -332 | -1,333 |
| Travel, training & conferences | -166 | -742 |
| Depreciation and amortization | -4,856 | -6,645 |
| Total | -45,783 | -39,844 |

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.

For the explanation on the increase of the research and development expenses we refer to Part 2, 'Performance 2020'.

## 1.2.8. / SALES & MARKETING EXPENSES

| | Years ended 31 December | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Employee benefit expenses | -10,369 | -11,126 |
| S&M consultancy & subcontracting | -929 | -1,259 |
| Sales and promotional expenses | -658 | -501 |
| Business development | -932 | -503 |
| Facilities, office & Other | -998 | -854 |
| Travel, training & conferences | -791 | -2,701 |
| Depreciation and amortization | -579 | -810 |
| Impairment of receivables | -480 | -256 |
| Total | -15,736 | -18,011 |

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

For the explanation on the increase of the sales and marketing expense we refer to Part 2, 'Performance 2020'.

## 1.2.9. / GENERAL & ADMINISTRATIVE EXPENSES

| | Years ended 31 December | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Employee benefit expenses | -10,783 | -8,778 |
| External advice | -683 | -927 |
| Facilities, office & other | -1,388 | -2,624 |
| Human resources | -1,030 | -1,027 |
| Travel, training & conferences | -162 | -444 |
| Depreciation and amortization | -572 | -351 |
| Total | -14,618 | -14,151 |

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.

For the explanation on the increase of the general and administrative expense we refer to Part 2, 'Performance 2020'.

## 1.2.10. / EMPLOYEE BENEFIT EXPENSES

| | Years ended 31 December | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Short term employee benefits | -50,194 | -45,509 |
| Post-employee benefit expense | -485 | -471 |
| Termination benefits | -71 | -499 |
| Share-based payments | -1,432 | -1,225 |
| Total | -52,182 | -47,704 |

Employee benefit expenses include payroll expenses of fixed employees, interim staff and consultants in a permanent position. The employee benefit expenses amounted to EUR 52.2m in 2020 compared to EUR 47.7m in 2019, a year-over-year increase of 9%. 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 | |
|---|---|---|
| | 2020 | 2019 |
| Operations staff | 143 | 120 |
| Research and development staff | 185 | 181 |
| Marketing and sales staff | 86 | 89 |
| General and administrative staff | 70 | 72 |
| Total headcount | 484 | 462 |
| | | |
| Average full time equivalents | 526 | 465 |

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 366 for 2020.

## 1.2.11. / FINANCIAL INCOME AND EXPENSE

| | Years ended 31 December | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Interest expense | -10,184 | -7,099 |
| Other financial expense | -4,385 | -401 |
| Total | -14,569 | -7,500 |
| Other financial result | -1,199 | -434 |
| Total | -1,199 | -434 |
| Financial result, net | -15,768 | -7,934 |

Net financial expenses amounted to EUR 15.8m in 2020 compared to EUR 7.9m in 2019 and included financial expenses in relation to the Company's convertible bond of EUR 9.0m (consisting of EUR 6.0m coupon payment and EUR 3.0m of debt appreciation) in 2020, compared to EUR 5.7m in 2019. The bond was issued in May 2019 and therefore only included one coupon in 2019. The other financial expenses include in 2020 a cash payment of EUR 4.3m in connection with the exercise of conversion rights.

The other financial result mainly consists of non-realized foreign exchange gains and losses of EUR 1.0m in 2020 compared to EUR 0.1m in 2019, due to a higher amount of dollars on our bank account.

## 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 earnings per share are equal.

The basis for the basic and diluted earnings per share is the net loss for the year attributable to the owners of the Group.

| | Years ended 31 December | |
|---|---|---|
| | 2020 | 2019 |
| Profit/loss for the period attributable to the owners of the Group (in EUR 000) | -62,934 | -64,068 |
| Weighted average number of ordinary shares for basic loss per share (in number of shares) | 56,610,506 | 56,074,525 |
| Basic loss per share (EUR) | -1.11 | -1.14 |

## 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 2019 | | | |
| Opening net carrying value | 6,419 | 161 | 6,579 |
| Additions | 300 | 94 | 394 |
| Disposals | 0 | -1 | -1 |
| Disposal depreciations | 0 | 0 | 0 |
| Amortization expense | -567 | -112 | -679 |
| | 0 | 0 | 0 |
| Closing net carrying value | 6,151 | 143 | 6,294 |
| As at 31 December 2019 | | | |
| Cost | 12,292 | 1,722 | 14,014 |
| Accumulated amortization | -6,140 | -1,580 | -7,720 |
| Net carrying value | 6,151 | 143 | 6,294 |
| Year ended 31 December 2020 | | | |
| Opening net carrying value | 6,151 | 143 | 6,294 |
| Additions | 0 | 15 | 15 |
| Disposals | 0 | 0 | 0 |
| Disposal amortizations | 0 | 0 | 0 |
| Amortization expense | -577 | -87 | -664 |
| 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 |

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 2020 is EUR 4.5 (2019: EUR 5.0m). The remaining useful life is 8 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 | 571 | 810 | 783 | 2,609 | 359 | 625 | 6 | 17,036 | 3,336 | 4,255 | 0 | 30,390 |
| Initial application IFRS 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 14,336 | 14,336 |
| Additions | 183 | 223 | 1,268 | 573 | 99 | 95 | 0 | 0 | 0 | 3,468 | 2,289 | 8,198 |
| Disposals | -1 | -12 | -5 | -246 | 0 | 0 | 0 | 0 | 0 | -638 | 0 | -902 |
| Disposal depreciation | 0 | 12 | 18 | 138 | 0 | 0 | 0 | 0 | 0 | 247 | 13 | 428 |
| Depreciation charge of the period | -226 | -356 | -512 | -1,145 | -78 | -366 | -6 | 0 | 0 | -1,365 | -4,988 | -9,042 |
| Transfer gross carrying amount | 0 | 69 | 838 | 0 | 0 | 19 | 0 | -17,014 | -11,002 | 0 | 27,090 | 0 |
| Transfers depreciations | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 7,666 | 0 | -7,666 | 0 |
| Currency translation gross carrying amount | 0 | 4 | 0 | 11 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 18 |
| Currency translation depreciations | 0 | 0 | 0 | -4 | 0 | 0 | 0 | 0 | 0 | 0 | -2 | -6 |
| Closing carrying amount | 527 | 750 | 2,390 | 1,936 | 380 | 373 | 0 | 22 | 0 | 5,967 | 31,076 | 43,421 |
| As at 31 December 2019 | | | | | | | | | | | | |
| Cost | 1,995 | 2,858 | 9,396 | 6,282 | 832 | 2,781 | 29 | 22 | 0 | 8,195 | 43,719 | 76,109 |
| Accumulated depreciation | -1,468 | -2,108 | -7,006 | -4,346 | -452 | -2,408 | -29 | 0 | 0 | -2,228 | -12,643 | -32,688 |
| Carrying amount | 527 | 750 | 2,390 | 1,936 | 380 | 373 | 0 | 22 | 0 | 5,967 | 31,076 | 43,421 |
| 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 |

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 | 2020 | 2019 |
| Non-current assets | | |
| Right-of-use assets - buildings | 10,919 | 12,373 |
| Right-of-use assets - manufacturing equipment | 14,541 | 16,954 |
| Right-of-use assets - cars | 2,007 | 1,700 |
| Right-of-use assets - office furniture | 35 | 50 |
| Total right-of-use assets | 27,502 | 31,077 |

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

| | Years ended 31 December | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Depreciation expense per type right-of-use assets | | |
| Buildings | 1,786 | 1,739 |
| Manufacturing equipment | 2,489 | 2,482 |
| Cars | 949 | 752 |
| Office furniture | 15 | 15 |
| Total depreciation expense | 5,239 | 4,988 |

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

In 2015, the Group acquired a financial participation of 13.5% in MyCartis NV through a contribution in kind for an amount of EUR 5.1m by Debiopharm Diagnostics SA. The investment in associates was fully impaired in 2019 as a consequence of changed activities of MyCartis and realized valuation levels of related recent capital increases.

## 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 | |
|---|---|---|---|---|
| | | | 2020 | 2019 |
| 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 amounts to EUR 2.9m in 2020. 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. Considering

the current situation in China related to the Corona-virus, the financial information could not be audited before the publication of this annual report.

Summarized statement of financial position:

| In EUR 000 | As of 31 December 2020 |
|---|---|
| Non-current assets | 3,617 |
| Current assets | 6,387 |
| Total assets | 10,004 |
| Non-current liabilities | 0 |
| Current liabilities | 1,032 |
| Total liabilities | 1,032 |

Summarized statement of comprehensive income:

| In EUR 000 | Year ended 31 December 2020 |
|---|---|
| Operating income | 1,406 |
| Operating expenses | -2,480 |
| Financial result, net | 22 |
| Income taxes | 0 |
| Result of the year | -1,052 |
| Other comprehensive income | 0 |
| Total comprehensive income | -1,052 |
| Share in total comprehensive income | -526 |

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 2019 | 2,358 |
| Investments of the year | 1,000 |
| Share of the result of the year | -526 |
| Share of the other comprehensive income | 0 |
| Dividends received | 0 |
| Elimination of unrealized gains and losses | 68 |
| Foreign exchange differences | -6 |
| As per 31 December 2020 | 2,894 |

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

Deferred taxes relate to the long-term portion of investment tax credit on research and development and amount to EUR 1.4m per 31 December 2020 (2019: EUR 1.6m). Recognized research and development tax credits in Belgium can be effectively repaid if a company has not been able to offset the tax credit against the corporation tax for the last five consecutive tax years. In 2020, EUR 0.3m of the Group's tax credit on research and development has become a short term receivable, see note 1.2.19.

| In EUR 000 | As of 31 December, 2020 | 2019 |
|---|---|---|
| Tax credit research and development | 1,593 | 1,594 |
| Other | -121 | 16 |
| Total | 1,472 | 1,609 |

## 1.2.18. / INVENTORIES

The inventory can be analyzed as follows:

| In EUR 000 | Per 31 December, 2020 | 2019 |
|---|---|---|
| Inventory | | |
| Raw materials | 4,950 | 5,799 |
| Semi-finished products | 746 | 495 |
| Finished products | 10,015 | 7,867 |
| Total | 15,712 | 14,161 |
| | | |
| Amount recognized as an expense | -26,284 | -21,328 |

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 2020, EUR 0.5 m of the total inventory value was older than 12 months (2019: EUR 1.0m) for which EUR 0.1m impairment was recognized (2019: EUR 0.3m). 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:

| In EUR 000 | As of 31 December, 2020 | 2019 |
|---|---|---|
| Trade receivables | 13,968 | 10,951 |
| Allowance for doubtful receivables | -480 | -256 |
| Total | 13,488 | 10,695 |

| | As of 31 December, 2020 | 2019 |
|---|---|---|
| VAT receivables | 2,133 | 1,870 |
| Tax credit research and development | 310 | 5,242 |
| Other receivables | 1,518 | 1,528 |
| Total | 3,960 | 8,640 |

Trade receivables have increased from EUR 10.7m per 31 December 2019 to EUR 13.5m per 31 December 2020.

At the reporting date, the Group has approximately EUR 5.1m (2019: EUR 4.4m) trade and other receivables that were past due but were not impaired. In 2020 an allowance for doubtful receivables was recorded for EUR 0.5m (2019: EUR 0.3m) 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 2020 or 1 January 2020 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 (2019: EUR 5.2m) 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 | 2020 | 2019 |
| Accrued grant income | 223 | 347 |
| Accrued collaboration income | 1,209 | 627 |
| Other accrued income | 29 | 15 |
| Deferred charges | 1,693 | 1,419 |
| Total | 3,154 | 2,407 |

Other current assets include accrued income mainly related to Flemish government grants for EUR 0.2 m (2019: EUR 0.3m). 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 2018 | 169 |
| Invoiced | -1,047 |
| Recognized in profit or loss | 1,505 |
| As per 31 December 2019 | 627 |
| Invoiced | -1,115 |
| Recognized in profit or loss | 1,697 |
| As per 31 December 2020 | 1,209 |

## 1.2.21. / CASH AND CASH EQUIVALENTS

The cash and cash equivalents can be analyzed as follows:

| | Per 31 December, | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Cash and cash equivalents | | |
| Cash at bank and on hand | 122,468 | 177,525 |
| Total cash and cash equivalents | 122,468 | 177,525 |
| Total restricted cash | 1,200 | 1,200 |
| Total cash and cash equivalents for cash flow purposes | 123,668 | 178,725 |

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 2019 and 31 December 2020. 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 EUR000 | Total share capital in EUR000 |
| At 31 December 2018 | 51,361,088 | 514 | -221,232 | -220,718 |
| Share issue - private placement 28 January 2019 | 5,000,000 | 50 | 0 | 50 |
| Share issue - exercise of stock options on 4 April 2019 | 21,000 | 0 | 0 | 0 |
| 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 |

The following capital transactions took place at the Company from 1 January 2020 until 31 December 2020:

→ On 7 December 2020, the Company announced the exercise of conversion rights of 10% of the total outstanding bond. This transaction resulted in an increase in share capital of EUR 0.01m and an increase in share premium of EUR 13.8m.

### VOTING RIGHTS

Each share gives the holders thereof the right to one vote. The shares are indivisible in respect of the Company and the Company only recognizes one owner per share as regards the exercise of the voting rights.

### DIVIDENDS

The Company has not declared or paid any dividends on its shares. Currently, the board of directors expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future.

## 1.2.23. / SHARE BASED PAYMENTS

The table below provides an overview of the movement in stock options since 31 December 2018:

| | 2008 Plan | 2013 Plan | 2015 Plan | 2017 Plan | 2018 Plan | 2020 Plan | 2020B Plan | Total |
|---|---|---|---|---|---|---|---|---|
| Total outstanding at 31 December 2018 | 19,101 | 504,595 | 249,988 | 1,340,000 | 274,900 | 0 | 0 | 2,388,584 |
| Options granted | 0 | 0 | 0 | 0 | 278,550 | 0 | 0 | 278,550 |
| Options exercised | 0 | -21,000 | 0 | 0 | 0 | 0 | 0 | -21,000 |
| Options forfeited | -19,101 | -1,056 | -40,370 | 0 | -27,001 | 0 | 0 | -87,528 |
| Options cancelled | 0 | | | 0 | 0 | 0 | | 0 |
| Total outstanding at 31 December 2019 | 0 | 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 | 0 | 293,375 | 210,052 | 1,212,365 | 570,935 | 695,476 | 860,000 | 3,842,203 |

*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 2020. In 2020 201,234 options were forfeited. A total of 293,375 options are still outstanding per 31 December 2020 of which:

- 21,611 options have an exercise price of EUR 8.1309
- 23,104 options have an exercise price of EUR 13.28
- 50,000 options have an exercise price of EUR 10.442
- 187,500 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 3.46 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 31/12/2020 | 0 | 0 | 0 | 0 | 7,319 | 140,625 |
| 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 2020, 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 2020 and the weighted average remaining contractual life is 2.3 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 31/12/2020 | 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 2020 no warrants were exercised and 127,635 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 31/12/2020 | 709,865 |
| 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 2020, 82,125 warrants were granted. No warrants were exercised and 37,639 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 31/12/2020 | 47,241 | 63,283 | 45,446 | 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 plan 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 2020 227,300 warrants were granted for the 2020 plan and 450,000 warrants were granted for the 2020B plan. No warrants were exercised and 1,500 warrants were forfeited.

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 | 2020 Plan Grant May 2020 | 2020 Plan Grant September 2020 | 2020 Plan Grant November 2020 |
|---|---|---|---|---|
| Number of warrants granted | 450,000 | 50,000 | 110,800 | 65,000 |
| Number of warrants not vested at 31/12/2020 | 450,000 | 50,000 | 110,800 | 65,000 |
| Exercise price | EUR 4.18 | EUR 4.81 | EUR 4.81 | EUR 4.53 |
| Expected dividend yield | 0 | 0 | 0 | 0 |
| Expected stock price volatility | 43% | 43% | 43% | 44% |
| Risk-free interest rate | -0.5% | -0.5% | -0.7% | -0.7% |
| Expected duration | 3.5 years | 3.5 years | 3.5 years | 3.5 years |
| Forfeiture rate | 0% | 0% | 0% | 0% |
| Fair value | EUR 1.74 | EUR 1.49 | EUR 1.46 | EUR 1.51 |

### ACCOUNTING FOR SHARE-BASED PAYMENT

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

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Share based compensation | 1,432 | 1,225 |
| Total | 1,432 | 1,225 |

## 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 2020, the Defined Benefit plans are a net asset and are therefore reported under 'Other non-current assets' in the consolidated statement of financial position.

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Provisions for pensions and similar obligations | -413 | 49 |
| Total | -413 | 49 |

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 2019 | 49 |
| Service cost | 485 |
| Pension expense/income | -1 |
| Company contributions | -750 |
| Actuarial gains/losses | -196 |
| As per 31 December 2020 | -413 |

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

| | 2020 |
|---|---|
| Discount rate | 0.90% |
| 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:

| | 2020 |
|---|---|
| Discount rate +0,5% | 174 |
| Discount rate -0,5% | -174 |

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 | 2020 | 2019 |
| Lease liability | 18,625 | 23,942 |
| Bank borrowings | 0 | 58 |
| Convertible debt | 125,260 | 136,158 |
| Total non-current | 143,885 | 160,158 |
| Lease liability | 6,615 | 6,295 |
| Bank borrowings | 58 | 125 |
| Total current | 6,673 | 6,420 |
| Total Financial liabilities | 150,557 | 166,578 |

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 2020 EUR 0.1m is outstanding under this facility.

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 2020 EUR 1.0m 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 increase 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 2020 EUR 8.9m 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 2017, Biocartis reached agreement with KBC and BNP Paribas Fortis for a committed multiple purpose credit facility of EUR 27.5m (not covered by a government guarantee). This facility consists of a EUR 18.5m rollover credit line and a EUR 9m working capital credit line. No amount has been withdrawn on this credit facility per 31 December 2020.

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 2020 EUR 0.6m 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 125.3m per 31 December 2020.

In addition, the Group also has access to a bank guarantee line of EUR 0.5m of which EUR 0.5m has been taken up for rental guarantees as per 31 December 2020, and a credit line with a bank of EUR 0.6m for currency hedging, of which EUR 0.0m has been taken up per 31 December 2020.

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 | 2013 | 7,910 | S | 3.35% | 31/05/2021 |
| Lease company | 2015 | 3,372 | S | 1.77% | 1/12/2021 |
| Bank | 2015 | 600 | S | 1.93% | 1/06/2021 |
| Lease company | 2016 | 17,319 | S | 1.87% | 1/12/2021 |
| Bank | 2018 | 1,000 | 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, | | | |
|---|---|---|---|---|
| | 2020 | | 2019 | |
| | Minimum lease payments | Present value of minimum lease payments | Minimum lease payments | Present value of minimum lease payments |
| Lease | | | | |
| < 1 year | 7,255 | 6,615 | 7,482 | 6,295 |
| > 1 and < 5 years | 15,682 | 14,171 | 19,928 | 17,860 |
| > 5 years | 4,842 | 4,454 | 6,318 | 6,082 |
| Total | 27,779 | 25,240 | 33,728 | 30,237 |
| Less interests | -2,537 | 0 | -3,250 | 0 |
| Present value | 25,242 | 25,240 | 30,478 | 30,237 |

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 2019 | 30,237 | 136,158 | 183 |
| Changes from financial cash flows | -7,042 | -13,859 | -125 |
| 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 | 2,961 | 0 |
| Lease additions | 2,045 | 0 | 0 |
| As per 31 December 2020 | 25,240 | 125,260 | 58 |

Some more details related to the lease liabilities such as interest expenses, expenses related to short term and low values lease and variable lease payments can be found in the table below. The Group's lease agreements do not include material restrictions or financial covenants.

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Depreciation expense of right-of-use assets | -5,395 | -5,151 |
| Interest expense on lease liabilities | -624 | -957 |
| Rent expense - short-term & low value leases | -197 | -395 |
| Rent expense - variable lease payments | 0 | 0 |
| Total amounts recognized in profit or loss | -6,215 | -6,503 |

## 1.2.26. / TRADE PAYABLES AND OTHER CURRENT LIABILITIES

| | As of 31 December, | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Trade payables | 13,907 | 9,070 |
| Total trade payables | 13,907 | 9,070 |

| | As of 31 December, | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Provision vacation pay and end-of-year premium & other social debt | 7,394 | 6,003 |
| VAT payable | 152 | 88 |
| Other | 40 | - |
| Other current liabilities | 7,587 | 6,091 |

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

## 1.2.27. / DEFERRED INCOME

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Grants | 658 | 859 |
| Partner income | 983 | 1,197 |
| Total | 1,641 | 2,056 |
| Current | 1,278 | 1,595 |
| Non-current | 363 | 461 |

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 2019 was EUR 1.2m, of which EUR 0.9m was recognized in revenue in 2020 and the remaining balance of EUR 0.3m is still outstanding and included in the deferred revenue balance of 31 December 2020.

| | Deferred partner income |
|---|---|
| As per 31 December 2018 | 2,029 |
| Invoiced | 5,605 |
| Recognized in profit or loss | -6,436 |
| As per 31 December 2019 | 1,197 |
| Invoiced | 3,369 |
| Recognized in profit or loss | -3,583 |
| As per 31 December 2020 | 983 |

## 1.2.28. / ACCRUED EXPENSES

Accrued expenses primarily include accruals for rental charges.

## 1.2.29. / INCOME TAXES

### 1.2.29.1. / COMPOSITION OF TAX EXPENSE

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | 2020 | 2019 |
| Current income tax | -307 | -165 |
| Deferred income tax | 79 | 66 |
| Total | -228 | -99 |

### 1.2.29.2. / TAX RECONCILIATION

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

| In EUR 000 | Years ended 31 December, 2020 | 2019 |
|---|---|---|
| Loss before taxes | -63,162 | -64,167 |
| Income tax credit calculated at 25%/29,58% | -15,791 | -18,981 |
| Effect of different tax rates | 0 | 0 |
| Effect of income that is exempt from taxation | -2,077 | -4,631 |
| Effect of expenses that are non-deductible in determining tax profit | 426 | -169 |
| Effect of unused tax losses and tax offsets not recognized as deferred tax assets | 17,441 | 23,781 |
| effect of tax credit for research and development | -309 | -311 |
| Effect of capital tax in Biocartis SA | 0 | 178 |
| Other | 82 | 37 |
| | -228 | -96 |
| Adjustments recognized in the current year in relation to the current tax of prior years | 0 | -3 |
| Income tax expense (profit) recognized in loss for the period | -228 | -99 |

### 1.2.29.3. / 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 408.2m (2019: EUR 341.1m). The tax losses of Biocartis NV for EUR 369.8m per 31 December 2020 (2019: EUR 313.6m) in Belgium will not expire as they can be carried forward indefinitely.

### 1.2.29.4. / RECOGNIZED DEFERRED TAX ASSETS

The Group has R&D tax credit carry-forwards in Belgium for a total amount of EUR 1.9m (2019: EUR 6.8m) for which a deferred tax asset of EUR 1.9m (2019: EUR 6.8m) has been recognized as the recognition criteria have been met as from 2014. Per 2020, EUR 0.3m of the total R&D tax credit has been classified as a current asset under 'other receivables'.

## 1.2.30. / FINANCIAL RISK MANAGEMENT

### 1.2.30.1. / 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.

### 1.2.30.2. / 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.

### 1.2.30.3. / 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 2020 and 2019.

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 | 2020 | 2019 |
| **Liabilities** | | |
| USD - United States | 2,762 | 222 |
| GBP - Great Britain | 12 | 7 |
| | | |
| **Assets** | | |
| USD - United States | 4,416 | 3,487 |
| GBP - Great Britain | 934 | 372 |

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 these currencies is not material.

### INTEREST RATE RISK

The interest rate risk is limited as the Group has only long-term borrowings with a fixed interest rate. Changes in interest rates will not increase/decrease profit or loss or other comprehensive income.

### OTHER MARKET RISK

The Group is not exposed to equity price risk or commodity price risk as it does not invest in these classes of investments.

### CREDIT RISK

Credit risk arises from cash and cash equivalents, short-term bank deposits, as well as credit exposure to collaboration partners. Credit risk refers to the risks that counterparty will default on its contractual obligations resulting in financial loss to the Group.

The Group has a limited number of collaboration partners and therefore has a significant concentration of credit risk. However, it has policies in place to ensure that credit exposure is kept to a minimum and significant concentrations of credit exposure are only granted for short periods of time to high credit quality collaboration partners. Credit exposure with regard to R&D partnering activities is concentrated with a limited number of creditworthy partners. In 2020 there are no costumers representing at least 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 multiple purpose credit facility of EUR 27.5m, as described in note 1.2.25. In addition, the Group also has access to a bank guarantee line of EUR 0.5m of which EUR 0.5m has been taken up for rental guarantees as per 31 December 2020, and an credit line with a bank of EUR 0.6m for currency hedging, of which EUR 0m has been taken up as per 31 December 2020. 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, | | | | | |
|---|---|---|---|---|---|---|
| | 2020 | | | 2019 | | |
| 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 | 13,907 | 6,668 | 7,587 | 9,070 | 6,668 | 6,091 |
| 1-3 years | | 10,453 | | | 11,804 | 0 |
| 3-5 years | | 138,718 | | | 156,113 | 0 |
| 5+ years | | 4,460 | | | 5,834 | 0 |
| **Total** | **13,907** | **160,299** | **7,587** | **9,070** | **180,420** | **6,091** |

## 1.2.31. / 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 2020 and 2019.
- 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 instruments (MyCartis) carried at fair value in the consolidated balance sheet on 31 December 2020 and 2019.

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 150.6m (2019: EUR 166.1m) have a fair value of EUR 150.6m (2019: EUR 165.3m).

# 1.2.32. / 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.

# 1.2.33. / COMMITMENTS

## 1.2.33.1. / 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 (2020: EUR 1.0m; 2019: EUR 0.4m). The Group had no other material commitments to capital expenditures on 31 December 2020.

## 1.2.33.2. / OPERATING COMMITMENTS

The Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 8.6m (2019: EUR 9.1m). It is expected that the majority of the commitments will be fulfilled in 2021.

## 1.2.33.3. / 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.

### 1.2.33.3.1. / 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 3 'Non-Financial Report 2020', 'Remuneration policy' in the Corporate Governance section.

### 1.2.33.3.2. / 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.

### 1.2.33.3.3. / SUBSIDIARIES

Details of the Company's subsidiaries at 31 December 2020 are as follows:

| Name of subsidiary | Principal activity | Place of incorporation and operation | Proportion of ownership interest and voting power held by the Group | |
|---|---|---|---|---|
| | | | 2020 | 2019 |
| Biocartis NV | Develop and market diagnostic platforms | Generaal de Wittelaan 11 B - 2800 Mechelen (België) | 100% | 100% |
| Biocartis US Inc | Market diagnostic platforms | 30 Montgomery Street, 9th Floor, Suite 970 Jersey City, NJ 07302 USA | 100% | 100% |
| Biocartis S.r.l. | Market diagnostic platforms | Milano (MI) Corso Vercelli 40 CAP 20145 Italy | 100% | 0% |

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.

## 1.2.34. / EVENTS AFTER THE BALANCE SHEET DATE

Two important events occurred after the reporting date:

- Achievement 2020 key business objectives – On 11 January 2021, Biocartis announced to have achieved its most recent key business objectives for 2020.
- The credit facility and guarantees from BNP Paribas Fortis have been canceled 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. No amounts have been drawn on this credit facility as per approval date of this annual report.

There were no further important events between 31 December 2020 and the approval date of this annual report.

## 1.2.35. / RELEVANT STANDARDS AND INTERPRETATIONS PUBLISHED, BUT NOT YET APPLICABLE FOR THE ANNUAL PERIOD BEGINNING ON 1 JANUARY 2020

- IFRS 17 Insurance Contracts (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 16 Property, Plant and Equipment: Proceeds before Intended Use (applicable for annual periods beginning on or after 1 January 2022, but not yet endorsed in the EU)
- 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, but not yet endorsed in the EU)
- Amendments to IFRS 3 Business Combinations: Reference to the Conceptual Framework (applicable for annual periods beginning on or after 1 January 2022, but not yet endorsed in the EU)

- Amendment to IFRS 4 Insurance Contracts – deferral of IFRS 9 (applicable for annual periods beginning on or after 1 January 2021)
- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform – Phase 2 (applicable for annual periods beginning on or after 1 January 2021)
- Amendment to IFRS 16 Leases: COVID-19-Related Rent Concessions (applicable for annual periods beginning on or after 1 June 2020)
- Annual Improvements to IFRS Standards 2018–2020 (applicable for annual periods beginning on or after 1 January 2022, 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

| In EUR 000 | Years ended 31 December, 2020 | 2019 |
|---|---|---|
| Revenues | 6,063 | 5,612 |
| Other operating income | 308 | 51 |
| **Total operating income** | 6,371 | 5,663 |
| Services and other goods | -2,253 | -2,186 |
| Salaries, social security contributions and pensions | -3,562 | -3,683 |
| Other operating expenses | -3 | -4 |
| **Operating expenses** | -5,818 | -5,873 |
| Financial income | 330 | 2,695 |
| Financial expenses | -10,719 | -93,526 |
| **Result from continuing operations** | -9,836 | -91,041 |
| Income taxes | -7 | 27 |
| **Net result** | -9,843 | -91,014 |

## 2.3.2. / BALANCE SHEET

| In EUR 000 | As of 31 December 2020 | 2019 |
|---|---|---|
| Financial fixed assets | 451,216 | 450,116 |
| **Non-current assets** | 451,216 | 450,116 |
| Trade receivables | 0 | 0 |
| Other receivables | 61,361 | 8,777 |
| Cash and cash equivalents | 61,731 | 125,116 |
| Transitory accounts | 67 | 41 |
| **Current assets** | 123,159 | 133,935 |
| **Total assets** | 574,375 | 584,051 |
| Legal share capital | 575 | 564 |
| Share premium | 550,289 | 535,301 |
| Accumulated deficit | -113,912 | -104,071 |
| **Total equity** | 436,952 | 431,794 |
| Financial debt | 135,000 | 150,000 |
| **Non-current liabilities** | 135,000 | 150,000 |
| Financial debt | 0 | 0 |
| Trade payables | 872 | 726 |
| Provision taxes | 0 | 0 |
| Salaries, social security contributions and pensions | 748 | 645 |
| Accrued charges | 803 | 885 |
| **Current liabilities** | 2,423 | 2,256 |
| **Total equity and liabilities** | 574,375 | 584,050 |

# 2.4. / DISCUSSION OF STATUTORY ACCOUNTS

## 2.4.1. / INCOME STATEMENT

Total operating income in 2020 amounted to EUR 6.4m (2019: EUR 5.7m) and consists mainly of expense recharges to the Biocartis Group NV subsidiaries. Operating expenses recorded in the period under review amounted to EUR 5.8m (2019 EUR 5.9m) and consist of salaries, social security contributions and pensions expenses for EUR 3.6m (2019: EUR 3.7m) and of expenses for services and other goods of EUR 2.3m (2019: EUR 2.2m). Services and other goods mainly consist of recurring general and administrative expenses.

Financial income amounted to EUR 0.3m (2019: EUR 2.7m) 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 10.7m (2019: EUR 93.5m) and contains interest expenses related to the convertible bond or EUR 6.0 compared to EUR EUR 3.9m in 2019. The financial expenses also include a cash payment of EUR 4.3 in connection with the incentivized exercise of conversion rights in relation to EUR 15m aggregate principal amount of Bonds. In 2019, the financial expenses included some non-recurring expenses, such as expenses made in relation of the issuance of the convertible bond of EUR 4.3m, impairment losses on financial fixed assets of EUR 5.0 driven due to the full impairment on the Company's participation in MyCartis. In 2019, Biocartis SA was liquidated and therefore an impairment of mEUR 76.8m was recorded of the Company's participation in Biocartis SA.

The net result after taxes for the period ended 31 December 2020 amounts to EUR -9.8m (2019: EUR 91.0m).

## 2.4.2. / BALANCE SHEET

### 2.4.2.1. / ASSETS

The financial fixed assets consist of shares in the Biocartis Group NV subsidiaries for EUR 445.2m (Biocartis NV, Biocartis US Inc. and Biocartis S.r.l.) and of the China joint venture for EUR 6.0m.

Other receivables amounted to EUR 61.4m (2019: EUR 8.8m) and mainly relate to receivables on the Biocartis Group NV subsidiaries, mainly related to financial advances. Cash and equivalents amounted to EUR 61.7m per 31 December 2020 (2019: EUR 125.1m). Deferred charges relate to prepaid expenses.

### 2.4.2.2. / EQUITY

Total equity per 31 December 2020 amounted to EUR 437.0m (2019: EUR 431.8m) and the legal share capital and share premium amount to respectively EUR 0.6m (2019: EUR 0.6m) and EUR 550.3m (2019: EUR 535.3m).

Following movements in equity were recorded during the reporting period:

→ On 7 December 2020, the Company announced the exercise of conversion rights of 10% of the total outstanding bond. This transaction resulted in an increase in share capital of EUR 0.01m and an increase in share premium of EUR 13.8m.

### 2.4.2.3. / FINANCIAL LIABILITIES

The financial liabilities are related to the convertible bond and amount to EUR 135m in 2020 and EUR 150m in 2019. The incentivized conversion resulted from an agreement with a holder of part of the Company's EUR 150m 4% senior unsecured convertible Bonds regarding the exercise of conversion rights in relation to EUR 15 million aggregate principal amount of the Bonds.

### 2.4.2.4. / OTHER LIABILITIES

As per 31 December 2020, trade payables amounted to EUR 0.9m (2019: EUR 0.7m), payables for salaries, social security contributions and pensions to EUR 0.7m (2019: EUR 0.6m) 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 2020 to EUR 574.4m (2019: EUR 584.1m).

## 2.5. / APPROPRIATION OF RESULTS

The statutory accounts of the Company reported a net loss of EUR 9.8m for the year 2020. The Board of Directors proposes to carry forward the statutory net loss of EUR 9.8m of 2020 to the following financial year.

# 2.6. / GOING CONCERN VALUATION RULES

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 financial plan and investment budgets of the company accounted for these losses and in line therewith the Company attracted financing. In 2019, Biocartis Group NV raised EUR 55.5 m in the context of a private placement and EUR 150.0m in by the issuance of a convertible bond. Taken into account the strong cash position of the Company at the end of 2020 as well as the expectations for 2021, the board of directors is of the opinion that the losses carried forward do not endanger the going concern of the Company, at least until the annual general meeting of the Company in 2022, and thus that the application of the valuation rules going concern is justified.

# 3. AUDITOR'S REPORT

## Biocartis Group NV

### Statutory auditor's report to the shareholders' meeting of Biocartis Group NV for the year ended 31 December 2020 - 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 11 May 2018, 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 2020. We have performed the statutory audit of the consolidated financial statements of Biocartis Group NV for 6 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 2020, the consolidated income statement, the 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 210.517 (000) EUR and the consolidated income statement shows a loss for the year then ended of 62.934 (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 2020 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 2020 amounts to 43 128 KEUR and mainly consist of:<br>• Product related revenues (31 893 KEUR) including various combinations of instruments and cartridges in stand-alone and multiple element sales agreements, operational reagent rental agreements and rental agreements; and<br>• Collaboration revenues (9 989 KEUR) 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.<br>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.<br>Furthermore, revenue transactions may be subject to manual adjustments.<br>The company's disclosures about revenue are included in Part 4, note 1.2.2.15 Revenue recognition and part 4, 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.<br>We obtained an understanding of the underlying processes and preventive and detective internal controls.<br>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.<br>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.<br>We inquired with management and read relevant meeting minutes to ensure completeness of the reported collaboration agreements.<br>We have tested a sample of revenue transactions related to product sales.<br>We have reviewed the manual entries to revenue for accuracy and validity. |

## 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 those charged with the audit committee regarding, amongst other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the audit committee with a statement that we have complied with relevant ethical requirements regarding independence, and we communicate with them about all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated to the audit committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our report unless law or regulation precludes any public disclosure about the matter.

## OTHER LEGAL AND REGULATORY REQUIREMENTS

### Responsibilities of the board of directors

The board of directors is responsible for the preparation and the content of the directors' report on the consolidated financial statements and other matters disclosed in the annual report on the consolidated financial statements.

### Responsibilities of the statutory auditor

As part of our mandate and in accordance with the Belgian standard complementary to the International Standards on Auditing (ISA) as applicable in Belgium, our responsibility is to verify, in all material respects, the director's report on the consolidated financial statements and other matters disclosed in the annual report on the consolidated financial statements, as well as to report on these matters.

## Aspects regarding the directors' report on the consolidated financial statements

In our opinion, after performing the specific procedures on the directors' report on the consolidated financial statements, this report is consistent with the consolidated financial statements for that same year and has been established in accordance with the requirements of article 3:32 of the Code of companies and associations.

In the context of our statutory audit of the consolidated financial statements we are also responsible to consider, in particular based on information that we became aware of during the audit, if the directors' report on the consolidated financial statements is free of material misstatement, either by information that is incorrectly stated or otherwise misleading. In the context of the procedures performed, we are not aware of such material misstatement.

## Statements regarding independence

- Our audit firm and our network have not performed any prohibited services and our audit firm has remained independent from the group during the performance of our mandate.
- The fees for the additional non-audit services compatible with the statutory audit, as defined in article 3:65 of the Code of companies and associations, have been properly disclosed and disaggregated in the notes to the consolidated financial statements.

## 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.

Zaventem, 31 March 2021

**The statutory auditor**

**Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises CVBA/SCRL**
Represented by Nico Houthaeve

# PART 5/ GLOSSARY & BIBLIOGRAPHY

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| 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. |
| 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 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 |

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| | 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 |

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| | 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 infectic damages its own tissues. When the infection-fighting processes turn on the body, they cause organs t function poorly and abnormally. Sepsis may progress to septic shock. This is a dramatic drop in bloc pressure that can lead to severe organ problems and death. Early treatment with antibiotics an 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. |

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13 Source: Research and Markets, Molecular Diagnostics - Global Market Trajectory & Analytics, https://www.researchandmarkets.com/reports/338507/molecular_diagnostics_global_market_trajectory?utm_source=dynamic&utm_medium=GNOM&utm_code=sbdxz7&utm_campaign=1393662+-+Global+Molecular+Diagnostics+Market+Analysis+2020+-+PCR+Technology+Leads+the+MDx+Market&utm_exec=cari18gnomd
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17 A molecular diagnostics company based in Santiago, Chile
18 A Palo Alto, CA (USA) based company developing personalized care solutions and targeted therapies for critically ill patients
19 Developed in collaboration with Immunexpress
20 In the US, distribution of the Idylla™ SARS-CoV-2 Test was initiated in Q3 2020 per US FDA Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), May 2020, Section IV.C. Commercial Manufacturer Development and Distribution of Diagnostic Tests Prior to EUA Submission
21 Excluding instruments returned by Exact Sciences in accordance with the termination agreement announced on 29 October 2020
22 Defined as the world excluding European direct markets, US, China and Japan
23 A companion diagnostic (CDx) test is a test used as a companion to a therapeutic drug, that helps predict if a patient is likely to respond to a treatment or not
24 Metastatic colorectal cancer
25 The collaboration was focused on the development of the Oncotype DX Breast Recurrence Score® Test and the Oncotype DX Genomic Prostate Score® (GPS™) Test on the Idylla™ platform. As a result of COVID-19, the project had been suspended earlier during 2020, with the project plan and timing under evaluation. The decision to terminate the agreement was driven by the uncertain timing of a product market release because of the pandemic and a decision by Exact Sciences to shift priorities to other initiatives
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31 All studies were performed with Idylla™ RUO assays, research use only, not for use in diagnostic procedures. Three studies also discussed new Biocartis assays in the area of infectious disease: the Idylla™ SARS-CoV-2 Assay and the SeptiCyte® RAPID on Idylla™

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40 Source: Pacific Bridge Medical, https://www.pacificbridgemedical.com/publication/ivd-registration-reimbursement-china/
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68 Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey

69 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

70 Based on RTqPCR analysis, combined with an advanced machine learning algorithm

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79 This represents a major challenge for many current molecular testing methods in a variety of different cancer types

80 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

81 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

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