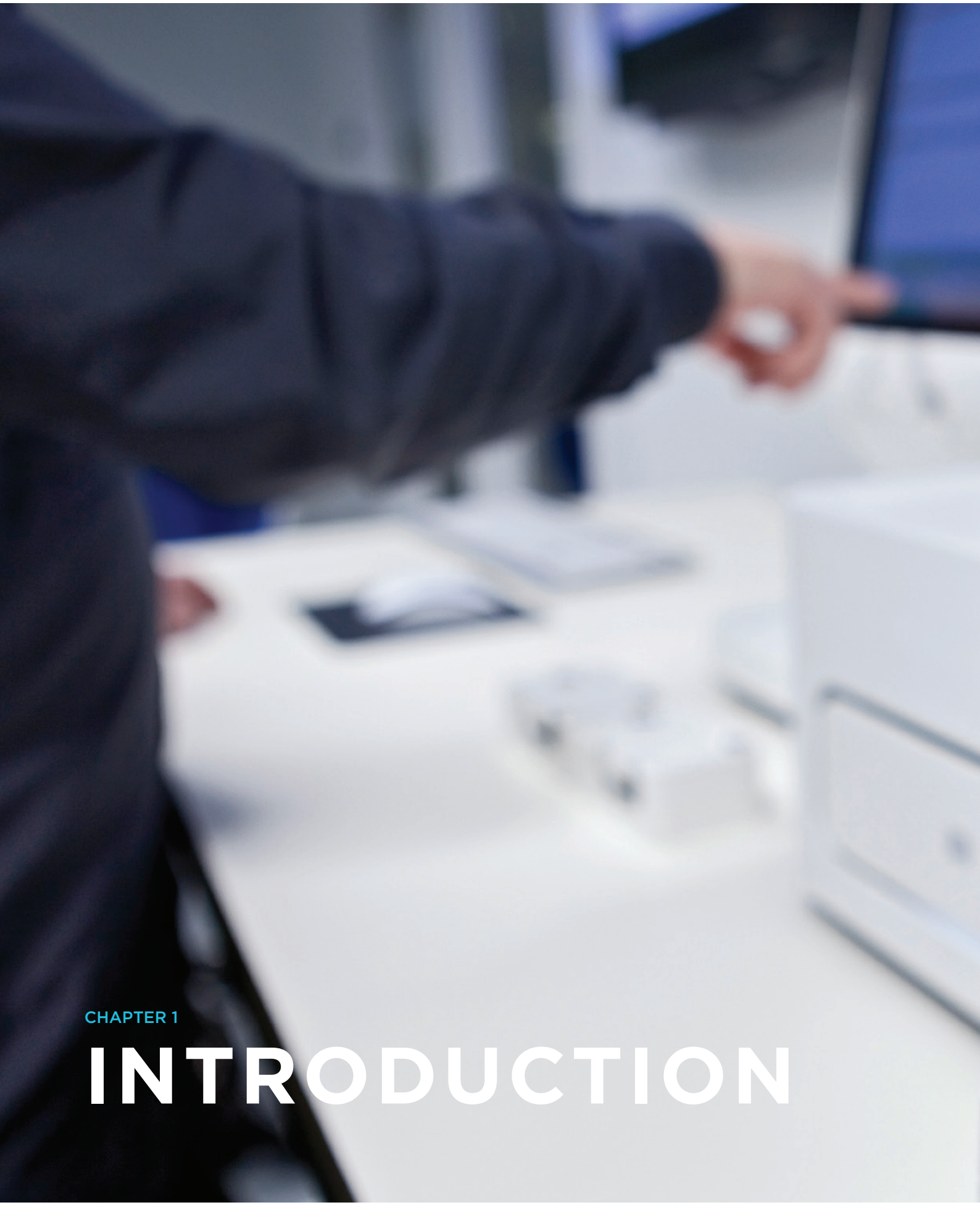
BIOCARTIS

ANNUAL REPORT 2019

HIGH PRECISION DIAGNOSTICS
FOR PERSONALIZED MEDICINE

CONTENTS



CHAPTER 1

INTRODUCTION

1.1 / BIOCARTIS AT A GLANCE

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

BIOCARTIS IS AN INNOVATIVE MOLECULAR DIAGNOSTICS 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, WITH A FOCUS ON ONCOLOGY.

BIOCARTIS' PROPRIETARY MOLECULAR DIAGNOSTICS (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
- COMMERCIALLY ACTIVE IN +70 COUNTRIES
- HEADQUARTERED IN BELGIUM (MECHELEN)
- R&D CENTERS IN THE US AND BELGIUM
- 465 EMPLOYEES[1]

HIGHLIGHTS 2019

- Installed base of over 1,300 Idylla™ instruments and 175K cartridges sold in 2019, + 32% versus 2018
- EUR 24.2m product revenues (+29% compared to 2018)
- Operating income increased with 32% to EUR 37.7m
- New US go-to-market strategy announced in September 2019
- Strengthening of the global commercial footprint with commercial launch by distribution partner Nichirei Biosciences in Japan[2]
- Two new test launches: the Idylla™ MSI Test (CE-IVD) and the liquid biopsy ctEGFR Mutation Assay (RUO[3])
- Entry into the immuno-oncology domain with signing of assay development collaborations with two strong partners, Kite/Gilead and Bristol-Myers Squibb Company
- 465 employees[1], 30 nationalities & balanced gender diversity 50% men and 50% women

1.2 / RESPONSIBILITY STATEMENT

The undersigned hereby declare that to the best of their knowledge: a) the annual accounts, which have been drawn up in accordance with the applicable accounting standards, give a true and fair view of the net equity, financial position and results of the Company and the companies included in the consolidation, and b) the annual report gives a true and fair view of the development and results of the business and the position of the Company and the companies included in the consolidation, as well as a description of the main risks and uncertainties they are confronted with.

HERMAN VERRELST
CHIEF EXECUTIVE OFFICER

CHRISTIAN REINAUDO
CHAIRMAN OF THE BOARD OF DIRECTORS

1.3 / DISCLAIMER AND OTHER INFORMATION

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 2019 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.

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 Dutch version shall prevail. An electronic version of the annual report 2019 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 2019 and 31 December 2019.

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. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. 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 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.

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 non-consolidated Belgian subsidiary company and references to 'the Group' or 'Biocartis' include Biocartis Group NV together with its subsidiaries.

USE OF THE IDYLLA™ TRADEMARK, LOGO AND CE-MARKING

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

CHAPTER 2

PERFORMANCE 2019

2.1 / MESSAGE FROM THE CHAIRMAN & CEO

"The year 2019 was an eventful year, but we finished it in a position of strength. Our 2019 results show a continued healthy growth in revenues and a cash position that allows us to further execute on our plans for the coming years. More importantly, we have a strong outlook for 2020 in which we expect to see an encouraging growth of our cartridge volumes. That is driven by a strong Q4 2019, our sizeable installed base, our new US go-to-market strategy which was announced in September 2019, a good outlook for Europe and RoW as well as the menu expansion realized in 2019 through the IVD-marking of our Idylla™ MSI Test and launch of our Idylla™ ctEGFR Mutation Assay. We are also excited about the new and increasing research use of our Idylla™ assays in exploring pan-tumor settings – pointing to a broader applicability of the test menu on the Idylla™ platform. We expect more publications on this topic over the course of 2020. In addition, towards end 2020 we expect to see important new assay launches, by ourselves and our partners, and we expect our first oncology US FDA filing. All of this will fuel growth for 2021 and beyond, also supported by the progress we are making in our commercial plans for China and Japan, both sizable untapped markets for Biocartis. We confidently look forward to 2020 and beyond."

HERMAN VERRELST, CEO BIOCARTIS AND CHRISTIAN REINAUDO, CHAIRMAN OF THE BOARD OF BIOCARTIS

INSTALLED BASE OF OVER 1,300 INSTRUMENTS

On 26 February 2019, we crossed the 1,000 mark with the installment of our 1,000th Idylla™ instrument, placed with the Diagnostic Medicine Institute at Geisinger, one of the leading oncology practices in the US. That was an important commercial milestone in the global commercial roll-out of Idylla™. Over the course of 2019 we managed to further increase our installed base to over 1,300 instruments. Besides this being an important driver for cartridge volumes, it also further strengthens our position in partnership discussions with both pharmaceutical companies and content partners.

DIRECT GO-TO-MARKET STRATEGY IMPLEMENTED FOR THE US

During 2019, our commercial strategies for Europe and RoW markets continued to translate in good growth rates. In the US, we announced a new go-to-market strategy in September 2019 after a slower than expected cartridge volume pick-up during H1 2019. We took action, which included the joint termination of our distribution agreement with Fisher Healthcare and putting the Biocartis' direct sales team in the drivers' seat to drive commercialization in the US going forward. This direct go-to-market strategy already demonstrated its effectiveness in Q4 2019, indicating that we are on track to further drive commercialization in the US.

REACHING INTO KEY ASIAN MARKETS

To establish a global Idylla™ commercial footprint, we also initiated commercialization in China and Japan. In China, the closing of the establishment of the joint venture with Wondfo ('China JV') was completed in Q1 2019. In Japan, one of the largest MDx markets in the Asia-Pacific region, Idylla™ was commercially launched in November 2019 by our distribution partner Nichirei Biosciences, following the registration of the Idylla™ Instrument and Idylla™ Console with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan in October 2019.

ENTRY INTO IMMUNO-ONCOLOGY WITH TWO STRONG PARTNERS

Immuno-oncology is a new and rapidly growing domain of oncology treatments that harness the body's immune system to fight cancer. As we highlighted during our strategy update in March 2019, Idylla™ is uniquely positioned to address the needs within this domain, where therapies are often costly and can result in significant side effects if not monitored closely. On 12 March 2019, we announced our collaboration agreement with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company developing leading immuno-oncology treatments, aimed at the registration as a companion diagnostic and use of the Idylla™ MSI test in connection with immuno-oncology therapies. Post the reporting period, on 5 March 2020, we announced an expansion to that agreement with the signing of a new immuno-oncology project with Bristol-Myers Squibb Company aimed at the registration of the Idylla™ MSI test in the People's Republic of China. Finally, on 1 June 2019, we announced a first immuno-oncology partnership with Kite, a Gilead Company, one of the leaders in the field of anti-cancer cell therapies, aimed at the development of Idylla™ assays to support Kite's therapies.

EXECUTING ONGOING MENU EXPANSION IN COLORECTAL AND LUNG CANCER

We strengthened the Idylla™ test menu in 2019 with two new, highly innovative assays. The Idylla™ MSI Test was launched as a CE-marked IVD test on 28 February 2019. It allows for fast and accurate information on a patient's MSI status directly from a single sample of FFPE colorectal cancer tumor tissue. Guidelines today recommend assessing the MSI status for all patients with colorectal or endometrial carcinomas for screening for Lynch Syndrome as well as for prognostic stratification and potential response to certain immunotherapies[4]. This test launch makes MSI testing now easy, rapid and accessible to a much larger patient population. On 25 October 2019, we launched the Idylla™ ctEGFR Mutation Assay (RUO). This assay is the liquid biopsy version of the solid biopsy Idylla™ EGFR Mutation Test (CE-IVD) but operates directly on only two ml of blood plasma. As such, this assay offers our customers all benefits of ease-of-use and speed which they have come to know with the Idylla™ platform, combined with liquid biopsy benefits which could provide great solutions in cases where cancer tissue is not or not sufficiently available.

GROWING THE IDYLLA™ ECOSYSTEM BY THE DAY

Since the commercial launch of our Idylla™ platform, we have built a sizeable customer base of Idylla™ users. In 2019, our collaborations with a wide range of key opinion leaders resulted in over 26 Idylla™ publications and multiple study abstracts, all demonstrating the quality and high performance of the Idylla™ products. These publications are important in the further market adoption of Idylla™. We were very pleased to see such studies be published at renowned conferences such as ESMO[5] (European Society for Medical Oncology), ASCO[6] (American Society of Clinical Oncology) and AMP[7] (Association of Molecular Pathology). In addition, we experienced an increased interest from partners as demonstrated by the announcements we made in 2019 around new collaborations. All in all, the interactions between our customers and partners are increasingly creating a unique and dynamic Idylla™ ecosystem which is further improving the platform's positioning, allowing all stakeholders to leverage on their platform investments.

ALL OF THE ABOVE HAS MADE US MORE RESILIENT AS A COMPANY. WE WANT TO THANK ALL OF OUR SHAREHOLDERS AND STAKEHOLDERS – CUSTOMERS, BUSINESS PARTNERS, SUPPLIERS, EMPLOYEES AND MANY OTHERS – FOR THEIR TRUST. TOGETHER WITH THEM, WE ARE LOOKING FORWARD TO MAKING IDYLLA™ THE GO-TO-PLATFORM IN RAPID ONCOLOGY MOLECULAR DIAGNOSTIC TESTING IN THE YEARS TO COME.

HERMAN VERRELST
CHIEF EXECUTIVE OFFICER

CHRISTIAN REINAUDO
CHAIRMAN OF THE BOARD OF DIRECTORS

2.2 / HIGHLIGHTS 2019 AND BUSINESS REVIEW

2.2.1 / COMMERCIAL HIGHLIGHTS

→ COMMERCIAL CARTRIDGE VOLUME

In 2019, Biocartis realized a commercial volume of approx. 175k Idylla™ cartridges, a year-over-year increase of approx. 32%. The European and RoW markets contributed most to the absolute volume growth. A promising pick-up in US cartridge volume was realized in Q4 2019.

→ INSTALLED BASE

The installed base of Idylla™ instruments increased to 1,310 as per year-end as a result of 337 new installations in 2019. Continued installed base growth was realized in European and US markets. RoW markets realized a strong ramp-up in new placements and initial instruments were placed in China.

→ EUROPEAN COMMERCIALIZATION

European direct markets realized a good and consistent performance both in terms of new instrument placements and cartridge volumes in 2019. This was mainly driven by a continued growing use of Idylla™ in first line testing, predominately by larger laboratory customers in Western Europe, and a solid expansion into the medium sized laboratory segments amongst others in Southern Europe.

→ US COMMERZIALIZATION

Biocartis implemented a new go-to-market strategy for the US market, following the joint termination of the distribution collaboration with Fisher Healthcare on 5 September 2019. Under the new go-to-market strategy Biocartis' US direct sales team will drive commercialization going forward with a focus on large tier 1 pathology labs where Idylla™ demonstrates its added value as a rapid and easy testing method complementary to other technologies such as Next Generation Sequencing (NGS). In H2 2019, the Biocartis US direct sales team was strengthened, all customers were successfully transitioned from Fisher Healthcare to Biocartis and actions to address amongst others US market specific operational lessons learned in H1 2019 were implemented. The successes realized in Q4 2019, including the addition of new high profile US Idylla™ users, support the decision making around the new go-to-market strategy.

→ RoW DISTRIBUTION MARKETS

In 2019, RoW realized a solid performance in cartridge volume growth and closed the year with a number of new instrument placements exceeding expectations. This performance was driven by the active commercialization in more than 50 countries on the back of a strong network of local distribution partners, and supported by numerous collaborations with pharma partners.

→ CHINA COMMERCIALIZATION

In 2019, Biocartis completed the closing of the joint venture ('China JV') with Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, which resulted in the first capital contribution by both partners and subsequently the payment by the China JV of a license fee to Biocartis. The China JV is aimed at the commercialization of the Idylla™ platform in China with a first focus on the establishment of local manufacturing capabilities and product registrations.

→ JAPAN COMMERCIALIZATION

On 7 January 2019, Biocartis announced to have signed an agreement with Nichirei Biosciences[8] ('Nichirei Bio') 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 Bio 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.

2.2.2 / MENU AND PARTNERSHIP HIGHLIGHTS

COLORECTAL CANCER MENU

CE-MARKING IDYLLA™ MSI TEST
On 28 February 2019, Biocartis announced the CE-marking of its fully automated Idylla™ MSI Test. MSI testing is currently recommended for all colorectal and endometrial cancers[9] but is still underused, mainly because of the high complexity of current methods. The Idylla™ MSI Test has been developed to overcome this drawbacks and its unique features could enable a broader penetration of MSI testing.

US FDA SUBMISSION IDYLLA™ MSI ASSAY
During 2019, further progress was made in the preparation of the 510(k) notification to the US FDA of the Idylla™ MSI Assay for colorectal cancer, of which the submission is expected end of 2020, subject to further feedback from US FDA interactions.

US FDA SUBMISSION IDYLLA™ RAS TESTS
During 2019, further progress was made in the preparation of the premarket approval (PMA) application for the Idylla™ RAS tests, of which the submission is expected in Q1 2021, subject to further feedback from US FDA interactions.

LUNG CANCER MENU

LAUNCH IDYLLA™ ctEGFR MUTATION ASSAY
On 25 October 2019, the Idylla™ ctEGFR Mutation Assay (RUO), the liquid biopsy version of the Idylla™ EGFR Mutation Test (CE-IVD), was launched. The Idylla™ ctEGFR Mutation Assay allows for the detection of 49 EGFR mutations[10] directly from 2 ml of blood plasma and provides results within approximately 160 minutes.

IDYLLA™ GENEFUSION PANEL (RUO)
During 2019, further progress was made in the development of the Idylla™ GeneFusion Panel. This assay is expected to be launched as RUO end 2020. Together with the Idylla™ EGFR Mutation Test (CE-IVD), the GeneFusion Panel will cover the majority of lung cancer biomarkers recommended by all major international guidelines. As such, a complete set of lung cancer biomarkers could be rapidly tested on Idylla™ following the launch of the Idylla™ GeneFusion Panel.

IMMUNO-ONCOLOGY MENU

MSI PARTNERSHIP BMS

On 12 March 2019, Biocartis announced the signing of a collaboration agreement with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company, focused on MSI testing in connection with immuno-oncology therapies. Bristol-Myers Squibb's Opdivo® (nivolumab) plus low-dose Yervoy®[11] (ipilimumab) is the first immuno-oncology combination treatment approved by the US FDA for MSI-High or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with certain chemotherapies[12]. The collaboration agreement allows for joint developments and registrations of the Idylla™ MSI test for use in a variety of indications, commercial settings and geographies. The first focus under the agreement is expected to be the registration in the US of the Idylla™ MSI assay as a CDx device in mCRC.

CELL THERAPY MONITORING PARTNERSHIP KITE/ GILEAD

On 1 June 2019, Biocartis announced a master development and commercialization agreement with Kite Pharma, Inc., a Gilead Company (NASDAQ: GILD), a pharmaceutical company engaged in the development of innovative cancer cell therapies. The collaboration aims at the development of molecular-based assays on the Idylla™ platform that are supportive to Kite's therapies. The speed and ease-of-use of the Idylla™ platform could enable regular and rapid monitoring of patients under such cancer cell therapies in a near patient setting, which is expected to help optimize patient management.

BREAST CANCER MENU

IDYLLA™ ONCOTYPE DX BREAST RECURRENCE SCORE® TEST (EXACT SCIENCES[13])

During 2019, Exact Sciences Corporate (NASDAQ: EXAS) progressed the development of an Idylla™ IVD version of the Oncotype DX IVD Breast Recurrence Score® test. Idylla™ instruments were placed in Q4 2019 at early access sites in Europe, beginning with France and Germany, as a preparation for the start of the validation studies which is expected to start in 2020. Furthermore, on 20 June 2019, Genomic Health announced that the German Federal Joint Committee (G-BA) issued a positive reimbursement decision for the Oncotype DX Breast Recurrence Score® test.

IDYLLA™ ABC PANEL (RUO)

Because of the emerging pipeline of drugs that target molecular biomarkers in advanced breast cancer ('ABC'), Biocartis and LifeArc[14] decided to strengthen the positioning of this assay. Going forward, it will be referred to as the Idylla™ Advanced Breast Cancer Panel and is positioned to target a multi-gene panel of predictive and resistance-inducing mutations based on an FFPE[15] sample type.

PAN-TUMOR TESTING POTENTIAL

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 of research into new applications include:

- KRAS mutations detected in FFPE lung samples[16]
- KRAS mutations detected in pancreatic cyst fluid samples[17]
- NRAS and BRAF mutations detected in FFPE melanoma samples[18]
- NRAS and BRAF mutations detected in thyroid Fine Needle-Aspirates (FNA) samples[19]

Additionally, various efforts are ongoing to demonstrate the feasibility of the Idylla™ MSI Test in multiple cancer types. Worldwide, more than 30 Idylla™ MSI studies[20] were initiated in 2019. Many of these 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[21].

IDYLLA™ PERFORMANCE DATA

In 2019, the performance of Idylla™ was the subject of over 26 publications[22] and multiple study abstracts, of which several were selected for publication at large scientific conferences such as ESMO[23] (European Society for Medical Oncology), ASCO[24] (American Society of Clinical Oncology) and AMP[25] (Association of Molecular Pathology).

- EUROPE

  19 new Idylla ™ performance publications in Europe, of which five Idylla™ study abstracts were selected for publication at the renowned ESMO congress and multiple study abstracts were selected for national conferences. All Idylla™ studies published at ESMO demonstrated excellent performance of Idylla™ compared to other methods, in combination with the ease of use and fast turnaround time of the Idylla™ platform. The studies included, amongst others, the Idylla™ MSI Assay (RUO) and a prototype of the Idylla™ ctEGFR Mutation Assay (RUO).

- UNITED STATES

  Five new Idylla™ publications in the US and six study abstracts were selected for publication at the USCAP congress, one study abstract was selected for the ASCO congress and five study abstracts were selected for the AMP congress. All studies published at AMP showed a strong performance of Idylla™ assays (RUO) compared to other methods including IHC[26] and NGS[27] in terms of concordance[28], ease of use, workflow automation and turnaround times. Some studies researched Idylla™'s capability to analyze different sample types[29] and smaller sample quantities.

2.2.3 / ORGANIZATIONAL AND OPERATIONAL HIGHLIGHTS

MANAGEMENT TEAM

In light of the Company's further international growth, expansion of its partner network and associated scaling of the organization, several changes to the Company's management team were effectuated in 2019:

- **Appointment Chief Operating Officer** – Piet Houwen joined Biocartis as its Chief Operating Officer in April 2019.
- **Appointment Global Head Pharma Collaborations and Partnering** – Dirk Zimmermann joined Biocartis in May 2019 as Global Head of Pharma Collaborations and Partnering.
- **Changes in the Chief Commercial Officer role** – Biocartis and Hilde Eylenbosch, the Company's Chief Commercial Officer, agreed to terminate their collaboration as per the end of April 2019. The tasks of the CCO have been reallocated to the Company's CEO and senior commercial management.

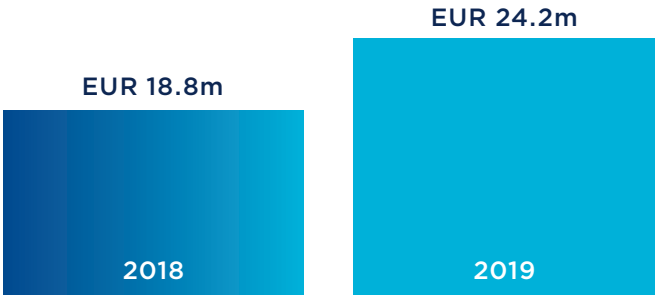
CARTRIDGE MANUFACTURING

In 2019, progress was made in the production transfer to the new cartridge manufacturing line and commercial manufacturing of the Idylla™ KRAS Mutation Test was started on this line. Additional assays are to be transferred to the new cartridge manufacturing line over the course of 2020, driving costs optimizations within the Company's cartridge manufacturing activities.

2.2.4 / FINANCIAL HIGHLIGHTS

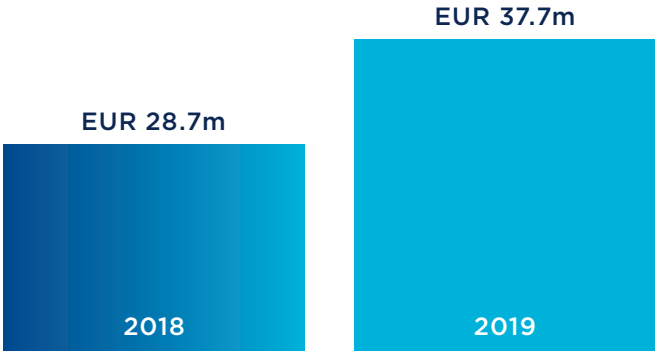
PRODUCT SALES REVENUES

Total product sales increased year-over-year with 29% to EUR 24.2m in 2019 (EUR 18.8m in 2018), as a consequence of higher Idylla™ cartridge sales (year-over-year growth of 23%) as well as Idylla™ platform sales (year-over-year growth of 49%).



TOTAL OPERATING INCOME

Total operating income amounted to EUR 37.7m in 2019, representing a year-over-year growth of 32% as a result of higher Idylla™ product sales, collaboration revenues (49% year-over year growth) and service revenues, partially offset by lower grant income.



CASH POSITION

Biocartis' cash position as per 31 December 2019 amounted to EUR 178.7m compared to EUR 63.5m as per 31 December 2018.

178.7m

OPEX

Total operating expenses (including cost of sales) amounted to EUR 93.3m, a year-over-year increase of 24% due to higher cost of sales and operational expenses.

EQUITY RAISE

On 28 January 2019, Biocartis raised an amount of EUR 55.5m in gross proceeds by means of a private placement via an accelerated bookbuild offering.

OPERATIONAL CASH FLOW

Total cash flow used in operating activities amounted to minus EUR 54.3m in 2019 versus minus EUR 42.0m in 2018

CONVERTIBLE BONDS ISSUE

On 2 May 2019, Biocartis issued EUR 150m senior unsecured convertible bonds due 9 May 2024. The convertible bonds were admitted to trading and listing on the regulated market of Euronext Brussels on 15 November 2019.

Additional details – see 'key figures for 2019' below for more details on the 2019 financials.

2.2.5 / FINANCIAL REVIEW 2019

The tables below show an overview of the key figures and a breakdown of operating income for 2019. A consolidated income statement, balance sheet, cash flow statement and statement of changes in equity of Biocartis Group NV is presented in chapter 5, 'Consolidated annual accounts'.

KEY FIGURES (EUR 1,000)	2019	2018	% CHANGE
Total operating income	**37,732**	**28,651**	**32%**
Cost of sales	-21,328	-15,349	39%
Research and development expenses	-39,844	-36,842	8%
Sales and marketing expenses	-18,011	-15,349	17%
General and administrative expenses	-14,151	-7,971	78%
Operating expenses	**-93,334**	**-75,511**	**24%**
Operational result	**-55,602**	**-46,860**	**19%**
Net financial result	-7,934	-1,402	466%
Share in the result of associated companies	-631	0	na
Income tax	99	109	-9%
Net result	**-64,068**	**-48,153**	**33%**
Cash flow from operating activities	-54,254	-41,993	29%
Cash flow from investing activities	-5,496	-5,820	-6%
Cash flow from financing activities	175,023	-1,508	-11714%
Net cash flow	**115,273**	**-49,320**	**-334%**
Cash and cash equivalents[1]	**178,725**	**63,539**	**181%**
Financial debt	166,578	35,335	371%

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

OPERATING INCOME (EUR 1,000)	2019	2018	% CHANGE
Collaboration revenue	**12,451**	**8,329**	**49%**
Idylla™ System sales	6,220	4,185	49%
Idylla™ Cartridge sales	18,004	14,658	23%
Product sales revenue	**24,224**	**18,843**	**29%**
Service revenue	769	639	20%
Total revenue	**37,444**	**27,811**	**35%**
Grants and other income	288	840	-66%
Total operating income	**37,732**	**28,651**	**32%**

PRODUCT SALES REVENUE BY TYPE (EUR 1,000)	2019	2018	% CHANGE
Commercial revenue	22,862	17,843	28%
Research & Development revenue	1,362	1,000	36%
Total product sales revenue	**24,224**	**18,843**	**29%**

INCOME STATEMENT

OPERATING INCOME

Collaboration revenue increased year-over-year with 49% to EUR 12.5m in 2019 driven by proceeds from R&D services that increased with 108% to EUR 9.0m and increased milestone revenues (EUR 0.9m, 9% year-over-year increase) which was partially offset by lower license fees (EUR 2.5m, 20% year-over-year decrease).

Total product sales amounted to EUR 24.2m in 2019 (EUR 18.8m in 2018), representing a year-over-year growth of 29%, and included Idylla™ cartridge sales of EUR 18.0m (EUR 14.7m in 2018) and Idylla™ system revenues of EUR 6.2m (EUR 4.2m in 2018).

Service revenue amounted to EUR 0.8m in 2019 versus EUR 0.6m in 2018. Recognized grants and other income amounted to EUR 0.3m in 2019 (EUR 0.8m in 2018) and consisted of R&D project support grants and training subsidies related to the establishment of a second cartridge manufacturing line. Driven by the aforementioned Biocartis' total operating income in 2019 amounted to EUR 37.7m versus 28.7m in 2018, representing an increase of 32%.

OPERATING EXPENSES

Total operating expenses in 2019 amounted to EUR 93.3m versus EUR 75.7m in 2018, an increase of 24%. This included cost of sales of EUR 21.3m in 2019 compared to EUR 15.3m in 2018 as the consequence of an overall increase in product volumes as well as higher operational costs for cartridge manufacturing due to expanded night and weekend shifts in order to meet volume demand. Operating expenses excluding cost of sales amounted to EUR 72.0m in 2019 versus EUR 60.2m in 2018 (year-over-year increase of 20%) as the result of an overall increase in research and development ('R&D'), sales and marketing ('S&M') and general and administrative expenses ('G&A'). As of the first of January 2019, Biocartis has adopted the new IFRS 16 standard for lease accounting (the modified retrospective approach was applied, i.e. comparatives will not be restated) as described below in the balance sheet section. The year-over-year net impact of this adoption on operating expenses is estimated to be an increase of around EUR 3.0m, of which the majority are non-cash depreciation expenses.

R&D expenses amounted to EUR 39.8m in 2019 versus EUR 36.8m in 2018 which represents a year-over-year increase of approx. 8%. This was predominantly driven by increased depreciation and amortization charges, employee benefit expenses and laboratory & cartridge costs which was partially offset by decreased facilities, office and other costs as well as the EUR 3.2m one-off impairment charge on certain patents in 2018. Sales and marketing expenses amounted to EUR 18.0m in 2019 compared to EUR 15.3m in 2018, a year-over year increase of 17%. This increase is predominantly a consequence of increased additional operational expenses incurred in relation to the expansion of the Company's sales and marketing team and related consultancy and subcontracting expenses. G&A expenses increased year-over-year with 78% due to overall organizational growth as well as a general cost allocation that is shifting more towards a commercial stage organizational structure.

OPERATING RESULT

The above resulted in an operational result for the period of EUR -55.6m, compared to EUR -46.9m in 2018, a year-over-year change of approx. 19%.

NET FINANCIAL RESULT AND INCOME TAXES

Net financial expenses amounted to EUR 7.9m in 2019 compared to EUR 1.4m in 2018 and included financial expenses in relation to the Company's convertible bond (see details in section balance sheet) of EUR 5.2m (consisting of EUR 3.0m coupon payment and EUR 2.2m of debt appreciation), the Company's subordinated loan of EUR 1.1m as well as commitment fees for the multiple purpose credit.

As the Company had no taxable income in 2019, income tax expenses consists of recognized research and development tax credits in Belgium.

NET RESULT

As a result of the foregoing, the net result for the year 2019 amounted to EUR -64.1m compared to EUR -48.2m in 2018.

BALANCE SHEET

ADOPTION NEW IFRS 16 STANDARD

As required, Biocartis has adopted the new IFRS 16 standard for lease accounting with date of initial application on 1 January 2019. This standard introduces a single lessee accounting model and requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, eliminating the distinction between operating and finance leases. The first time adoption of IFRS 16 has an impact on the Group's balance sheet as well as results in a reclassification of operational expenses in the Group's income statement. Concretely, as of 1 January 2019, Biocartis also recognizes its operational leasing contracts (i.e. for buildings, company cars and office furniture) on its balance sheet in addition to the Group's financial leasing contracts (i.e. for manufacturing equipment). This resulted in a one-off increase in property, plant and equipment of EUR 14.3m and lease liabilities of EUR 15.8m on 1 January 2019. Furthermore, as property, plant and equipment is depreciated over time, the income statement recognizes deprecation charges and financing expenses for all the recognized leases versus previously the recognition of lease payments as e.g. building rent or facility & office expenses.

NON-CURRENT ASSETS

Intangible assets predominantly consist of patents and licenses on third-party intellectual property and amounted to EUR 6.3m as per the end of 2019 versus EUR 6.6m end of 2018 as the consequence of EUR 0.4m of additions and EUR 0.7m of amortization expenses.

During 2019, property plant & equipment increased with EUR 13.0m to EUR 4.3m. This increase was driven by a EUR 14.1m net impact of IFRS 16, EUR 5.0m of actual capital expenditures (mainly related to capitalization of instrumentation placed at clients under leasing or rental contracts and investments in cartridge manufacturing equipment) and a depreciation charge of around EUR 6.1m.

Financial assets amounted to EUR 0.0m as per the end of 2019 versus EUR 5.0m end of 2018. This decrease was driven by a full impairment of the Company's participation in MyCartis NV as the consequence of changed activities of MyCartis NV and realized valuation levels of related recent capital increases.

Investments in associates and joint ventures was added to the balance sheet in 2019 in relation to the formal closing of the China joint venture and amounted to EUR 2.4m as per end of 2019.

Deferred tax assets per 31 December 2019 amounted to EUR 1.6m versus EUR 6.6m end of 2018 and relate to tax credits for research and development in Belgium. This decrease is driven by the re-allocation of the short-term portion of these tax credits (EUR 5.2m) to the line item other receivables under current assets on the Company's balance sheet.

CURRENT ASSETS

Inventory amounted to EUR 14.1m as per end 2019 compared to 11.9m as per end 2018. This year-over-year increase was driven by higher inventory levels of finished products and raw materials, partially offset by lower inventory levels for semi-finished products. Trade receivables increased to EUR 10.7m as per year-end 2019 (EUR 9.7m end of 2018) as a consequence of higher overall commercial volumes and the change in go-to-market strategy for the US market. Other receivables increased from EUR 3.8m in 2018 to EUR 8.6m in 2019 as the consequence of the allocated short-term portion of tax credits, partially offset with lower VAT receivables.

The Company's cash and cash equivalents end of 2019 amounted to EUR 178.7m compared to EUR 63.5m end of 2018.

EQUITY POSITION

Biocartis' total equity end of 2019 amounted to EUR 84.5m compared to EUR 87.4m end of 2018. This decrease was driven by the negative operating result for 2019 that was to a large extent offset by proceeds from the Company's equity increase in January 2019, the equity component of the Company's convertible bond (see description of financial debt) as well as a correction for non-cash share-based payment expenses.

FINANCIAL DEBT

Total financial debt end of 2019 amounted to EUR 166.6m, representing an increase of EUR 131.2m compared to end of 2018. This was the result of the issuance of the Company's convertible bond, an increase in lease liabilities due to amongst others the first time adoption of IFRS 16 and the early repayment of the Company's subordinated loan. The IFRS accounting treatment of the Company's convertible bond has resulted in an allocation of the EUR 150m nominal amount to financial debt of EUR 133.5m and equity of EUR 12m (as adjusted for related transaction costs) as per the end of 2019.

The repaid subordinated loan had a nominal amount of EUR 15m, carried a 7% interest rate, had an initial duration of 5 years and was due September 2021. The cash out related to the early repayment of this loan amounted to EUR 17.5m based on the nominal amount of the loan and capitalized interest.

DEFERRED INCOME

Deferred income decreased in 2019 to EUR 2.0m (EUR 3.0m end of 2018) as a consequence of net revenue recognition from pending and new collaboration agreements.

CURRENT LIABILITIES

Trade payables end of 2019 amounted to EUR 9.1m, representing an increase of EUR 1.1m compared to the EUR 8.0m that was outstanding end of 2018. Other current liabilities increased in 2019 with EUR 1.9m to EUR 6.1m and consisted predominantly of provisions for vacation pay and for variable compensation schemes.

CASH FLOW STATEMENT

CASH FLOW USED IN OPERATING ACTIVITIES

The cash flow from operating activities in 2019 amounted to EUR -54.3m compared to EUR -42.0m in 2018, a change of EUR 12.3m. This increase is the result of a higher operating loss and higher investments in working capital for the period that was partially offset by increased non-cash adjustments (mainly driven by a higher depreciation charge and higher non-cash elements in the net financial result).

CASH FLOW USED IN INVESTING ACTIVITIES

The cash flow from investing activities in 2019 amounted to EUR -5.5m (compared to EUR -5.8m in 2018) and consisted of the initial capital contribution made to the China joint venture and capitalized Idylla™ systems as well as investments in laboratory and manufacturing equipment.

CASH FLOW USED IN FINANCING ACTIVITIES

The cash flow from financing activities in 2019 amounted to EUR 175.0m (compared to EUR -1.5m in 2018) which was driven by the issuance of the convertible bonds (net proceeds of EUR 145.5m) and by the capital raise (net proceeds of EUR 53.4m), partially offset by the repayments of borrowings (predominantly the Company's subordinated loan) of EUR 23.7m.

NET CASH FLOW

Driven by the aforementioned, the total net cash flow in 2019 amounted to EUR 115.3m compared to EUR -49.3m in 2018.

2.2.6 / IMPORTANT EVENTS AFTER THE REPORTING DATE

Please see chapter 5 under 'Events after the balance sheet date'.

CHAPTER 3

BUSINESS ACTIVITIES

3.1 / ONCOLOGY MOLECULAR DIAGNOSTICS AND ITS MARKET

The study of diseases has led to the discovery of macromolecules, called biomarkers, associated with specific diseases or treatment response. These biomarkers can be detected in patient samples such as blood, urine, sputum, saliva or tissue such as tumor tissue. Molecular diagnostics (MDx) is the primary tool used to identify such biomarkers. Knowing which biomarker drives a tumor enables the use of a new generation of more effective treatments, called personalized medicine, which are tailored to the genetic profile of a patient. These treatments have better health outcomes, leading to reduced healthcare costs.

This means that rapid access to accurate data about relevant cancer mutations and treatment resistance is vital. It creates the opportunity for early disease interception[30] reducing the anxiety while waiting for results and the time before starting the best possible treatment. Current technologies in molecular oncology are complex, require a lot of hands-on time and are often 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[31]. This causes delay to the fast delivery of results, preventing rapid initiation of correct therapy. In the meantime the tumor grows, which is detrimental in case of aggressively growing cancers.

Fast initiation of immunotherapy or targeted therapy as first-line treatment is crucial for cancer patients, as it increases overall survival rates[32]. 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. Ninety-five percent of the patients have to wait more than a week in order to receive the biomarker results[33]. 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. For more information, we refer to 'strategy' below.

THE GLOBAL ONCOLOGY **MDx** MARKET

...IS EXPECTED TO REACH AN APPROXIMATE ANNUAL GROWTH RATE (CAGR) OF 15% BETWEEN 2019-2025, ACCORDING TO A REPORT BY MARKET INSIGHTS REPORTS[34]. A GROWING CANCER INCIDENCE, RISING SHIFT TOWARDS PRECISION MEDICINE AND FAVORABLE HEALTH REIMBURSEMENT POLICIES ARE LIKELY TO FOSTER THE GROWTH OF THE GLOBAL ONCOLOGY MOLECULAR DIAGNOSTICS MARKET. GEOGRAPHICALLY, NORTH AMERICA IS EXPECTED TO DOMINATE THE GLOBAL ONCOLOGY MOLECULAR DIAGNOSTICS MARKET BETWEEN 2019-2026 DUE TO, AMONGST OTHERS, THE RAPID ADOPTION OF ADVANCED DIAGNOSTICS TECHNIQUES AND FAVORABLE HEALTH REIMBURSEMENT POLICIES. IN ASIA PACIFIC, THE ONCOLOGY MOLECULAR DIAGNOSTICS MARKET IS PREDICTED TO GROW AT A SIGNIFICANT RATE DUE TO THE GROWING GERIATRIC POPULATION, RISING RESEARCH ON PRECISION MEDICINES AND HIGH UNMET CANCER NEEDS[35]. IN TERMS OF TECHNOLOGIES, POLYMERASE CHAIN REACTION OR PCR, THE TECHNOLOGY ON WHICH IDYLLA™ TESTS ARE BASED, REMAINS THE BASE OF MOST MOLECULAR TECHNIQUES CURRENTLY AVAILABLE[36].

3.2 / MISSION

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

3.3 / HISTORY

2018

Partnership agreement signed with Immunexpress for the development and commercialization of Immunexpress' RAPID SeptiCypte™ test on Idylla™. Partnership agreement signed with AstraZeneca. Partnership agreement with Exact Sciences (formerly Genomic Health Inc.) expanded to the domain of urology with the development of the Idylla™ Oncotype DX Genomic Prostate Score® test. Establishment of the US R&D center. Establishment of a joint venture with Wondfo[37], a fast growing diagnostics leader in China

2017

Biocartis Inc., established in the US. Content partnership agreements signed with MRC Technology (a medical research charity), ETPL (the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research) and Genomic Health (now part of Exact Sciences) for the development of the Idylla™ Oncotype DX Breast Recurrence Score® test. Biocartis signs its first CDx agreement for Amgen's drug Vectibix® (panitumumab)

2016

First pharma partnership agreements signed with Merck KGaA (Darmstadt, Germany) and Amgen

2015

Biocartis listed on Euronext Brussels through an IPO in April 2015

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

2013

Biocartis' MDx platform is named Idylla™

2012

Awarded '2012 Technology Pioneer Award' by the World Economic Forum

2011

R&D activities move to Mechelen (Belgium)

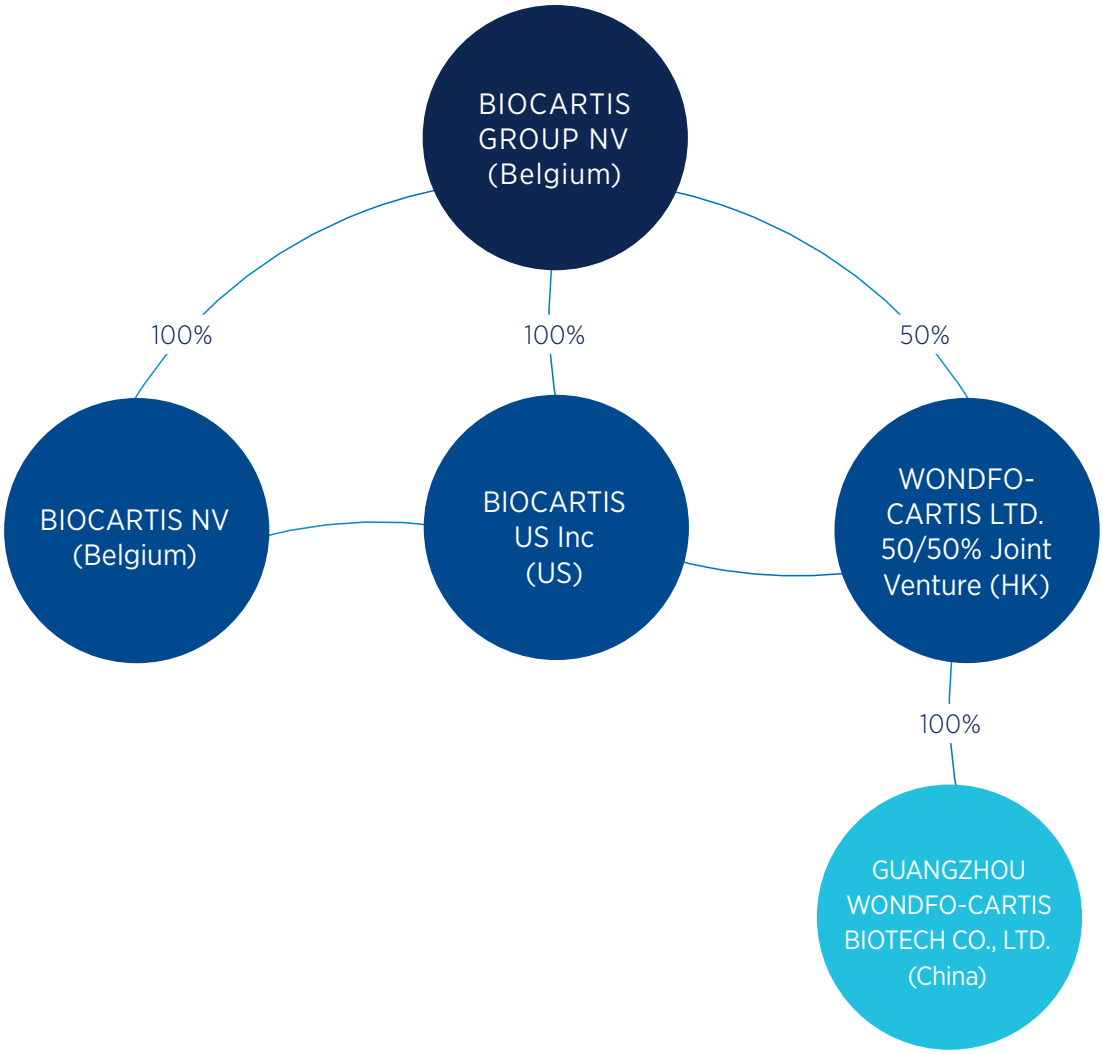
2010

Acquisition of the 'Apollo' platform (now Idylla™) from Koninklijke Philips NV

2007

Biocartis was founded in Switzerland

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 2019 IS AS FOLLOWS:



The headquarters of Biocartis Group NV are located in Mechelen, Belgium, incorporated on 24 November 2014, 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 R&D Center in Raritan (New Jersey, US) and a US commercial office in Jersey City (New Jersey, US). Furthermore, Biocartis' joint venture, Wondfo-Cartis Ltd., was established in 2018 in China as a joint venture owned 50% by Biocartis Group and 50% by Wondfo Biotech (HK) Co., Ltd.

3.4 / STRATEGY

Biocartis is focused on executing a profitable growth strategy that builds value in the oncology MDx market by making personalized medicine an everyday reality.

The oncology MDx market is growing rapidly due to a rise in global incidence of cancer, an increased need for molecular testing as more and more targeted applications become available and due to an increased decentralization of testing. Biocartis' Idylla™ platform is uniquely positioned in this market as it:

- Has the ability to combine advantages of point-of-care testing with the performance of lab reference testing. This enables molecular testing in virtually any lab setting;
- Allows for a reduction of time-to-results from weeks to hours; and
- Offers sample-to-result (i.e. full automation) capabilities for both solid and liquid biopsies.

Biocartis' menu strategy for the Idylla™ platform is driven by several market trends in the oncology MDx market. These trends include the increasing number of targeted cancer therapies, the potential of pan-cancer therapies, the rise of gene signatures that target applications beyond therapy selection, the emergence of immuno-oncology as new cancer treatment paradigm, and the growing adoption of liquid biopsy testing which allows for accessing tumor information via liquid samples.

Cumulatively, these trends provide a highly favorable environment for the Idylla™ platform and a menu strategy focused on four strategic growth pillars where Idylla™'s unique selling points have the best potential to make a difference:

→ TARGETED THERAPIES

In the short-term, Biocartis will continue to build a strong menu of guideline-driven therapy selection tests. Colorectal and lung cancer are of particular importance as Biocartis aims to provide a comprehensive actionable panel of first-line tests for both segments. Future development areas for therapy selection include test development for additional cancer types as well as leveraging select current as well as pipeline tests – both initially intended for cancer-specific use – toward pan-tumor applications.

→ IMMUNO-ONCOLOGY

Recently established as the newest pillar of cancer treatment, immunotherapy represents an attractive commercial opportunity for Biocartis. 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

As the evidence for clinical utility of liquid biopsy testing is growing, Biocartis will focus on key applications where Idylla™'s speed is required and thus represents a critical competitive advantage. These include on-therapy monitoring and post-treatment MRD assessment for solid tumors, as well as select long-term recurrence monitoring applications in hematological cancers where guidelines already exist.

→ PROPRIETARY GENE SIGNATURES

To complement its internal Idylla™ menu development, Biocartis is envisioning additional partnerships with commercial entities who own validated, proprietary, high-value oncology gene signatures in order to port these onto the Idylla™ platform for higher market penetration. This will result in additional cancer franchises for Idylla™ and the expansion of the platform into new customer segments within the oncology MDx market.

Biocartis aims to accelerate its menu expansion through partnerships:

→ PARTNERSHIPS WITH PHARMACEUTICAL AND BIOTECH COMPANIES

The focus here is on the (joint) development 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

The focus here is on the 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:

The focus here is on the development of Biocartis Idylla™ tests, predominantly in collaboration with IVD developers. This will allow 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 pipeline can be found in Biocartis' corporate presentation available on www.investors.biocartis.com.

3.5 / SUSTAINABILITY

In defining its initial sustainability approach and disclosures, Biocartis has amongst others taken into account some of the most wide-spread sustainability frameworks, namely the Sustainable Development Goals[38] (SDG) and the Global Reporting Initiative (GRI) guidelines[39]. The SDG framework includes 17 goals which were developed by the United Nations Development Programme in January 2016 and are considered to be the guiding universal sustainability framework. The GRI guidelines represent the global reference for sustainability reporting[40]. 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. Both frameworks cover the broader topics around the well-known 'people, planet, profit' pillars. In this section, we provide 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.

SUSTAINABILITY IN OUR DNA

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

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

HERMAN VERRELST
CEO BIOCARTIS

HOW WE CREATE VALUE FOR SOCIETY

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

HOW WE SUPPORTED THE SUSTAINABLE DEVELOPMENT GOALS IN 2019

In 2019, 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 facing our world.

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

ENABLING PERSONALIZED MEDICINE FOR CANCER PATIENTS WORLDWIDE THROUGH RAPID, EASY & HIGHLY ACCURATE MDx TESTING

In 2019:

- Installed base of 1,310 Idylla™ instruments
- 175k cartridge volume
- Broad menu of Idylla™ tests supporting patients worldwide, with two new test launches: the Idylla™ MSI Test and the Idylla™ ctEGFR Mutation Assay (RUO)
- Strengthening the worldwide global footprint with the establishment of a joint venture in China and with the launch of the Idylla™ platform by Nichirei Biosciences in Japan

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

A SAFE & HEALTHY WORKPLACE

In 2019:

- Providing a safe & healthy workplace for all employees
- No lethal accidents or accidents causing disability in the workplace
- Close to 16,000 training hours

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

A BALANCED GENDER DIVERSITY

In 2019:

- 465 employees[1] across 30 nationalities
- 50%-50% balanced gender diversity

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

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

DELIVERING GROWTH

In 2019:

- +18% employees[1]
- +29% product revenues
- +32% Idylla™ cartridge volume
- + 337 Idylla™ instruments added to the installed base

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

REDUCING OUR ENVIRONMENTAL IMPACT

In 2019:

- Awareness raising campaign on the impact of the use of biocides
- Implementation of 'waste islands' for better recycling & waste management

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

BUILDING A GLOBAL IDYLLA™ ECOSYSTEM WITH PARTNERS

In 2019:

- +49% collaboration revenues
- First two partnerships in immuno-oncology with Kite/Gilead and BMS
- 26 abstracts, posters and publications on Idylla™ data demonstrating high performance
- Annual fundraising actions by employees supporting 7 different non-profit organizations in the area of cancer and health

Further information on our sustainability activities can be found below under '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 chapter 4 'Corporate Governance' for more information.

- **We integrate long term value creation in our remuneration policy.** We refer to the remuneration report under chapter 4, 'Corporate Governance' for more information.

- **We see diversity as a key talent management driver of our business.** For more information we refer to chapter 3 'Business activities' under 'Stakeholders', section 'Employees' and chapter 4 'Corporate Governance'.

- **We aim to use materials that do no harm our environment and contribute to a sustainable supply chain.** We refer to chapter 3, 'Business activities' under section 'Oncology MDx and its market', section 'Environment' as well as under 'Stakeholders', section 'Suppliers'.

- **We want to create a healthy and safe working environment for our employees.** We refer to chapter 3 'Business activities' under 'Stakeholders', section 'Employees' for more information.

- **We strive to have a positive societal impact on a local level.** We refer to chapter 3 'Business activities' under 'Stakeholders', section 'Employees' for more information.

3.6 / 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.

3.6.1 / PRODUCTS

EU: CE-MARK

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

BIOCARTIS? Today, all Biocartis Idylla™ IVD products carry a CE-mark. An overview is available under the chapter 3.11 'Products'. Biocartis is preparing for the application of the Regulation on IVD medical devices by assessing all current IVD products against the new requirements, and ensuring that new IVD products under development are meeting the new standards.

US: FDA MARKETING AUTHORIZATION

WHAT? The US requires more 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[41].

BIOCARTIS? 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 more stringent Pre-Market Approvals (PMA). The Idylla™ instrumentation is exempt from 510(k) premarket notification requirements[42].

CHINA

In China, the National Medical Products Administration (NMPA) is the administrative body responsible for the regulation of medical devices on the Chinese mainland. China's medical device classification system shares some similarities with US standards, such as the categorization into Class I, Class II and Class III devices.

JAPAN

All medical devices in Japan require registration with the Ministry of Health, Labor and Welfare. There are four major classes of medical devices: General medical devices (Class I), Controlled medical devices (Class II) and Specially controlled medical devices (Class III and Class IV). Biocartis' partner in Japan, Nichirei Biosciences, completed the registration of the Idylla™ Instrument and Idylla™ Console with the Pharmaceuticals and Medical Devices Agency (PMDA) as a General medical devices (Class I) in Japan in October 2019.

REST OF WORLD (ROW) MARKETS

In many RoW 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

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 3.11 'Products'. In many of the markets that Biocartis operates in, such RUO products may be offered for sale if for example IVD products are not yet approved for sale or distribution.

3.6.2 / DATA PRIVACY

As a company increasingly managing large amounts of data both internal as generated by the users of its products, Biocartis is fully committed to protecting and safeguarding personal data. Biocartis takes privacy seriously and continuously works on improving its privacy and security framework. In 2019, further action was taken relating to the EU General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA). These actions included:

- Providing in-depth privacy training to all Biocartis employees by the Biocartis Data Privacy Officer, tailored to their access to and use of personal data
- Informing our customers on topics such as security, privacy and data protection efforts
- Including the Data Protection by Design and Default principles in Biocartis' products and services
- Initiating preparatory work for an ISO 27001 compliance project to continuously improve the security of the personal data entrusted to Biocartis

3.6.3 / 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. Since 2018, Biocartis has taken the necessary actions to ensure Sunshine transparency reporting in the US on certain payments or other transfers of value provided to US physicians or teaching hospitals and other research entities.

3.7 / 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[43]. 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 easily navigate this diverse reimbursement landscape, as the use of our highly flexible Idylla™ platform can be adopted 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[44]. 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[45]. As such, the adoption level of tests can differ per cancer type and per province.

JAPAN

All medical devices in Japan require registration with the Ministry of Health, Labor and Welfare. There are four major classes of medical devices: General medical devices (Class I), Controlled medical devices (Class II) and Specially controlled medical devices (Class III and Class IV). Biocartis' partner in Japan, Nichirei Biosciences, completed the registration of the Idylla™ Instrument and Idylla™ Console with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan as a General medical devices (Class I) in October 2019.

ROW

Reimbursement in RoW 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.

3.8 / QUALITY

Quality plays a crucial role in Biocartis' ambition to enhance the healthcare outcome for oncology 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 14971:2012 (Medical devices—Application of risk management to medical devices)
- EN IEC 62304:2006 (Medical device software—Software life cycle processes)
- EN IEC 62366:2008 (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 2019 were:

- The recertification of the Biocartis QMS against the ISO 13485:2016 standard and the successful expansion of the scope of the MDSAP certificate to include the Japanese regulations, covering the design and development activities, manufacturing and testing activities and customer related processes in Mechelen (Belgium). Compliance of the Biocartis' QMS with the Japanese requirements is critical in achieving clearance to sell the Idylla™ platform and its oncology assays in Japan.

- The revision of the Biocartis Quality Policy, which accurately describes the foundations on which the Biocartis activities and services are built and maintained, now including and highlighting the key company values (customer centricity, continuous improvement, cross-functional teamwork, accountability, result-driven, quality mindset and leadership). The new Quality Policy furthermore underlines the commitment from Biocartis' management to comply with regulatory requirements, to maintain the effectiveness of the quality management system and to ensure customer satisfaction. It acts as a driver for continuous improvement of the Biocartis products and services and serves as the basis to define the company's Quality Objectives.

3.9 / ENVIRONMENT

Biocartis works on carefully managing 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[46] directive regarding the Restriction of Hazardous Substances in electrical and electronic equipment
- The WEEE directive[47] 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[48]

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 internal environmental audits are performed to identify improvement areas

In 2019, Biocartis performed a review of all applicable new environmental legislation (Europe/Belgium/Flanders) to ensure full compliance. This review included legislation relating to:

- Biocides (listing, evaluation & registration check of products used by Biocartis and that are covered by biocide regulations, as well as awareness raising throughout the organization on the impact of biocide use, for example through a training to laboratory personnel)
- Update of the Biocartis waste manual with the Flemish '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 2019 included:

- Installing an energy efficient cooling equipment for the first manufacturing line 'ML1'
- Implementing a maintenance & inspection program, including for heating and cooling systems, and screening and integration of specific environmental obligations in maintenance contracts
- Working on general office improvement areas, such as installing waste islands for better recycling of plastics, paper and other waste, and providing sustainable drinking bottles for all employees
- Other initiatives included actions on sustainable mobility, such as providing a shuttle service between Mechelen train station and the Biocartis offices and the building of a new bicycle shed

3.10 / 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 is overseen by Biocartis' IP department. The current patent portfolio was built through acquisitions of third-party patents, patent applications and knowledge, as well as through internal creation and relates to various aspects of the Idylla™ platform. Furthermore, Biocartis also has exclusively licensed specific third-party technologies. Currently, Biocartis' patent portfolio consists of 28 proprietary families comprising issued and pending patents worldwide. Additionally, Biocartis relies on a combination of trade secrets, design rights, trademarks, copyright laws, non-disclosure agreements, non-exclusive licenses and other contractual provisions and technical measures that help Biocartis maintain and develop its competitive IP position.

3.11 / PRODUCTS

3.11.1 / THE IDYLLA™ PLATFORM

"We offer rapid & easy molecular diagnostic solutions aimed at enabling faster & more accurate treatment decisions for oncology 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:

SCAN SAMPLE

STEP 1: THE PATIENT SAMPLE INFORMATION IS ENTERED VIA THE CONSOLE BY SCANNING THE BARCODE ON THE SAMPLE CONTAINER, OR BY MANUAL ENTRY OF THE PATIENT SAMPLE IDENTIFICATION CODE.

SCAN CARTRIDGE

STEP 2: THE PATIENT SAMPLE IS LINKED TO THE CARTRIDGE BY SCANNING THE BARCODE OF THE CARTRIDGE. THE CONSOLE AUTOMATICALLY RECOGNIZES WHICH TEST THE USER INTENDS TO PERFORM.

LOAD SAMPLE

STEP 3: THE PATIENT SAMPLE IS ADDED INTO THE CARTRIDGE. BY CLOSING THE LID, THE CARTRIDGE IS SEALED TO PREVENT CONTAMINATION OF THE INSTRUMENT OR LABORATORY.

INSERT CARTRIDGE

STEP 4: THE CARTRIDGE IS INSERTED INTO ONE OF THE AVAILABLE INSTRUMENTS, WHICH WILL SUBSEQUENTLY EXECUTE THE APPROPRIATE TEST PROTOCOL. AFTER COMPLETION OF THE TEST, RESULTS ARE DISPLAYED ON THE CONSOLE.

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.

3.11.2 / MENU OF IDYLLA™ ONCOLOGY MOLECULAR DIAGNOSTIC TESTS

As per end 2019, Biocartis offered 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[49]. About 46% of all metastatic colorectal tumors harbor KRAS gene mutations[50] and about 5% of all metastatic colorectal tumors harbor NRAS gene mutations[51]. According to ESMO[52], NCCN[53], ASCO[54] and CAP/AMP/ASCO[55] guidelines, genotyping of clinically actionable mutations[56] 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[57]. 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%[58].

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[59] and ESMO[60] . 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™ 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[61]. 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[62].

Guidelines recommend assessing the MSI status for all patients with colorectal (or endometrial[63]) carcinomas for screening for Lynch Syndrome as well as for prognostic stratification and immunotherapy[64]. 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[65].

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

- 120 minutes sample-to-result
- 18 NRAS mutations and 4 & 5 BRAF mutations, directly on FFPE tissue sections (5-10µm) from mCRC
- ~ 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™ ctNRAS-BRAF MUTATION TEST (CE IVD, DIAGNOSTIC USE)

- 110 minutes sample-to-result
- 18 NRAS mutations and 4 & 5 BRAF mutations , directly on 1 ml plasma
- ~ 1 minute hands-on time

"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)[66]. 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[67].

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 assecond-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[68]. 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%[69].

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)

- 110 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. This pan-cancer application of targeted therapies in turn pushes 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 of research into new applications include:

- → KRAS mutations detected in FFPE lung samples[70]
- → KRAS mutations detected in pancreatic cyst fluid samples[71]
- → NRAS and BRAF mutations detected in FFPE melanoma samples[72]
- → NRAS and BRAF mutations detected in thyroid Fine Needle-Aspirates (FNA) samples[73]

Additionally, various efforts are ongoing to demonstrate the feasibility of the Idylla™ MSI Test in multiple cancer types. Worldwide, more than 30 Idylla™ MSI studies[74] were initiated in 2019. Many of these 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[75].

3.12 / STAKEHOLDERS

3.12.1 / PARTNERS

Partnerships are a cornerstone in Biocartis' Idylla™ platform and test menu expansion strategy. End of 2019, 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 as the development partner 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[76], 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. Post the reporting period, on 22 January 2020, Biocartis announced to have broadened this partnership to additional countries within and outside Europe. At the same time Biocartis announced to have entered into a 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 will be 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.

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. Post the reporting period, 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.

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.

EXACT SCIENCES

On 13 September 2017, Biocartis and Exact Sciences (formerly Genomic Health Inc[77].) announced to have signed an exclusive agreement to develop an IVD version of the Oncotype DX Breast Recurrence Score® test on Idylla™, which examines the activity of 21 genes in a patient's breast tumor tissue to provide personalized information for tailoring treatment. As the only test proven to predict chemotherapy benefit, the Oncotype DX Breast Recurrence Score test® is included in all major cancer guidelines worldwide. On 3 December 2018, both partners announced to have expanded their exclusive collaboration into the field of urology with the development of an IVD version of the Oncotype DX Genomic Prostate Score® (GPS™) test on Idylla™ and potentially additional cancer tests that can be performed locally by laboratory partners and in hospitals around the world.

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 Test, while Immunexpress will lead commercialization of the SeptiCyte® RAPID Test in the US.

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).

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

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, aimed at the commercialization of Idylla™ oncology products in mainland China. The joint venture is50% 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.

3.12.2 / CUSTOMERS & PATIENTS

GO-TO-MARKET STRATEGY

→ THE PATHOLOGIST AND 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.

→ IDYLLA™ USER SETTINGS: FROM LARGE TO SMALL PATHOLOGY LABS, HOSPITALS AND UROLOGY CENTERS

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. Furthermore, Biocartis is expanding to other potential Idylla™ user settings through partnerships such as the Genomic Health partnership (now part of Exact Sciences) which expanded in 2018 to the domain of urological cancer testing. Here, the anticipated Idylla™ Oncotype DX GPS test for prostate cancer can support not only pathology labs but also local urology centers across the world in making better informed treatment decisions for prostate cancer patients.

→ DIRECT AND INDIRECT SALES CHANNELS

End 2019, 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.

- → **Distributor sales strategy RoW and Japan:** In RoW countries[78], Biocartis collaborates with a vast network of distributors in geographies that accept CE-marking. Since 2017, Biocartis has focused on assisting its distribution partners in commercially supporting market adoption of the Idylla™ platform, 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. On 7 January 2019, Biocartis announced to have signed an agreement with Nichirei Bioscience for the product registration and exclusive distribution of Idylla™ oncology tests in Japan.

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

Furthermore, our partnerships with pharmaceutical oncology treatment companies such as with Amgen and Merck KGaA (Darmstadt, Germany) allow our 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 Exact Sciences for the development of the Oncotype DX Breast Recurrence Score test ® 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)

Biocartis connects with its customers through a variety of channels, including:

- **Conferences**: In 2019, Biocartis participated in about 85 pathology and oncology conferences worldwide.
- **Customer trainings & meetings:** In 2019, Biocartis organized nine customer events, including Idylla™ User meetings, Idylla™ Technician Training Days and Key Opinion Leader (KOL) meetings. Furthermore, as a minimum, every customer receives the Idylla™ User training at the moment of the instrument placement.
- **Sales representative team:**
  - Biocartis sales team: With many sales people having extensive backgrounds and experience in molecular biology or oncology, Biocartis ensures a professional and high quality dialogue with its customers.
  - Dedicated team of Customer support and Customer service employees.
- **Websites:** End of 2019, Biocartis launched the new customer portal as part of the rebranded global website and a new investor relations website was launched in October 2019.

US, THE LARGEST SINGLE MARKET FOR ONCOLOGY MDX TESTING IN THE WORLD

THE US IS THE LARGEST SINGLE MARKET FOR ONCOLOGY MDX TESTING IN THE WORLD, WITH AN EXPECTED MARKET SIZE OF USD 1.45BN BY 2020, REPRESENTING OVER 45% OF THE GLOBAL MARKET[79]. 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. 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[80].

THE FIRST GO-TO-MARKET FOCUS IN THE US 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.

Biocartis is in continuous dialogue with KOLs, both oncologists and pathologists, which serve as true Idylla™ ambassadors in the market. KOLs have an important role in providing continuous feedback on the Idylla™ product offering. Activities in 2019 consisted of:

- **Abstracts and publications**: The performance of Idylla™ was the subject of over 26 publications[81] and multiple study abstracts, of which several were selected for publication at large scientific conferences such as ESMO[82] (European Society for Medical Oncology), ASCO[83] (American Society of Clinical Oncology) and AMP[84] (Association of Molecular Pathology).
  - Europe - 19 new Idylla™ performance publications in Europe, of which five Idylla™ study abstracts were selected for publication at the renowned ESMO congress and multiple study abstracts were selected for national conferences. All Idylla™ studies published at ESMO demonstrated excellent performance of Idylla™ compared to other methods, in combination with the ease of use and fast turnaround time of the Idylla™ platform. The studies included, amongst others, the Idylla ™ MSI Assay (RUO) and a prototype of the Idylla™ ctEGFR Mutation Assay (RUO).
  - US – Five new Idylla™ publications in the US and six study abstracts were selected for publication at the USCAP congress, one study abstract was selected for the ASCO congress and five study abstracts were selected for the AMP congress. All studies published at AMP showed a strong performance of Idylla™ assays (RUO) compared to other methods including IHC[85] and NGS[86] in terms of concordance[87], ease of use, workflow automation and turnaround times. Some studies researched Idylla™'s capability to analyze different sample types[88] and smaller sample quantities.
- **Key Expert Meetings:** In 2019, Biocartis organized a KOL meeting with experts to assess current trends and market opportunities in oncology MDx testing. The meeting took place during the ESMO meeting in Barcelona, Spain on 26 September 2019 and focused on colorectal and lung cancer as well as immuno-oncology in connection to the future Idylla™ product portfolio. In total, 10 experts from key European countries attended to share their insights and knowledge on progress made in molecular oncology testing.

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.

3.12.3 / SUPPLIERS

Biocartis works closely with its suppliers to ensure that they meet Biocartis' requirements in terms of quality, safety and environment compliance through:

- **Risk assessments:** Biocartis performs thorough risk assessments to get an overview of potential risks, before starting supplier collaboration
- **Business continuity plans** are established in order to avoid or mitigate potential internal and external threats, such as IT, power outage, fire
- **Agreements:** Various agreements (such as quality, manufacturing) are made with suppliers outlining Biocartis' 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 2019 WERE:

- Sustaining the cartridge manufacturing output on the first manufacturing line (ML1), and the transfer of the Idylla™ KRAS Mutation Test to the newly installed and qualified second automated manufacturing line (ML2)
- Continued organizational capability development through investment in talent and through the roll out of LEAN Manufacturing principles
- Continue a companywide program geared at establishing readiness for anticipated US FDA audit inspections and IVDR regulations

In 2019, the supplier audits did not indicate any critical observations. For each observation made an appropriate corrective action plan has been established.

3.12.4 / EMPLOYEES

"In realizing its vision, Biocartis wants to facilitate an environment for its employees where people are committed every day to improve other people's lives."

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 should enables us to be a customer- partner- and service-oriented organization.

In 2019, key focus areas in our people strategy were:

- Developing our competency framework with focus on leadership competencies, for example by introducing a leadership program oriented towards self-awareness and result-oriented mindsets
- Improving the governance structure to fostering accountability and decision-making at the right level and providing fast escalation and issue resolution when needed
- Enhancing project execution capability with the integration of clinical validity, regulatory compliance and quality mindset skills
- Expanding our talent acquisition program including strategic resource planning and expansion of our compensation & benefits strategy
- Fine-tuning our learning & development framework including reworking roles, responsibilities and accountabilities to create opportunities for employee growth

DIVERSITY & INCLUSIVENESS

With 465 employees[1] end of 2019 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. Biocartis does not discriminate based on age, skin color, disability, gender, marital status, nationality, race, religion, or sexual orientation. Biocartis upholds a policy of hiring and promoting the best person for the job, based on proven performance and assessment of potential, and in line with business principles. Biocartis looks at diversity and inclusion from a value-add perspective: it helps to build a more innovative, agile, productive workforce that best serves the needs of the Biocartis customers and patients across the world.

Inclusion at Biocartis is about belonging to a company where every employee is valued, heard, empowered as an individual belonging to a community that brings a whole new meaning to rapid and easy MDx and healthcare– accessible to all patients across the world.

End of 2019, the Biocartis workforce of 465 employees[1] counted:

NATIONALITIES IN 2019

30

GENDER DIVERSITY

50/50

WORKFORCE EVOLUTION

270 2015

308 2016

318 2017

394 2018

465 2019

TRAINING & DEVELOPMENT

In supporting its employees to their full potential, Biocartis' training & development program covers different aspects of skills & capacity development:

Training plans:

- 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:

- At the start of his/her employment, each employee attends a Welcome Day to make the new hires feel welcome and give them the tools they need when taking up their new job. The program helps employees understand what is expected and how they contribute to the Biocartis mission and vision. In 2019, 24 Welcome Days and four induction sessions were held for all new employees to provide them with all the information they need within the first months joining Biocartis
- A mix of corporate training programs are offered throughout the year, including for example technical writing, business acumen, soft skills trainings and IT
- Together with the manager, employees can define an individualized learning & development program based on goals, competence management and career plans
- Finally, Biocartis also offers other 'open' learning formats such as quarterly staff meetings, Biocartis Corporate Training Program and 'lunch & learn' sessions, or ad hoc expert speaker sessions from e.g. KOLs

In 2019, the Biocartis workforce followed close to 16,000 training hours.

EMPLOYEE WELLBEING

Well-being at work means ensuring employees are safe, physically and mentally healthy, satisfied, engaged and working in an efficient manner. Well-being at work contributes to a culture of recognition and support, to work-life balance, to employees' growth and development and to good communication and collaboration.

Important actions to mention in the Biocartis Employee Wellbeing strategy in 2019 were:

- Reinforcing of the employee engagement cycle by clarifying goals and employee's contribution to these goals, and by promoting continuous feedback and coaching
- Strengthening of the Biocartis competency framework to provide people leaders and employees with a clear model of the required & valued skills and behaviors in their roles as a solid basis for career development and HR planning
- Organizing wellbeing campaigns with key note speakers on topics such as mental health & resilience, focus, digital detox, the importance of sleep and introduction to a smoke stop program

We also continued to:

- Encourage cross-functional teamwork incl. shared responsibilities in smaller, more agile teams
- Offer flexible working schedules where possible
- Celebrate big & small successes through regular employee events such as a Spring BBQ or the annual Corporate Day
- Encourage daily wellbeing initiatives such as promoting company sports events, providing a locked bicycle storage to promote sustainable commuting, delivering weekly fresh fruit for employees and supporting employee fundraising actions for the 'Music for Life' campaign where employees collected funds for seven non-profit organizations in the area of cancer and health

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 furthermore commits to train and inform all its employees, contractors and visitors worldwide, as well as its partners 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 2019:

- 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 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. Two workplace accidents occurred and six accidents occurred during commuting to & from the workplace. The accidents caused only minor injuries. Where possible, improvement actions were taken to avoid future workplace injuries

WORKPLACE ACCIDENTS

2

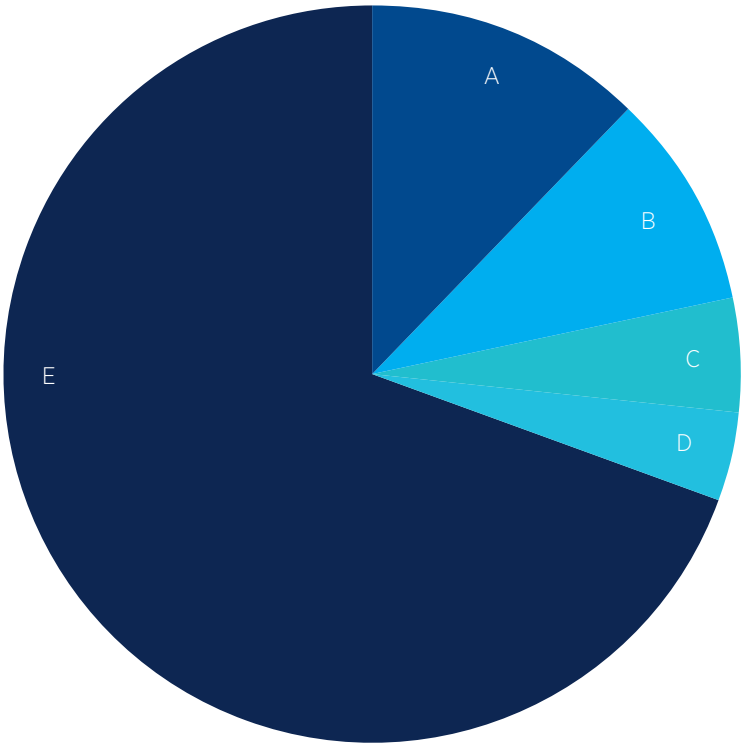
ACCIDENTS DURING COMMUTING

6

3.12.5 / 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 2019 and the transparency notifications received until that date, the shareholder structure of the Company was as follows:



A: Invesco Ltd.[1]:	12.4%
B: Johnson & Johnson Innovation – JJDC, Inc.[2]:	9.7%
C: Debiopharm Innovation Fund S.A.[3]:	4.9%
D: ParticipatieMaatschappij Vlaanderen NV (Flemish Region)[4]:	4.2%
E: Other institutional and retail investors	68.9%

[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] Debiopharm Innovation Fund S.A. (formerly Debiopharm Diagnostics S.A.) is controlled by Après-demain Holding S.A., which is controlled by Thierry Mauvernay.
[4] 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.

OUTSTANDING SHARES AND SHARE CAPITAL

Biocartis' shares are traded on Euronext Brussels following the company's IPO in April 2015 under symbol BCART (ISIN code BE0974281132). On 31 December 2019, the share capital of the Company amounted to EUR 563,850.88 represented by 56,382,088 shares. In addition, as at such date, 3,390,544 shares could still be issued by the Company as follows:

- 494,699 shares can be issued upon the exercise of 494,699 outstanding stock options (each stock option having the form of a warrant) that are still outstanding under the '2013 Plan' for employees, consultants and management members, entitling the holders thereof to acquire one new share per option ('2013 Stock Options');
- 234,794 shares can be issued upon the exercise of 234,794 outstanding stock options (each stock option having the form of a warrant) that are still outstanding under the '2015 Plan' for employees, consultants, management members and directors, entitling the holders thereof to acquire one new share per option ('2015 Stock Options');
- 1,340,000 shares can be issued upon the exercise of 1,340,000 outstanding stock options (each stock option having the form of a warrant) that are still outstanding under the '2017 Plan' for the CEO, entitling the holder thereof to acquire one new share per option ('2017 Stock Options'); and
- 1,321,051 shares can be issued upon the exercise of 1,321,051 outstanding stock options (each stock option having the form of a warrant) that are still outstanding under the '2018 Plan' for (mainly) certain selected employees of the Company and its subsidiaries, as well as for consultants of the Company and its subsidiaries, independent directors of the Company and directors of the Company's subsidiaries, entitling the holders thereof to acquire one new share per option ('2018 Stock Options').

The total number of fully diluted shares consequently amounted to 56,382,088 as of 31 December 2019. More information on the Company's stock options and warrants can be found below and in the Remuneration Report.

STOCK BASED INCENTIVE PLANS

On 31 December 2019, the Company had four stock based incentive plans:

- The 2013 Plan
- The 2015 Plan
- The 2017 Plan
- The 2018 Plan

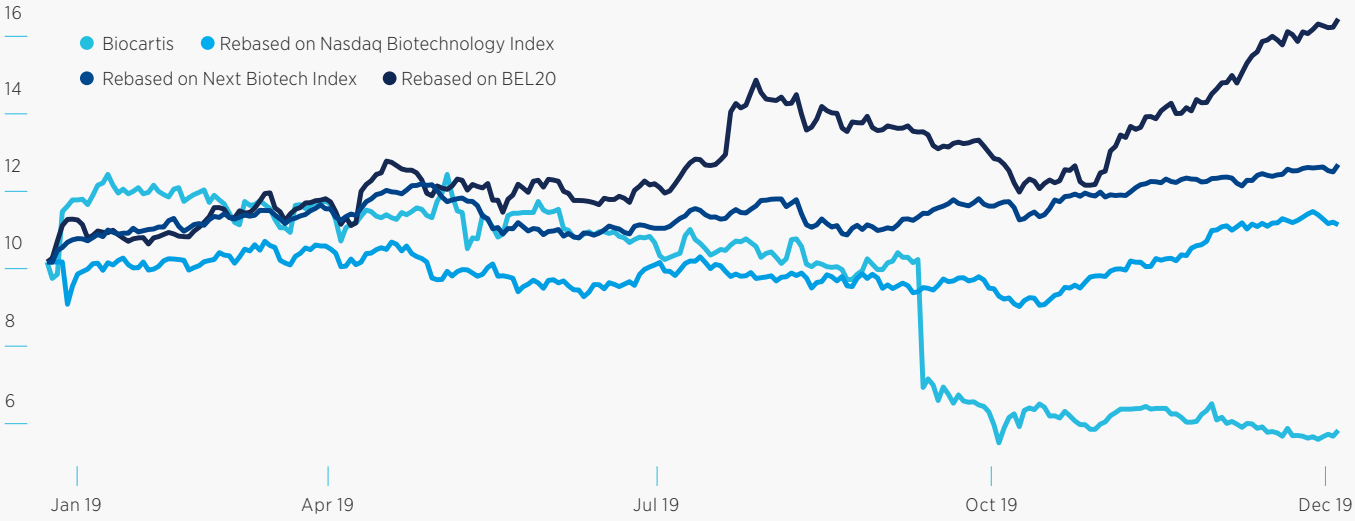
More information on these plans can be found in chapter 4 'Corporate governance', under 'Remuneration report'.

SHARE PERFORMANCE

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

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

BIOCARTIS SHARE PERFORMANCE 2019



* Rebased at Biocartis share price on 2 January 2020 / Source: Bloomberg

The closing price of the Biocartis share on 31 December 2019 was EUR 5.72.

TRADING VOLUME

Below is a summary of the 2019 trading volumes of Biocartis' share.

BCART	2019	2018	CHANGE %
Average daily volume	134,687	75,903	44%
Average daily value	9.56	12.36	-29%
Total traded volume	34,345,170	19,355,234	44%
Total traded value	606,959,025	487,298,753	20%

ANALYST COVERAGE

The Biocartis share was covered by seven brokers end of 2019:

BROKER	ANALYST	RATING END 2019	TARGET PRICE END 2019
Berenberg	Michael Ruzic-Gauthier	Buy	Under review due to change in covering analyst
Degroof Petercam	Thomas Guillot	Buy	Under review due to change in covering analyst
KBC Securities	Lenny Van Steenhuyse	Buy	EUR 13.50
Kempen & Co	Alexandru Cogut	Buy	EUR 16.00
Kepler-Cheuvreux	Kris Kippers	Buy	EUR 11.00
NIBC*	Dylan van Haaften Anita Yé	Buy	EUR 10.00
Bryan-Garnier	Change in covering analyst	Buy	EUR 13.50

*NIBC halted all capital markets activities including research as of end January 2020.

FINANCIAL CALENDAR 2020

5 March 2020	Full year results 2019
2 April 2020	Publication Annual Report 2019
23 April 2020	Q1 2020 Business Update
8 May 2020	Annual General and Extraordinary Meeting Biocartis Group NV
3 September 2020	H1 2020 results
12 November 2020	Q3 2020 Business Update

INVESTOR RELATION DETAILS

For any investor relation related questions, please contact:

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3.13 / 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 ONCOLOGY 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. 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 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 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 oncology 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 utilizing 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) that use the Idylla™ platform, the Idylla™ tests and/or any future products. 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 its regulatory obligations;
- Do not successfully commercialize the Idylla™ platform;
- Do not conduct its 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;
- Merge with 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 distribution collaboration with Fisher Healthcare (part of Thermo Fisher Scientific Inc.) for the US market. Under this collaboration, Fisher Healthcare had exclusive distribution rights on the Idylla™ tests and non-exclusive distribution rights on the Idylla™ instruments. On 5 September 2019, however, the Company and Fisher Healthcare announced that they jointly agreed to terminate, with immediate effect, their collaboration for distribution for the US market. The Company also announced that, going forward, Biocartis' US direct sales team will drive US commercialization and will be further expanded according to market needs.

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 is currently in the process of transferring its commercial volume to this new production line. Due to the high level of complexity of the cartridge manufacturing process, there can be no assurance that such technology transfer can be completed in time, nor 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 specification;
- Biocartis' delays in or poor performance of 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 HAS ONLY LIMITED EXPERIENCE IN COMMERCIALIZING MDX PLATFORMS AND TESTS AND THEREFORE MAY NOT BE SUCCESSFUL IN FURTHER GROWING ITS COMMERCIALIZATION INFRASTRUCTURE.

Biocartis has limited experience in deploying a commercialization infrastructure in diagnostics markets 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 and scientific 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 PRIVACY AND SECURITY OF PERSONAL INFORMATION BIOCARTIS COLLECTS.

Although all of the data on the Idylla™ platform is designed to be de-identified 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.

Biocartis' failure to accurately anticipate the application or interpretation of such laws as Biocartis develops its products, a failure to comply with their requirements (such as evolving encryption and security requirements) or an allegation that defects in Biocartis' products have resulted in non-compliance by Biocartis' customers, 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 will depend on any agreements (or lack thereof) to be negotiated between the UK and the EU during the ongoing transition period and, in particular, any arrangements for the UK to retain access to EU markets. The overall impact thereof on Biocartis will remain uncertain for the foreseeable future.

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

The recent outbreak of COVID-19 poses a potential risk to the result of operations of the Company. As at the date of this annual report, certain countries in which the Company is operating its business are being affected. The Company added a disclaimer to its guidance for 2020 which states that its commercial projections for 2020 assume a moderate impact of the COVID-19 outbreak, as well as a stabilization of the situation around the April 2020 timeframe. The extent of the risk posed by COVID-19 is however still unclear. If the impact of the outbreak is more severe or prolonged than anticipated, it could be that Biocartis' operations are more severely affected than what is currently expected, further impacting commercialization and potentially having an impact on the Company's production and R&D activities. This may have a materially adverse impact on the result of operations 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 2019, Biocartis' patent portfolio consisted of 28 proprietary patent families comprising issued and pending patents worldwide whose patent life will expire between 2022 and 2038, and multiple in-licensed patent families providing additional strength to the patent portfolio.

On 31 December 2019, the value of the Idylla™ platform was protected by a group of 48 patent families (26 proprietary

patent families and 22 in-licensed patent families) and four invention disclosures, comprising issued patents and pending patent applications worldwide, covering the platform technology (basic system, fluidics, ultra-sonification, thermal control, downstream analysis and signal processing) 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, 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, except for one non-substantial opposition which was still outstanding on 31 December 2019. 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 48 patent families of which 22 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 services 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. 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), when designated, 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 (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 two 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, when designated, may have limited resources and experience backlogs in the transition period leading up to the May 2022 effective date of the new regulation'.

All 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, WHEN DESIGNATED, 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 (the 'Competent Authority') 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 the 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 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, specific guidance from Notified Bodies regarding expectations for CE-marking are yet to be 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 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 by the administration 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 2019 was EUR -55.6m. As of 31 December 2019, Biocartis had an accumulated deficit of EUR -397.6m. 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. Any of the foregoing could have a materially adverse effect on Biocartis' financial condition and results of operations.

BIOCARTIS MAY FACE RISKS ASSOCIATED WITH PREVIOUS OR FUTURE ACQUISITIONS AND DISPOSALS OF COMPANIES, ASSETS, SOLUTIONS AND TECHNOLOGIES, AND ITS BUSINESS COULD BE HARMED IF BIOCARTIS IS UNABLE TO ADDRESS THESE RISKS.

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

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

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.

CHAPTER 4

CORPORATE GOVERNANCE

4.1 / INTRODUCTION

During 2019, the Company applied the Belgian Code on Corporate Governance as published on 12 March 2009 (the '2009 Corporate Governance Code'), which can be consulted on the website of the Belgian Corporate Governance Committee (https://www.corporategovernancecommittee.be/en). In accordance with the 2009 Corporate Governance Code, 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 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 website www.biocartis.com under 'Investors'.

The Company strived to comply with the rules of the 2009 Corporate Governance Code as much as possible. Nonetheless, the board of directors is of the opinion that certain deviations from the provisions of the 2009 Corporate Governance Code were justified in view of the activities and size of the Company, and the specific circumstances in which the Company operates. These deviations are described below under chapters 4.3 'Committees of the Board of Directors' (under subchapter 'Audit Committee') and 4.5 'Remuneration Report.

As from 1 January 2020, the Company applies the 2020 Belgian Code on Corporate Governance (the '2020 Corporate Governance Code') which can also be consulted on the website of the Belgian Corporate Governance Committee (https://www.corporategovernancecommittee.be/en). 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 2020 Corporate Governance Code.

4.2 / BOARD OF DIRECTORS

COMPOSITION

The table below gives an overview of the members of the Company's board of directors on 31 December 2019.

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	2020
Leo Steenbergen[(3)]	Non-executive, independent director	2018	2020
Ann-Christine Sundell	Non-executive, independent director	2018	2020
Harry Glorikian[(4)]	Non-executive, independent director	2018	2020
Roald Borré	Non-executive director	2014	2020

Notes:
(1) Permanently representing CRBA Management BV.
(2) Permanently representing Luc Gijsens BV.
(3) Permanently representing CLSCO BV.
(4) Permanently representing Scientia II LLC.

Christian Reinaudo joined the Company's board of directors as independent chairman in May 2018. Mr. Reinaudo joined Agfa-Gevaert, a leading ehealth & digital imaging solutions provider, as president of the Agfa HealthCare business group and member of the executive committee, on 1 January 2008. 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. 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.

Leo Steenbergen has a longstanding international experience having served both privately held and listed companies as CFO or general manager, including at Galapagos, Telenet and the Bekaert Group. He is director and member of the audit committee of the private equity held Metallum Holdings in The Netherlands, a leading European recycling and refining company of non-ferro metal scrap with operations in Belgium and Spain. Prior to that, Mr. Steenbergen was active in a variety of senior international finance and administration roles at Hewlett Packard Europe and served as director in several companies based in Europe, the US, Canada, Australia and Hong Kong.

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 chairman of the board of Oy Medix Biochemica group Ab and Serres Oy, vice chairman of the board and chairman of the audit committee of Raisio Oyj, board member and chairman of the remuneration committee of Immunovia Ab, member of the board and audit committee of Revenio Group Oyj, Committee Member of Raisio Oyj's Research Foundation, and holder of AConsult. Mrs. Sundell holds an MSc in biochemistry from Åbo Akademi, Turku, Finland.

Harry Glorikian is an influential global business expert with more than three decades of experience building successful ventures in North America, Europe, Asia and the rest of the world. He is well known for achievements in life sciences, healthcare, diagnostics, healthcare IT and the convergence of these areas. Mr. Glorikian currently serves as general partner at New Ventures Funds. Prior to that, he served as an 'Entrepreneur In Residence' to GE Ventures – New Business Creation Group. He serves on the board of GeneNews Ltd. and Transparency Life Sciences and several other companies. He is also a co-founder and advisory board member of DrawBridge Health. Previously he co-founded and held the position of managing director and head of consulting services for Scientia Advisors, which was acquired by Precision for Medicine in November 2012. Among his other professional roles, Mr. Glorikian served as senior manager for global business development at PE Applied Biosystems, founded X-Cell Laboratories, managed global sales at Signet Laboratories and held various roles at BioGenex Laboratories. Mr. Glorikian holds a Masters of Business Administration from the Boston University and a BA in General Biology from San Francisco 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 10 May 2019 reappointed Roald Borré as non-executive director of the Company for a term of one year, and confirmed the appointment of Scientia II LLC, represented by Harry Glorikian, as director of the Company, replacing Harry Glorikian. The mandates of Luc Gijsens BV, represented by Luc Gijsens, CLSCO BV, represented by Leo Steenbergen, Ann-Christine Sundell, Scientia II LLC, represented by Harry Glorikian, and Roald Borré will end after the annual shareholders' meeting of 8 May 2020. 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.

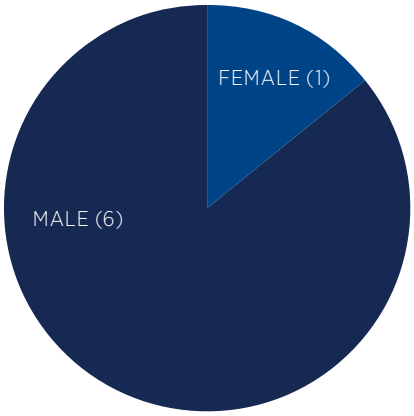
NAME	FUNCTIONAL BACKGROUND & EXPERTISE	GENDER	AGE	NATIONALITY
Christian Reinaudo[1]	ehealth & digital imaging solutions Managing companies International business	Male	65	France
Herman Verrelst	Molecular diagnostics Software solutions Entrepreneurship	Male	46	Belgium
Luc Gijsens[2]	Finance Capital markets Corporate and investment banking	Male	66	Belgium
Leo Steenbergen[3]	Finance General management Accounting and auditing	Male	67	Belgium
Ann-Christine Sundell	Life sciences Diagnostics Strategy and operations	Female	55	Finland
Harry Glorikian[4]	Life sciences and healthcare Diagnostics Private equity	Male	54	United States
Roald Borré	Corporate finance and M&A Investment funds Accounting and auditing	Male	47	Belgium

Notes:
[1] Permanently representing CRBA Management BV.
[2] Permanently representing Luc Gijsens BV.
[3] Permanently representing CLSCO BV.
[4] Permanently representing Scientia II LLC.

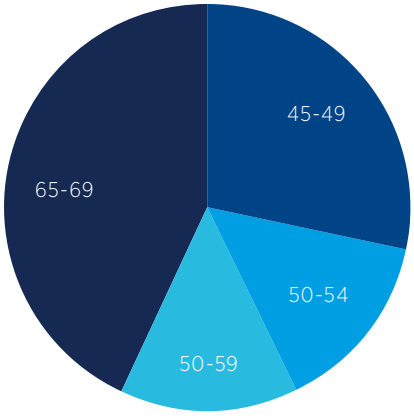
The board is well aware of the provisions of Belgian company law that require at least one third of the directors of a listed company to be of a different gender than the other directors. The rules on gender diversity set out in Belgian company law will apply to the Company as from 1 January 2021, being the first day of the sixth year after the Company's IPO in 2015. Currently, the Company has one female director on its board of directors on a total of seven 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 would benefit from additional profiles with board experience in internationally operating (listed) companies, experience in commercialization of oncology molecular diagnostics products and/or corporate business development. Moreover, the board is of the opinion that although most board members have operated internationally, it may gain from additional diversity in terms of nationality.

In 2019, there were no new members appointed to the board. The board of directors will however continue to make every effort to propose candidate directors who satisfy the gaps in diversity identified above for nomination by the general shareholders' meetings going forward. The board of directors will make every effort to propose female candidate directors for nomination by the next general shareholders' meeting.

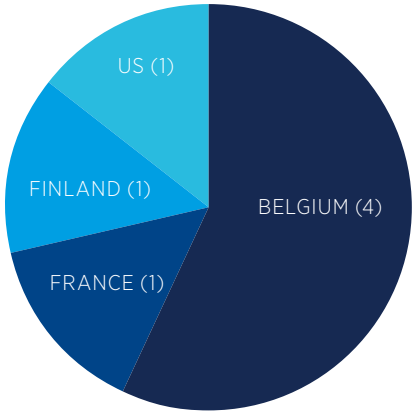
GENDER



AGE



NATIONALITY



ACTIVITY REPORT

In 2019, the board of directors held eleven 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 at 31 December 2019 was 100%, save for CLSCO BV (represented by Leo Steenbergen) and Roald Borré who were excused during three board meetings, and Scientia II LLC (represented by Harry Glorikian) who was excused during one board meeting.

During the meetings of the board of directors, the board among others reviewed the Group's strategy, operations and commercial performance, discussed business development opportunities, discussed and approved the Company's equity raising and issuance of convertible bonds (and related listing prospectus), discussed various corporate governance, nomination and remuneration matters, the regular updates of the financial performance and the budget for the financial year 2020. The board further reviewed the development of the different activities of the Group on the basis of reports prepared by the executive management team, and approved a new organization structure. 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. The board also started an externally facilitated evaluation relating to its size, composition, performance and interaction with the executive management and the board committees in accordance with the 2009 Corporate Governance Code. Such evaluation was however only completed in 2020.

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 2019:

Christian Reinaudo[1]	CRBA Management BV Agfa Gevaert NV Domo Chemicals GmbH
Herman Verrelst	South Bay Ventures (SBV) BV Opdorp Finance BV Heran BV Icometrix FlandersBio VZW
Luc Gijsens[2]	Luc Gijsens BV Arvesta NV PMV NV KMDA VZW KMDA NV Global Rental Properties NV
Leo Steenbergen[3]	CLSCO BV Metallo Holding NV Metallo Spain Metallo Holdings BV LEDSky BV LEDSky Africa Antwerp Metals NV
Ann-Christine Sundell	Medix Biochemica Group Oy Serres Oy Revenio Group Oyj Raisio Oyj Immunovia AB Blueprint Genetics Oy (this mandate ended in 2020) AConsult
Harry Glorikian[4]	GeneNews Ltd. Transparency Life Sciences
Roald Borré	FNG Groep NV High Wind NV Capricorn Cleantech Fund NV Media Invest Vlaanderen NV Flange Holding NV Laboratoria Smeets NV Innovation Fund NV Kebony AS Kebony Belgium NV Kebony Norge AS Kebony Danmark A/S Kebony Sverige AB ALZV vzw

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 interest 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 523 of the Belgian Companies Code of 7 May 1999 (which still applied to the Company in 2019), 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 523 of the Belgian Companies Code of 7 May 1999 was applied once in 2019 during the meeting held on 21 February 2019. The extract of the minutes of those meetings is as follows:

"Prior to discussing the next item, Mr. Herman Verrelst, director 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 warrants under the warrant plan 2017 regarding performance year 2018, the determination of the KPIs for his variable remuneration package regarding performance years 2019 to 2021, and the KPIs for the vesting of his performance-based warrants regarding performance year 2019.

In accordance with Article 523 of the Belgian Companies Code, Mr. Herman Verrelst, has decided that he 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 523 of the Belgian Companies Code, the auditor of the Company, Deloitte Bedrijfsrevisoren BV CVBA, permanently represented by Mr. Gert Vanhees, will be informed of the existence of the conflict of interest. Furthermore, the relevant sections of these minutes will be entirely 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 2018 and assessed the degree to which these goals were achieved in 2018. The Board was of the opinion that overall 72% of the goals were achieved and resolved to approve the amount of the variable remuneration for the CEO relating to performance year 2018 on this basis (i.e., an amount of EUR 135,000).

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 warrants under the warrant plan 2017 for the CEO for performance year 2018. The Board considered that 83% of the KPIs were achieved. Therefore, after discussion, the Board resolved to approve that 139,025 performancebased warrants under the warrant plan 2017 relating to the performance year 2018 have vested. The other 28,475 performance-based warrants relating to the performance year 2018 will not vest, but will not immediately lapse and will not immediately become null and void. Rather, these warrants are carried over to performance year 2019 as a potential surplus amount for performance year 2019 (and only for performance year 2019) and can still vest in case of over performance in performance year 2019 in accordance with the warrant agreement with Herman Verrelst.

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 2019-2021. For the 1-year target (for 2019), the proposal is:

- *To use total revenue and gross margin on product revenues as the KPIs having a weight of 70% (each KPI having an equal weight of 35%). In case of achievement of any of these KPIs of 70%, 40% of the percentage of the variable remuneration will be payable, while every incremental percentage of achievement will result in 2% extra being payable (e.g., if 70% of a certain KPI is achieved, 40% of the variable remuneration to which the KPI relates shall be payable; if 80% of a certain KPI is achieved, 60% of the variable remuneration to which the KPI relates shall be payable), provided that the maximum amount payable shall be equal to 100%. In case of an achievement of less than 70% of a certain KPI, no variable remuneration to which such KPI relates shall be payable.*
- *That the other 30% will be determined by the Board on the basis of the other KPIs proposed by the Remuneration and Nomination Committee which can be categorized into menu, manufacturing, and organization.*

The 1-year target will be applied for 75% of the on-target bonus for performance year 2019, while the other 25% relates to the 2-year target determined by the Board in 2018. For the 2-year (2020) and 3-year (2021) target, the proposal is to use total revenue and gross margin on product revenues as the KPIs having a weight of 100% (each KPI having an equal weight of 50%). The same mechanism for linking achievement to variable remuneration being payable shall be used as set out above in section B, first bullet. The Board wants to repeat that the 2-year target for 2020 will be applied for 25% of the

on-target bonus for performance year 2020, while another 25% relates to the 3-year target determined by the Board in 2018, and 50% will relate to the 1-year target which is still to be determined by the Board. The 3-year target for 2021 will be applied for 25% of the on-target bonus for performance year 2021, while another 25% will relate to a 2-year target and another 50% will relate to a 1-year target which are both still to be determined by the Board.

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

More information on the remuneration of Herman Verrelst in 2019 can be found in the Remuneration Report below.

The procedure pursuant to Article 524 of the Belgian Companies Code of 7 May 1999 was not applied in 2019.

4.3 / COMMITTEES OF THE BOARD OF DIRECTORS

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

AUDIT COMMITTEE

COMPOSITION

According to Belgian company law, the audit committee consists of non-executive directors only, at least one member of the audit committee must be an independent director, the members of the audit committee must have a collective expertise relating to the activities of the Company, and at least one member of the audit committee must have the necessary competence in accounting and auditing. The following three directors are members of the audit committee: Luc Gijsens BV, permanently represented by Luc Gijsens (chairman), Roald Borré, and CLSCO BV, permanently represented by Leo Steenbergen. 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 2019, the audit committee held three meetings which were attended by all members, except for one meeting during which Roald Borré was excused. This is a deviation from principle 5.2/28 of the 2009 Corporate Governance Code that provided that the audit committee should meet at least four times a year. The board decided to discuss certain matters related to quality, compliance and internal control directly within the board in 2019, resulting in one audit committee meeting being cancelled. 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 convertible bonds issued by the Company. The audit committee assessed the declarations regarding internal control and risk management in the annual report 2018. It also discussed the cooperation with the external auditor of the Company, Deloitte Bedrijfsrevisoren BV ovve CVBA, represented by Gert Vanhees, and the proposal to rotate the audit partner in 2020. The audit committee approved a new policy to be followed in case of 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 2019 during the last meeting of the audit committee held in 2019. 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: CRBA Management BV, permanently represented by Christian Reinaudo (chairman), CLSCO BV, permanently represented by Leo Steenbergen, and Ann-Christine Sundell. 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 2019, 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 executive management. Furthermore, the committee discussed and approved the achievement of the 2018 company goals and related variable remuneration of the executive management, and set the 2019 company goals. It discussed the HR and operational strategy of the Company, and approved a new organization structure. It initiated 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 2018 annual report. The remuneration and nomination committee reported systematically to the board of directors and ensured the co-operation of the executive management and the HR department of the Company where required.

4.4 / EXECUTIVE MANAGEMENT

COMPOSITION

On 31 December 2019, the executive management was composed of the CEO, CFO, COO and CTO[1].

NAME	AGE	FUNCTION
Herman Verrelst	46	Chief executive officer (CEO)
Ewoud Welten[2]	36	Chief financial officer (CFO)
Piet Houwen[3]	52	Chief operating officer (COO)
Benoit Devogelaere	39	Chief technology officer (CTO)

[1] Since March 2020, the executive management of the Company is composed of the CEO, CFO and COO;
[2] Mr. Welten resigned as CFO of Biocartis with effect as of end of March 2020;
[3] Permanently representing Scmiles BV.

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

Ewoud Welten was the chief financial officer (CFO) until end of March 2020. He joined Biocartis in September 2015, coming from international investment bank Kempen & Co where he worked as vice president corporate finance. He

has a proven track record in the life sciences and healthcare sector as a corporate financier, in which position he managed numerous international capital market transactions including IPOs, secondary fundraisings and M&A transactions. Mr. Welten holds a Master Degree in financial economics (distinction) from the Erasmus University Rotterdam, the Netherlands. Mr. Welten decided to resign as CFO of Biocartis to pursue an opportunity in the Netherlands, closer to his home and family.

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).

Benoit Devogelaere is the chief technology officer (CTO). He started his career in the pharmaceutical sector (Johnson and Johnson) in virology. In 2011, he joined Biocartis to lead the first CE-IVD marking of an Idylla™ test. In 2013, he joined Cartagenia, a provider of diagnostic software, as R&D operating manager to further expand the Cartagenia product portfolio. In 2015, following the acquisition of Cartagenia by Agilent Technologies (NYSE: A), Mr. Devogelaere relocated to Silicon Valley, US, where he was responsible for several aspects of the portfolio strategy, product roadmapping and technology scouting. End of 2017, Mr. Devogelaere joined Biocartis as chief technology officer. He holds a Master in biological engineering and a PhD in medical sciences (University of Leuven, Belgium).

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 2019, the executive management consisted of the CEO, CFO, COO and CTO. 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 'Business activities', chapter 3 'Employees', 'Diversity & Inclusiveness'.

4.5 / REMUNERATION REPORT

DETERMINATION OF REMUNERATION OF DIRECTORS AND MEMBERS OF EXECUTIVE MANAGEMENT

The procedure for establishing the remuneration policy and determining the remuneration of the members of the board of directors and the members of the executive management is determined by the board of directors on the basis of proposals from the remuneration and nomination committee. The remuneration of the members of the board of directors is determined by the general shareholders' meeting. The remuneration of the members of the executive management is determined by the board of directors, upon recommendation of the remuneration and nomination committee.

REMUNERATION POLICY

PRINCIPLES

Biocartis' remuneration policy is designed to enable Biocartis to:

- Attract and retain talented individuals
- Promote continuous commercial and operational improvements
- Link remuneration and performance, motivating people to deliver increased shareholder value through superior business results

The remuneration of the non-executive directors is reviewed against market practice at regular occasions, in particular at the occasion of the search for potential new board members. Their remuneration is composed of a fixed fee and an attendance fee. Until 2019, the independent directors were entitled to share options (having the form of subscription rights) which are not linked to any performance criteria. Since 1 January 2020, the independent directors are however no longer entitled to share options. The directors who are also a member of the executive management are remunerated for their executive management mandate only, and not for their director mandate.

The remuneration of the CEO and the other members of the executive management consists of:

- An annual fixed base salary
- A variable remuneration (cash bonus)
- Participation in share option plans and certain other components

The variable remuneration is structured so as to link rewards to corporate and/or individual performance of the executives. These objectives are established annually by the board of directors upon recommendation of the remuneration and nomination committee. The level of achievement of the objectives of the members of the executive management is reviewed in the beginning of the first subsequent year by the remuneration and nomination committee and finally established by the board of directors.

RELATIVE IMPORTANCE OF EACH COMPONENT OF THE REMUNERATION

For 2019:

- Herman Verrelst's fixed remuneration as CEO was equal to EUR 375,000 and his variable remuneration could be maximum EUR 187,500 (being 50% of his fixed remuneration)
- The variable remuneration of the CFO, COO and CTO could be maximum 20% of their respective annual fixed remuneration

In addition, the members of the executive management participate in share option plans (having the form of subscription rights) and enjoy a number of benefits such as group and hospitalization insurance and certain other components, the monetary value of which is however limited.

PERFORMANCE-RELATED PREMIUMS IN SHARES, OPTIONS OR OTHER RIGHTS TO ACQUIRE SHARES

The share options granted under the 2013 Plan, 2015 Plan and 2018 Plan are not linked to any performance criteria, except for the share options granted to Benoit Devogelaere, CTO of Biocartis, under the 2013 plan of which 50% will vest if and to the extent certain objective and verifiable key performance indicators are achieved, while the other 50% are not linked to any performance criteria (time-based vesting).

50% of the share options granted to Herman Verrelst under the 2017 Plan are not linked to any performance criteria (time-

based vesting), while the other 50% will vest if and to the extent of the CEO achieving certain objective and verifiable key performance indicators. These share options are not considered as variable remuneration, nor as fixed remuneration or annual remuneration pursuant to Belgian company law. More information can be found under 'Characteristics of the share option plans'.

REMUNERATION POLICY FOR THE NEXT TWO FINANCIAL YEARS (2020-2021)

The Company is reviewing its remuneration policy in view of the new and upcoming rules on board and executive remuneration. For instance, the Company will no longer grant share options to independent directors.

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 each of Ann-Christine Sundell and Scientia II LLC, represented by Harry Glorikian, 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.

SHARE BASED AWARDS:

Upon advice of the remuneration and nomination committee and pursuant to the approval by the general shareholders' meeting of 11 May 2018, each independent director of the Company was entitled to receive up to 15,000 share options (each share option having the form of a subscription right). Part of the share options under the 2018 Plan were used for this purpose. In accordance with the decision of the general shareholders' meeting of 11 May 2018, the share options under the 2018 Plan can, under certain circumstances, be exercised before the third anniversary of the grant date and do not form part of the variable remuneration nor of the annual remuneration for the purposes of Belgian company law. The granting of share options to independent directors was contrary to provision 7.7 of the 2009 Corporate Governance Code that provided that non-executive directors should not be granted any share options. The Company justified this as it allowed to limit the portion of remuneration in cash that it would otherwise need to pay to attract or retain internationally renowned experts with the most relevant skills, knowledge and expertise, as this is customary for directors active in companies in the biotech and life sciences industry, and as the portion of the remuneration payable in share options is limited. The board of directors was of the opinion that the granting of share options had no negative impact on the functioning of the independent directors. Since 1 January 2020, the Company no longer grants share options to independent directors.

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

REMUNERATION OF THE MEMBERS OF THE BOARD OF DIRECTORS IN 2019

Based on what is set out above, the remuneration of the directors for the performance of their director mandate in 2019 is as follows:[1]

NAME	ANNUAL FIXED FEES	ATTENDANCE FEES	TOTAL
Directors in office on 31 December 2019			
CRBA Management BV, represented by Christian Reinaudo	EUR 50,000	EUR 23,500	EUR 73,500
Luc Gijsens BV, represented by Luc Gijsens	EUR 18,000	EUR 24,000	EUR 42,000
CLSCO BV, represented by Leo Steenbergen	EUR 12,000	EUR 22,000	EUR 34,000
Ann-Christine Sundell	EUR 12,000	EUR 31,000	EUR 43,000
Scientia II LLC, represented by Harry Glorikian	EUR 12,000	EUR 19,500	EUR 31,500
Roald Borré[2]	EUR 12,000	EUR 18,500	EUR 30,500
Directors whose mandate expired in 2019			
Peter Piot	EUR 4,274	EUR 10,500	EUR 14,774
Hilde Windels BV, represented by Hilde Windels	EUR 4,253	EUR 10,500	EUR 14,753

Notes: [1] Amounts of annual fixed fees are pro-rated taking into account the changes to the composition of the board with effect as from the annual shareholders' meeting dated 10 May 2019. / [2] Mr. Borré renounced his historical and future remunerations as director and member of the audit committee of the Company, and indicated that these amounts are to be paid to charity.

As indicated above, Herman Verrelst is not remunerated for his director mandate.

The table below provides an overview of the number of share options held by the directors on 31 December 2019:

NAME	GRANTED AND ACCEPTED IN 2019	EXERCISED IN 2019	NULL AND VOID IN 2019	TOTAL HELD ON 31 DEC 2019	PLAN
Directors in office on 31 Dec2019					
CRBA Management BV, represented by Christian Reinaudo	0	0	0	15,000	2018
Luc Gijsens BV, represented by Luc Gijsens	0	0	0	10,000	2018
CLSCO BV, represented by Leo Steenbergen	0	0	0	10,000	2018
Ann-Christine Sundell	0	0	0	10,000	2018
Scientia II LLC, represented by Harry Glorikian	0	0	0	10,000	2018
Directors in office on 31 Dec 2019	**GRANTED AND ACCEPTED IN 2019**	**EXERCISED IN 2019**	**NULL AND VOID IN 2019**	**TOTAL HELD ON 31 DEC 2019**	**PLAN**
Peter Piot	0	0	0	20,000	2015,2018
Hilde Windels BV, represented by Hilde Windels	0	0	0	17.500	2013

REMUNERATION OF THE MEMBERS OF THE EXECUTIVE MANAGEMENT

PRINCIPLES

The remuneration of the members of the executive management is determined by the board of directors, upon recommendation of the remuneration and nomination committee. The remuneration of the members of the executive management consists of the following main remuneration components:

- Annual fixed base salary
- Variable remuneration (cash bonus)
- Participation in share option plans
- Group and hospitalization insurance
- Other components

For 2019, Herman Verrelst's fixed remuneration as CEO was equal to EUR 375,000 and his variable remuneration could be maximum EUR 187,500 (being 50% of his fixed remuneration). The remuneration of the CEO for 2019 was structured so as to link variable remuneration 75% to 1-year company goals and 25% to 2-year company goals.

For the 1-year goals (set at the beginning of 2019), total revenue and gross margin on product revenues are used as KPI having a weight of 70% (each KPI having an equal weight of 35%) while 30% relates to goals with respect to menu, manufacturing, and organization. In case of achievement of any of these KPIs of 70%, 40% of the percentage of the variable remuneration is payable, while every incremental percentage of achievement results in 2% extra being payable (e.g., if 70% of a certain KPI is achieved, 40% of the variable remuneration to which the KPI relates shall be payable; if 80% of a certain KPI is achieved, 60% of the variable remuneration to which the KPI relates shall be payable), provided that the maximum amount payable shall be equal to 100%. In case of an achievement of less than 70% of a certain KPI, no variable remuneration to which such KPI relates shall be payable. For the 2-year goals (set in 2018), only KPIs relating to total revenue and gross margin on product revenues are used. The same 1-year KPIs as mentioned above were used to determine the vesting of the share options under the share option plan 2017 for the CEO for performance year 2019.

For 2019, the variable remuneration of the CFO, COO and CTO could be maximum 20% of their respective annual remuneration. The same 1-year goals were used as those set out above for the CEO.

The members of the executive management were also eligible to participate in the share option plans of the Company and were reimbursed for certain costs and expenses made in the performance of their function. The members of the executive management that have an employment contract could also benefit from a pension plan, company car with fuel card, laptop and certain other minor elements.

REMUNERATION OF THE MEMBERS OF THE EXECUTIVE MANAGEMENT IN 2019

The following remuneration and compensation was paid to the CEO and the other members of the executive management with respect to 2019:

AMOUNTS IN EUR[1]	HERMAN VERRELST	OTHER EXECUTIVES
Annual base salary	EUR 375,000.00	EUR 612,836.39
Variable remuneration	EUR 73,125.00	EUR 75,538.32
Company car	-	EUR 28,252.40
Pension plan[2]	-	EUR 16,574.20
Other elements[3]	-	EUR 6,933.39
Total	EUR 448,125.00	EUR 740,134.70

Notes: [1] The column 'Other executives' captures the remuneration of the CFO, COO and CTO, as well as the remuneration of Citros vof, represented by Hilde Eylenbosch, who acted as Chief Commercial Officer until 30 April 2019. / [2] The Biocartis pension plan is a defined contribution plan covering life (pension), decease, disability and premium relief. / [3] The other elements include meal vouchers, medical plan and representation allowances.
This table does not include the severance payment which was made to the CCO (see below).

The table below provides an overview of the number of share options held by the members of the executive management on 31 December 2019:

NAME	GRANTED AND ACCEPTED IN 2019	EXERCISED IN 2019	NULL AND VOID IN 2019	TOTAL HELD	PLAN
Executives in service on 31 December 2019					
Herman Verrelst	0	0	127,635	1,212,365	2017
Ewoud Welten	20,000	0	0	82,500	2015,2018
Scmiles BV, represented by Piet Houwen	65,000	0	0	65,000	2018
Benoit Devogelaere	50,000	0	0	237,500	2013,2018

Executives no longer in service on 31 December 2019	GRANTED AND ACCEPTED IN 2019	EXERCISED IN 2019	NULL AND VOID IN 2019	TOTAL HELD	PLAN
Citros vof, represented by Hilde Eylenbosch[(1)]	0	0	32,242	40,258	2015,2018

Note: [(1)] The consultancy agreement between Biocartis and Citros vof, represented by Hilde Eylenbosch, was terminated with effect as from 30 April 2019.

For an overview of the features of the share options, see also 'Characteristics of the share option plans'.

CONTRACTUAL PROVISIONS REGARDING COMPENSATION FOR SEVERANCE FOR THE MEMBERS OF EXECUTIVE MANAGEMENT

The CEO and COO are self-employed. Their contracts contain customary provisions regarding remuneration, non-competition and confidentiality.

The managing director contract of the CEO is entered into for an indefinite period of time and can be terminated by either the CEO or Biocartis at any time subject to a prior notice of six months (or, in case of termination by Biocartis, the payment of an equivalent indemnity equal to six monthly installments of the fixed annual fee). In certain cases, the contract can be terminated by the CEO or Biocartis with immediate effect.

The consultancy services contract of the COO was entered into for an indefinite period of time and can be terminated by either the COO or Biocartis at any time subject to a prior notice of three months (or, in case of termination by Biocartis, the payment of an indemnity equal to the pro rata fee for that period). In certain cases, the contract can be terminated by Biocartis or the COO with immediate effect.

The CFO and CTO are employees. Their contracts contain customary provisions regarding remuneration, non-competition and confidentiality, are entered into for an undetermined period of time, and can be terminated by either the employee or Biocartis at any time subject to a prior notice (or the payment of an indemnity in lieu of notice) in accordance with the provisions of the Belgian Act of 3 July 1978 concerning Employment Contracts and the Belgian Act of 26 December 2013 concerning the Introduction of a Single Status between Workers and Employees on Notice Periods and Carenz Day and Accompanying Measures. The contract can be immediately terminated by Biocartis in case of serious cause.

CLAW-BACK RIGHT OF THE COMPANY RELATING TO VARIABLE REMUNERATION

In 2019, there were no contractual provisions in place between the Company and the CEO or the other members of the executive management that would give the Company a contractual right to reclaim from the executives the variable remuneration that would be awarded based on erroneous financial information.

SEVERANCE PAYMENTS FOR DEPARTING MEMBERS OF THE EXECUTIVE MANAGEMENT

Biocartis and Citros vof, represented by Hilde Eylenbosch, agreed to terminate the consultancy agreement for the latter's role as Chief Commercial Officer with effect as of 30 April 2019. In this framework, Biocartis made a severance payment equal to the fee corresponding to three months' services (or EUR 56,250.00).

CHARACTERISTICS OF THE SHARE OPTION PLANS

On 31 December 2019, Biocartis had four outstanding share based incentive plans, namely (i) the 2013 share option plan (the '2013 Plan'), (ii) the 2015 share option plan (the '2015 Plan'), (iii) the 2017 share option plan (the '2017 Plan'), and (iv) the 2018 share option plan (the '2018 Plan'), the main characteristics of which are described below.

2013 PLAN

On 25 August 2011, the general shareholders' meeting of Biocartis SA approved the 2013 Plan, enabling Biocartis SA to grant a maximum of 1,000,000 share options (each share option having the form of a subscription right) to selected staff members (consisting of employees, consultants and members of the management). On 25 November 2014, the 2013 Plan was rolled up in order to relate to the shares of the Company instead of the shares of Biocartis SA.

The 2013 Plan is a dilutive plan, implying that new shares are issued upon the exercise of the respective share options. The key features of the share options under the 2013 Plan are as follows: (i) each share option can be exercised for one share, (ii) the share options are granted for free, i.e. no consideration is due upon the grant of the share options unless the grant stipulates otherwise, (iii) the share options have a term of ten years when they were created but this term is contractually reduced to seven years upon grant of the share options, (iv) the exercise price of the share options is determined at the time of the grant of the share options, and (v) in principle the share options vest in 48 monthly instalments, subject to acceleration in case of a change of control event. The vesting of 50% of the share options granted to Benoit Devogelaere is time-based (15,625 share options will vest on each of the first and second anniversary dates of the date of grant and 31,250 share options will vest on each of the third and fourth anniversary dates of the date of grant), while the other 50% will vest if and to the extent certain objective and verifiable key performance indicators are achieved. The exercise windows of the 2013 Plan are 16-31 March, 16-30 September and 1-15 December.

Prior to the IPO of the Company, a total number of 720,340 share options have been granted under the 2013 Plan, having an exercise price of EUR 8.1308. The exercise price of the share options that have been granted since the IPO of the Company is determined on the basis of the stock exchange price of the shares of the Company at the time of the grant or an average price calculated over a previous period.

On 31 December 2019, a total of 494,699 share options were outstanding (i.e. share options under the 2013 Plan which have been created under the plan and which had not yet been exercised or became null and void for any reason).

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 share option plan, enabling the Company to grant a maximum of 262,934 share options (each share option having the form of a subscription right) 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 share options. The key features of the share options under the 2015 Plan are as follows: (i) each share option can be exercised for one share, (ii) the share options are granted for free, i.e. no consideration is due upon the grant of the share options, (iii) the share options have a term of ten years when they were created, but this term is contractually reduced to seven years, (iv) the exercise price of the share options is determined at the time of the grant of the share options, and (v) in principle the share options vest in 48 monthly instalments, subject to acceleration in case of a change of control event. The exercise price of the share options is determined on the basis of the stock exchange price of the shares of the Company at the time of the grant or an average price calculated over a previous period. The exercise windows of the 2015 Plan are 16-31 March, 16-30 September and 1-15 December.

On 31 December 2019, a total of 210,052 share options were outstanding (i.e. share options under the 2015 Plan which have been created under the plan and which had not yet been exercised or became null and void for any reason).

2017 PLAN

On 11 September 2017, a share option plan was established pursuant to which 1,340,000 share options (each share option having the form of a subscription right) 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 share options. The key features of the share options under the 2017 Plan are as follows: (i) each share option can be exercised for one share, (ii) the share options are granted for free, i.e. no consideration is due upon the grant of the share options, (iii) the share options have a term of five years as from 11 September 2017, (iv) the exercise price of the share options is determined at the time of the grant of the share options (i.e., EUR 9.92), and (v) 50% of the share options will vest over a period of four years (12.5% of the share options will vest on each of the first four anniversary dates of the date of grant), while the other 50% of the share options will vest if and to the extent of the CEO achieving certain objective and verifiable key performance indicators. The exercise windows of the 2017 Plan are 16-31 March, 16-30 September and 1-15 December.
On 31 December 2019, a total of 1,212,365 share options were outstanding (i.e. share options under the 2017 Plan which have been created under the plan and which had not yet been exercised or became null and void for any reason).

2018 PLAN

On 10 September 2018, a share option plan was established by the board of directors pursuant to which 1,335,426 share options (each share option having the form of a subscription right) were issued, enabling the Company to grant a maximum of 1,335,426 share options to selected staff members (consisting of employees, consultants and members of the management) and directors.

The 2018 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective share options. The key features of the share options under the 2018 Plan are as follows: (i) each share option can be exercised for one share, (ii) the share options are granted for free, i.e. no consideration is due upon the grant of the share options, (iii) the share options have a term of ten years when they were created, but this term is contractually reduced to seven years, and (iv) the exercise price of the share options is determined at the time of the grant of the share options. In principle and subject to acceleration in case of a change of control event, the share options vest (a) for employees or consultants of the Company or a subsidiary of the Company or for directors of a subsidiary of the Company as follows: 25% of the share options vest on March 30 of the year following the year in which the date of grant occurs, and 6.25% of the share options vest at the end of each subsequent calendar quarter; or (b) for directors of the Company as follows: the share options vest in X equal instalments on each anniversary date of the date of his or her appointment as director of the Company, whereby X is equal to the duration of his or her director's mandate expressed in years. Certain share options granted under the 2018 Plan in 2019 to, among others, certain members of executive management, vest on 1 January 2023 (cliff vesting). The exercise price of the share options is determined on the basis of the stock exchange price of the shares of the Company at the time of the grant or an average price calculated over a previous period. The exercise windows of the 2018 Plan are 16-31 March, 16-30 June, 16-30 September and 1-15 December.

On 31 December 2019, a total of 1,307,425 share options were outstanding (i.e. share options under the 2018 Plan which have been created under the plan and which had not yet been exercised or became null and void for any reason). On 3 March 2020, the Company cancelled the then outstanding pool of 696,976 share options (i.e. share options not yet offered to, and accepted by, the beneficiaries under the 2018 Plan).

2020 PLAN

On 3 March 2020, a share option plan was established by the board of directors pursuant to which 696,976 share options (each share option having the form of a subscription right) were issued, enabling the Company to grant a maximum of 696,976 share options to selected members of the personnel of the Company and/or its subsidiaries.

The 2020 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective share options. The key features of the share options under the 2020 Plan are as follows: (i) each share option can be exercised for one share, (ii) the share options are granted for free, i.e. no consideration is due upon the grant of the share options, (iii) the share options have a term of ten years when they were created, but this term is contractually reduced to seven years, and (iv) the exercise price of the share options is determined at the time of the grant of the share options. In principle and subject to acceleration in case of a change of control event, 25% of the share options vest on March 30 of the year following the year in which the date of offer occurs, and 6.25% of the share options vest at the end of each subsequent calendar quarter. The exercise price of the share options is determined on the basis of the stock exchange price of the shares of the Company at the time of the offer or an average price calculated over a previous period. The exercise windows of the 2020 Plan are 16-31 March, 16-30 June, 16-30 September and 1-15 December.

4.6 / SHARE CAPITAL AND SHARES

ISSUE OF SHARES BY THE COMPANY IN 2019

On 1 January 2019, the share capital of the Company amounted to EUR 513,610.88, represented by 51,361,088 shares. On 28 January 2019, the Company increased its share capital with an amount of EUR 50,000 in the framework of a private placement via an accelerated bookbuild offering, resulting in the issuance of 5,000,000 new shares. There was one capital increase resulting from the exercise of share options under the 2013 Plan, resulting in the issuance of 21,000 new shares and an increase of the share capital of EUR 210. Consequently, on 31 December 2019, the total share capital of the Company amounted to EUR 563,820.88, represented by 56,382,088 shares. An overview of the major shareholders of the Company on 31 December 2019 based on the transparency notifications received until that date can be found in the section 'Major Shareholders' under paragraph 3.12.5. '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 56,382,088 shares of the Company outstanding at 31 December 2019, 76,518 were registered shares and 56,305,570 were dematerialized shares. All shares belong to the same class and are freely transferable. All shares are issued and fully paid-up.

RIGHTS ATTACHED TO SHARES OF THE COMPANY

Each share in the Company (i) entitles its holder to one vote at the general shareholders' meetings, (ii) represents an identical fraction of the Company's share capital and has the same rights and obligations, and shares equally in the profits and losses of, the Company, and (iii) gives its holder a preferential subscription right to subscribe for new shares, convertible bonds or subscription rights in proportion to the part of the share capital represented by the shares already held. The preferential subscription right can be restricted or cancelled by a resolution approved by the general shareholders' meeting, or by the board of directors subject to an authorization of the general shareholders' meeting, in accordance with the provisions of Belgian company law and the Company's articles of association. Pursuant to Article 11 of the articles of association, the exercise of the voting rights of all shares owned by the relevant shareholder are suspended if and as long as the board of directors calls for the payment of shares which are not fully paid-up and such calls have not been performed by such shareholder. However, all shares in the Company are currently fully paid-up. Pursuant to Article 12 of the articles of association, the Company may suspend all rights attached to a security when such security is held by more than one person, until such time as one sole person has been identified to the Company as the holder of the security.

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

RIGHT OF THE BOARD OF DIRECTORS TO INCREASE THE SHARE CAPITAL OF THE COMPANY

On 13 April 2015, the general shareholders' meeting authorized, subject to and with effect as from the closing of the IPO of the Company (which took place on 28 April 2015), the board of directors to increase the share capital of the Company within the framework of the authorized capital with a maximum of 100% of the share capital after completion of the IPO (i.e., EUR 391,440.13).

The general shareholders' meeting further decided that the board of directors, when exercising its powers under the authorized capital, is authorized to restrict or cancel the statutory preferential subscription rights of the shareholders (within the meaning of Belgian company law). This authorization includes the restriction or cancellation of the preferential subscription rights for the benefit of one or more

specific persons (whether or not employees of the Company or its subsidiaries). The authorization is valid for a term of five years as from the date of the publication of the authorization in the Annexes to the Belgian State Gazette (Belgisch Staatsblad/Moniteur belge), i.e., until 13 May 2020.

On 21 November 2016, the Company increased its share capital with an amount of EUR 40,589.17 in the framework of the closing of a private placement via an accelerated bookbuild offering launched on 17 November 2016 within the framework of the authorized capital. On 1 December 2017, the Company increased its share capital with an amount of EUR 64,000.00 in the framework of the closing of a private placement via an accelerated bookbuild offering launched on 28 November 2017 within the framework of the authorized capital. On 10 September 2018, the board used its powers under the authorized capital for an amount of EUR 13,354.26 in the framework of the issuance of the share option plan 2018. On 28 January 2019, the Company increased its share capital with an amount of EUR 50,000.00 in the framework of the closing of a private placement via an accelerated bookbuild offering launched on 23 January 2019 within the framework of the authorized capital. On 2 May 2019, the board used its powers under the authorized capital in the framework of the issuance of 1,500 convertible bonds due 9 May 2024.

The board of directors will propose to the extraordinary shareholders' meeting of 8 May 2020 (or 9 June 2020 should the required attendance quorum not be reached at the first meeting) to renew the authorized capital.

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 corporate 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 2019, 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 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 17.5m credit contract dated 10 October 2017 entered into between KBC Bank NV, the Company and Biocartis NV (as amended), of which the change of control clause was approved by the annual shareholders' meeting held in 2018 and 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 EUR 10.0m credit contract dated 6 October 2017 entered into between BNP Paribas Fortis NV, the Company and Biocartis NV (as amended), of which the change of control clause was approved by the annual shareholders' meeting held in 2018 and whereby BNP Paribas Fortis NV is entitled, without the need 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 upon a substantial change in the shareholder structure of the borrowers that could affect the composition of the management bodies (and the persons entrusted with the management and daily management) 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 the change of control clause was approved by the special shareholders' meeting held on 27 September 2019 and 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. These plans are described in more detail in the Remuneration Report (see 'Characteristics of the share option plans').

4.7 / EXTERNAL AND INTERNAL CONTROL

EXTERNAL CONTROL

In 2019, the Company's statutory auditor was Deloitte Bedrijfsrevisoren CVBA, represented by Gert Vanhees. 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 statutory auditor has been reappointed for the statutory term of three years at the Company's annual shareholders' meeting held on 11 May 2018.

In 2019, a total amount of EUR 152,700 was paid to the statutory auditor. This amount includes the following elements: EUR 137,000 for audit fees, and EUR 22,324.5 for work performed in relation to legal mission work and other non-audit services 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 will 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.

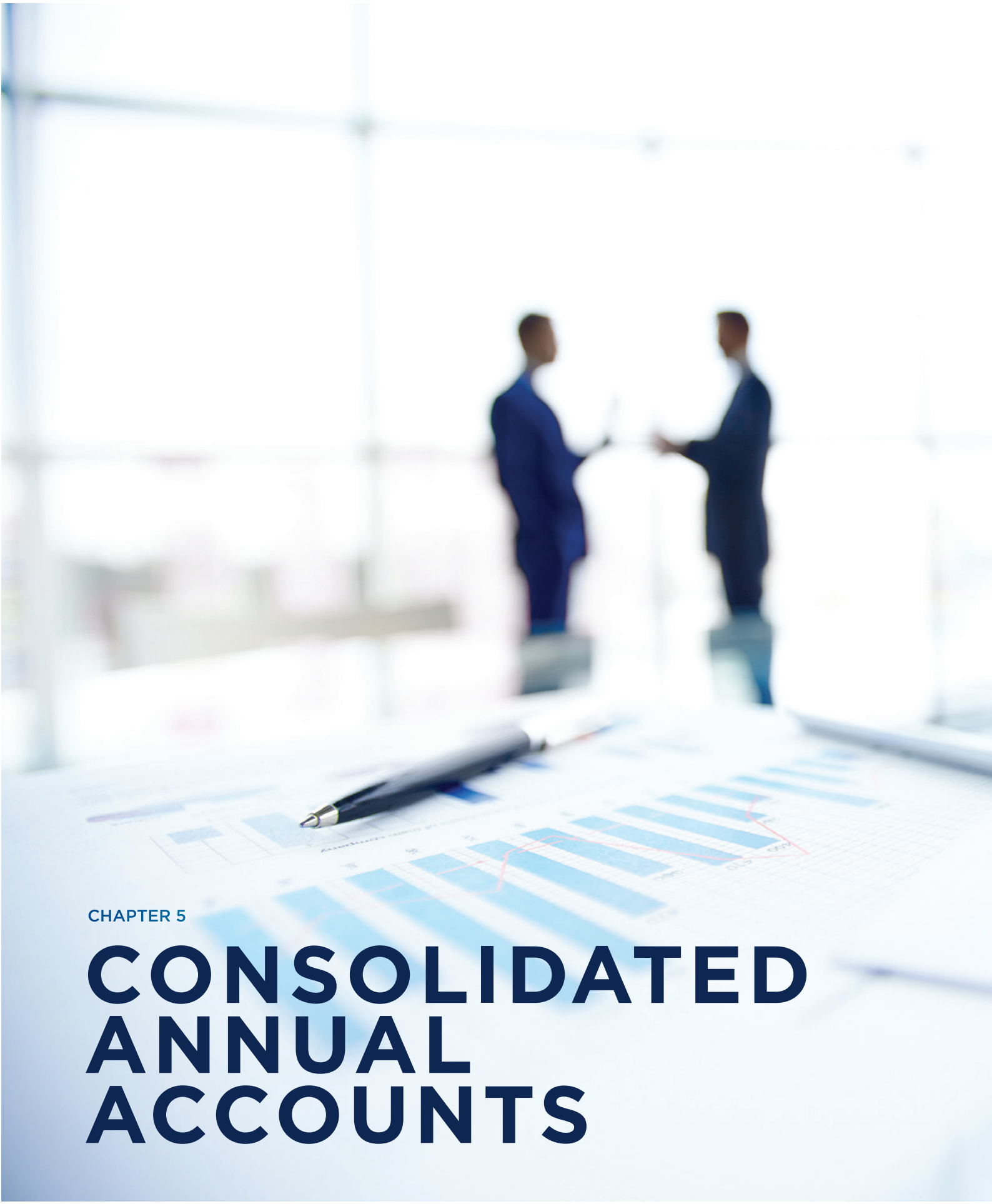
In order to ensure the quality and reliability of the financial information, Biocartis has established and is continuously improving and further automating its key standardized information flow processes, consistent throughout the organization. The most important financial processes are designed to ensure 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 'Products'.

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.



CHAPTER 5

CONSOLIDATED ANNUAL ACCOUNTS

5.1 / CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED 31 DECEMBER 2019 AND 2018

5.1.1. / CONSOLIDATED INCOME STATEMENT

In EUR 000	Notes	Years ended 31 December, 2019	2018
Collaboration revenue	5.2.4	12,451	8,329
Product sales revenue	5.2.4	24,224	18,843
Service revenue	5.2.4	769	639
Total revenue		**37,444**	**27,811**
Other operating income			
Grants and other income	5.2.5	288	840
Total operating income		**37,732**	**28,651**
Cost of sales	5.2.6	-21,328	-15,349
Research and Development expenses	5.2.7	-39,844	-36,842
Sales and Marketing expenses	5.2.8	-18,011	-15,349
General and Administrative expenses	5.2.9	-14,151	-7,971
Total operating expenses		**-93,334**	**-75,511**
Operating loss for the year		**-55,602**	**-46,860**
Financial expense	5.2.11	-8,008	-1,565
Other financial results	5.2.11	74	163
Financial result, net		**-7,934**	**-1,402**
Share in the results of associates		-631	0
Loss for the year before taxes		**-64,167**	**-48,262**
Income taxes	5.2.28	99	109
Loss for the year after taxes		**-64,068**	**-48,153**
Attributable to owners of the Company		-64,068	-48,153
Earnings per share			
Basic and diluted loss per share	5.2.12	-1,14	-0.94

5.1.2. / CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In EUR 000	Notes	Years ended 31 December, 2019	2018
Loss for the year		**-64,068**	**-48,153**
Other comprehensive income (loss), not to be reclassified to profit or loss:			
Re-measurement gains and losses on defined benefit plan	5.2.24	-171	-23
Income taxes on items of other comprehensive income		58	8
Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss:			
Exchange differences on translation of foreign operations		-113	123
Decrease in fair value of investment in associates		-5,052	
Total comprehensive loss for the year		**-69,346**	**-48,045**
Attributable to owners of the Company		-69,346	-48,045

5.1.3. / CONSOLIDATED STATEMENT OF FINANCIAL POSITION

In EUR 000	Notes	As of 31 December, 2019	2018
Assets			
Non-current assets			
Intangible assets	5.2.13	6,294	6,579
Property plant and equipment	5.2.14	43,421	30,391
Investment in associates	5.2.15	0	5,052
Investment in joint ventures	5.2.16	2,358	0
Other non-current receivables		13	11
Deferred tax assets	5.2.17	1,609	6,569
		53,695	**48,602**
Current assets			
Inventories	5.2.18	14,161	11,919
Trade receivables	5.2.19	10,695	9,744
Other receivables	5.2.19	8,640	3,751
Other current assets	5.2.20	2,407	1,830
Cash and cash equivalents*	5.2.21	178,725	63,539
		214,628	**90,783**
Total assets		**268,323**	**139,385**
Equity and liabilities			
Capital and reserves			
Share capital	5.2.22	-220,668	-220,718
Share premium	5.2.22	698,027	632,769
Share based payment reserve	5.2.23	4,670	3,445
Accumulated deficit	5.2.22	-397,550	-328,145
Total equity attributable to owners of the Company		**84,479**	**87,351**
Non-current liabilities			
Provisions	5.2.24	49	28
Borrowings and lease liabilities	5.2.25	24,000	30,221
Convertible debt	5.2.25	136,158	
Deferred income	5.2.27	461	6
Accrued charges	5.2.28	0	1,501
		160,668	**31,756**
Current liabilities			
Borrowings and lease liabilities	5.2.25	6,420	5,114
Trade payables	5.2.26	9,070	7,973
Deferred income	5.2.27	1,595	3,010
Other current liabilities	5.2.26	6,091	4,181
		23,176	**20,278**
Total equity and liabilities		**268,323**	**139,385**

*Cash and cash equivalents for 31 December 2019 include EUR 1.2m restricted cash related to KBC Lease financing

5.1.4. / CONSOLIDATED CASH FLOW STATEMENT

In EUR 000	Notes	Years ended 31 December, 2019	2018
Operating activities			
Loss for the year		-64,068	-48,153
Adjustments for			
Depreciation and amortization	5.2.13/5.2.14	9,719	4,273
Impairment losses	5.2.7/5.2.14	476	3,456
Income taxes in profit and loss	5.2.29	-99	109
Financial result, net	5.2.11	7,934	1,402
Net movement in defined benefit obligation	5.2.24	-150	-15
Share of net profit of associate and joint venture		631	
Share based payment expense	5.2.23	1,225	1,065
Other		37	-19
Changes in working capital			
Net movement in inventories	5.2.18	-3,858	-2,859
Net movement in trade and other receivables and other current assets	5.2.19/5.2.17	-1,182	-4,060
Net movement in trade payables & other current liabilities	5.2.26	1,507	2,893
Net movement in deferred income	5.2.27	-960	229
		-48,788	**-41,679**
Interests paid		-5,288	-215
Taxes paid	5.2.29	-178	-99
Cash flow used in operating activities		**-54,254**	**-41,993**
Investing activities			
Interests received		8	8
Acquisition of property, plant & equipment	5.2.14	-2,121	-5,571
Acquisition of intangible assets	5.2.14	-394	-257
Acquisition of investment in a joint venture	5.2.16	-2,989	
Cash flow used in investing activities		**-5,496**	**-5,820**
Financing activities			
Proceeds from the issue of a convertible bond		145,438	0
Net proceeds from the issue of ordinary shares, net of transaction costs	5.2.22	53,360	2,102
Repayment of borrowings	5.2.25	-23,738	-3,580
Bank charges		-37	-29
Cash flow from financing activities		**175,023**	**-1,507**
Net increase / (decrease) in cash and cash equivalents		**115,273**	**-49,320**
Cash and cash equivalents at the beginning of the year		63,539	112,765
Effects of exchange rate changes on the balance of cash held in foreign currencies		-87	94
Cash and cash equivalents at the end of the year*		**178,725**	**63,539**

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

5.1.5 / CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

		Attributable to owners of the Group						
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 2018		**-220,722**	**630,670**	**2,381**	**-45**	**-280,046**	**132,240**	**132,240**
Loss for the period						-48,153	-48,153	-48,153
Re-measurement gains and losses on defined benefit plan	5.2.24				-23		-23	-23
Consolidation translation difference						123	123	123
Total comprehensive loss					**-23**	**-48,030**	**-48,053**	**-48,053**
Share-based payment expense	5.2.23			1,064			1,064	1,064
Share issue - exercise of stock options on 5 April 2018	5.2.22	2	1,807				1,809	1,809
Share issue – exercise of stock options on 4 October 2018	5.2.22	1	239				240	240
Share issue – exercise of stock options on 20 December 2018	5.2.22	1	53				53	53
Other						-2	-2	-2
Balance as at 31 December 2018		**-220,718**	**632,769**	**3,445**	**-67**	**-328,078**	**87,351**	**87,351**
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	5.2.24				-171		-171	-171
Consolidation translation difference						-113	-113	-113
Other comprehensive income					-5,052		-5,052	-5,052
Total comprehensive income					**-5,223**	**-64,181**	**-69,404**	**-69,404**
Share-based payment expense	5.2.23			1,225			1,225	1,225
Share issue – private placement on 28 January 2019	5.2.22	50	55,450				55,500	55,500
Costs related to private placement on 28 January 2019	5.2.22		-2,311				-2,311	-2,311
Share issue - exercise of stock options on 4 April 2019	5.2.22	0	171				171	171
Issuance of convertible bond on 9 May 2019	5.2.25		11,948				11,948	11,948
Balance as at 31 December 2019		**-220,668**	**698,027**	**4,670**	**-5,291**	**-392,259**	**84,480**	**84,480**

5.2 / NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

5.2.1 / GENERAL INFORMATION

Biocartis Group NV, a company incorporated in Belgium with registered address at Generaal de Wittelaan 11 B, 2800 Mechelen, Belgium (the 'Company') and its subsidiaries (together, the 'Group') commercialize an innovative and proprietary molecular diagnostics ('MDx') platform that offers accurate, highly-reliable molecular information from virtually any biological sample, enabling fast and effective diagnostics treatment selection and treatment progress monitoring. The Group's mission is to become a global, fully integrated provider of novel molecular diagnostics solutions with industry-leading, high clinical value tests within the field of oncology. The Company has established subsidiaries in Mechelen (Belgium), New Jersey (US) and a joint venture in Hong Kong (China).

The consolidated financial statements have been authorized for issue on 4 March 2020 by the board of directors of the Company (the 'board of directors').

5.2.2 / SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

5.2.2.1 / STATEMENT OF COMPLIANCE

The consolidated financial statements of the Group for the year ended 31 December 2019 have been prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and as adopted by the European Union.

5.2.2.2 / BASIS OF PREPARATION

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

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

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

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

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

The Group has adopted the following new and revised standards and interpretations issued by the IASB that are relevant to its operations and effective for accounting periods beginning on 1 January 2019:

- IFRS 16 Leases
- IFRIC 23 Uncertainty over Income Tax Treatments
- Amendments to IAS 19 Plan Amendment, Curtailment or Settlement
- Amendments to IAS 28 Long term interests in Associates and Joint Ventures
- Amendments to IFRS 9 Prepayment Features with Negative Compensation
- Annual improvements to IFRS Standards 2015-2017 Cycle

IFRS 16 LEASES

IFRS 16 supersedes IAS 17 Leases and related interpretations. The standard sets out the principles for the recognition, measurement, presentation and disclosure of leases for lessees and lessors.

Lessees are required to account for all leases under a single on-balance sheet accounting model, eliminating the distinction between operating and finance leases. Therefore, IFRS 16 will have an impact on the Group's balance sheet as the Group's operating leases are to be recognized under property, plant and equipment. Lessor accounting under IFRS 16 is not substantially changed under IAS 17. Lessors will continue to classify leases as either operating or finance leases using similar principles as in IAS 17. Therefore, the accounting treatment of the e.g. Group's reagent rental agreements is not impacted.

The Group adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of 1 January 2019. Under this method, the standard is applied retrospectively, which means that comparatives will not be restated. Furthermore, The Group decided to use the modified B retrospective method, which means that the assets will be measured at an amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments. All lease liabilities were recognized on the balance sheet based on the present value of the remaining lease payments, discounted using the incremental borrowing rate at the date of initial application. The Group applied the following available practical expedients:

- No reassessment whether a contract is, or contains, a lease at the date of initial application;
- Leases for which the lease term ends within 12 months of the date of initial application will be considered as short-term leases. As such, the short-term lease exemption will be used;
- Lease contracts for which the underlying asset has a value in new of below EUR 5,000 are considered as low value leases and hence exempt from recognition;
- A single discount rate is applied to a portfolio of lease contracts with reasonable similar characteristics;
- Reliance on previous assessments on whether leases are onerous instead of performing an impairment review;
- Use hindsight in determining the lease term for contracts that contain options to extend or terminate the lease.

The impact on the consolidated statement of financial position of adopting IFRS 16 is as follows:

In EUR 000	As at 31 December 2019	As at 1 January 2019
Assets		
Right-of-use assets in PPE	31,077	35,133
Assets held under lease in PPE	-16,955	-20,796
Total assets	**14,123**	**14,336**
Liabilities		
Non-current lease liabilities	13,504	13,583
Current lease liabilities	2,244	2,228
Accrued charges	-1,474	-1,475
Total liabilities	**14,273**	**14,336**

The accrued charges in the table above, are related to deferred rental expenses that was recognized before the application of IFRS 16, and which is deducted from the right-of-use assets when applying IFRS 16.

The gross impact on the consolidated income statement of adopting IFRS 16 is as follows:

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

Based on the foregoing, as at 1 January 2019:

- Right-of-use assets of EUR 35.1m were recognized under property, plant & equipment; this includes the lease assets recognized previously under finance leases of EUR 20.8m that were reclassified from assets held under lease.
- Additional lease liabilities of EUR 15.8m (included in lease liabilities) were recognized.
- Accrued lease payments of EUR 1.5m related to previous operating leases were derecognized.

The lease liabilities as at 1 January 2019 can be reconciled to the operating and finance lease commitments as of 31 December 2018 as follows:

In EUR 000	
Operating lease commitments as at 31 December 2018	**14,070**
Weighted average incremental borrowing rate as at 1 January 2019	4.18%
Initial discounted operating lease commitments as 1 January 2019	**13,054**
Commitments relating to short-term & low-value assets	-201
Indexation effect	2,675
Other	283
Final discounted operating lease commitments as 1 January 2019	**15,811**
Finance lease liabilities recognized as at 31 December 2018	17,556
Payments in optional extension periods not recognized as at 31 December 2018	0
Lease liabilities as at 1 January 2019	**33,367**
Of which are:	
Current lease liabilities	6,018
Non-current lease liabilities	27,349
	33,367

The other new standards, as referred to above, 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 2019, are listed in note 5.2.35.

5.2.2.3 / CONSOLIDATION PRINCIPLES

The consolidated financial statements comprise the financial statements of the Company and entities controlled by the Company as at 31 December 2019.

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

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

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

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

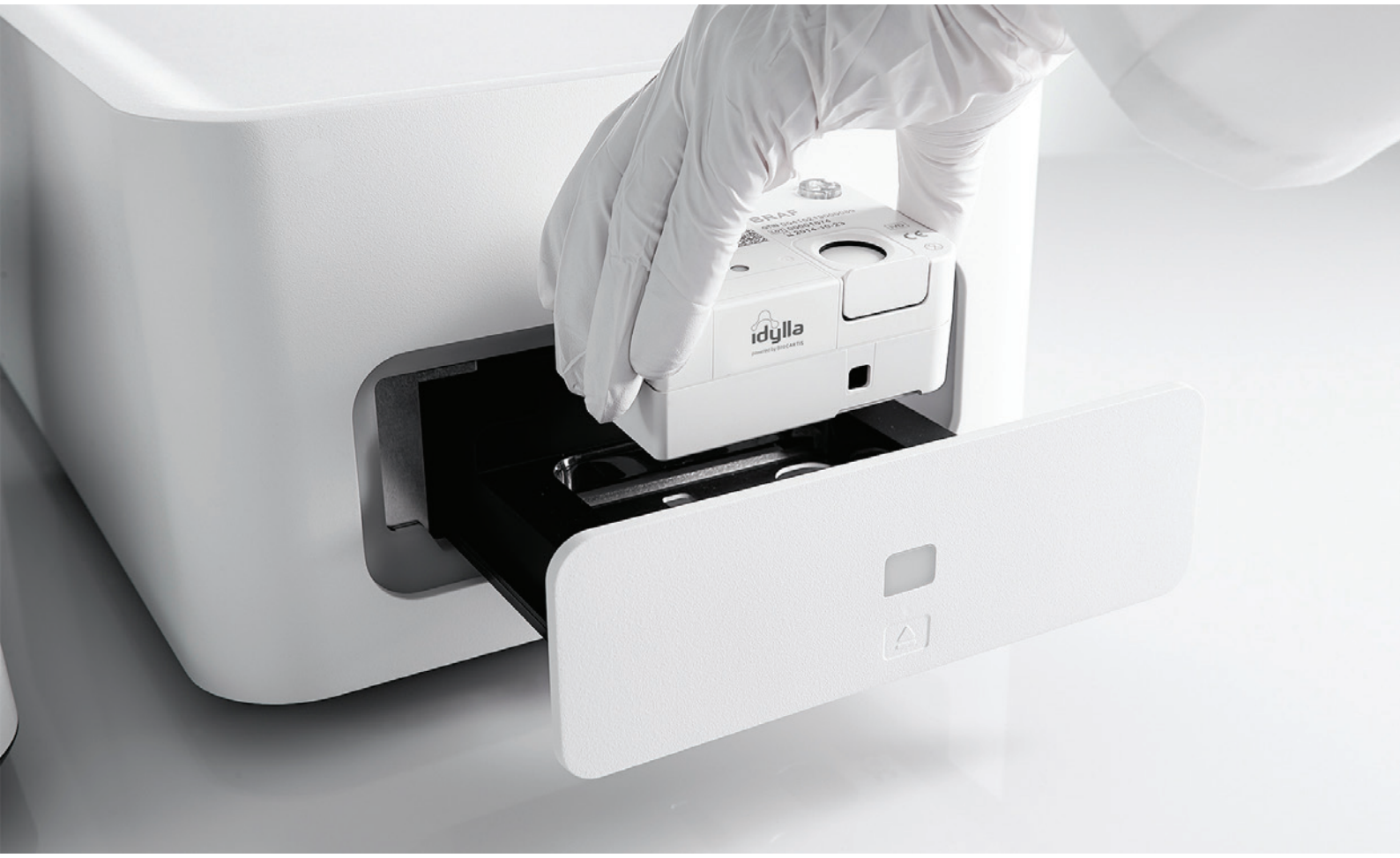
A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction. If the Group loses control over a subsidiary, it derecognizes the related assets (including goodwill), liabilities, non-controlling interest and other components of equity while any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

All transactions between Group companies have been eliminated upon consolidation.

5.2.2.4 / FOREIGN CURRENCY TRANSLATION

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

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



5.2.2.5 / JOINT VENTURES

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

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

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

5.2.2.6 / INTANGIBLE ASSETS

RESEARCH AND DEVELOPMENT COSTS

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

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

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

SEPARATELY ACQUIRED INTANGIBLE ASSETS

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

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

	ESTIMATED USEFUL LIFE
Patents	Patent life
Licenses	3 to 20 years
ICT, software	3 to 5 years

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

5.2.2.7 / PROPERTY, PLANT AND EQUIPMENT

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

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

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

The Company 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 Company and the cost of the item can be measured reliably, such as the replacement of an identified component of an asset.

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

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

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

The Company 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 Company estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's or cash-generating unit's (CGU) fair value less costs of disposal and its value in use.

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

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

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

5.2.2.9 / INVENTORY

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

Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

5.2.2.10 / FINANCIAL INSTRUMENTS

FINANCIAL ASSETS

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

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

Financial assets are initially measured at fair value. Transactions costs that are directly attributable to the acquisition of financial assets (other than financial assets at fair value through profit or loss) are added to the fair value of the financial assets, as appropriate, on initial recognition. Transactions costs directly attributable to the acquisition of financial assets at fair value through profit or loss are recognized immediately in profit or loss.

AT AMORTIZED COST

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

The effective interest method is a method of calculating the amortized cost of a debt instrument and of allocating interest income over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the debt instrument, or, where appropriate, a shorter period, to the net carrying amount on initial recognition. Trade and other receivables after and within one year are recognized initially at fair value and subsequently measured at amortized cost, i.e. at the net present value of the receivable amount, using the effective interest rate method, less allowances for impairment.

AT FAIR VALUE

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

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

DERECOGNITION

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

IMPAIRMENT OF FINANCIAL ASSETS

The Group assesses on a forward looking basis the expected credit losses associated with its financial assets carried at amortized cost. The impairment methodology applied depends on whether there has been a significant increase in credit risk. For trade receivables, the group applies the simplified approach permitted by IFRS 9 – Financial

Instruments, which requires expected lifetime losses to be recognized from initial recognition of the receivables. The amount of the allowance is deducted from the carrying amount of the asset and is recognized in the income statement.

FINANCIAL LIABILITIES

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

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

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

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

DERECOGNITION

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

CONVERTIBLE DEBT

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

EQUITY INSTRUMENTS

Equity instruments (e.g. share capital and employee warrant plans) issued by the Company 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.

5.2.2.11 / CASH AND CASH EQUIVALENTS

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

5.2.2.12 / INCOME TAXES

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

CURRENT TAX

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to calculate the amount are those that are enacted or substantively enacted, at the reporting date in the countries where the Group operates and generates taxable income.

DEFERRED TAX

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date. Deferred tax liabilities

are recognized for all taxable temporary differences, except when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

Deferred tax assets are recognized for all deductible temporary differences, the carry-forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profits will be available against which the deductible temporary differences, and the carry-forward of unused tax credits and unused tax losses can be utilized, except when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

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

R&D INVESTMENT TAX CREDITS

Current IFRSs have no specific accounting principles with respect to the treatment of investment tax credits as these are scoped out of IAS 20 Accounting for Government Grants and Disclosure of Government Assistance and IAS 12 Income Taxes. As a result, the Company 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 the company has not been able to offset the tax credit against the corporation tax for the last five consecutive tax years. Therefore in 2019, EUR 5.2m of the Company's tax credit on research and development has become a short term receivable.

5.2.2.13 / EMPLOYEE BENEFITS

SHORT-TERM EMPLOYEE BENEFITS

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

POST-EMPLOYMENT BENEFITS

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

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

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

Defined benefit costs are categorized as follows:

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

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

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

SHARE-BASED PAYMENT ARRANGEMENTS

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

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

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

5.2.2.14 / PROVISIONS

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

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

5.2.2.15 / REVENUE RECOGNITION

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

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

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

Transactions with customers and collaboration partners may include multiple deliverables (performance obligations). The Group evaluates whether the obligations towards its customers or collaboration partners are distinct on a stand-alone basis or in the context of the contract. If the Group determines that multiple performance obligations exist, the transaction price is allocated to each performance obligation based upon the best estimate of the stand-alone selling prices of each obligation.

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

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

COLLABORATION REVENUE

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

REAGENT RENTAL CONTRACTS

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

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

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

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

REGULAR RENTAL CONTRACTS

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

SERVICE REVENUE

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

5.2.2.16 / GRANTS

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

R&D GRANTS

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

INVESTMENT GRANTS

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

5.2.2.17 / LEASES

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

Biocartis as lessee with IFRS 16

The Group applies a single recognition and measurement approach for all lease, expect for short-term leases and leases of low-value assets. The Group recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

RIGHT-OF-USE ASSETS

The Group recognizes right-of-use assets at the commencement date of the lease (i.e. the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any re-measurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. If there is no reasonable certainty that the Group will obtain ownership by the end of the lease term, the right-of-use asset shall be fully depreciated over the shorter of the lease term and its useful life. The right-of-use assets are also subject to impairment, refer to the accounting policies in note 5.2.2.8.

LEASE LIABILITIES

The corresponding liability to the lessor is included in the consolidated balance sheet as a financial liability. At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of the lease payments to be made over the lease term. The lease payments include fixed payments less any lease incentives receivable, variable lease payments that depend on an index or a rate and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating the lease, if the lease term reflects the Group exercising the option to terminate. Variable lease payments that do not depend on an index or a rate are recognized as expenses in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is re-measured if there is a modification, a change in lease term, a change in the lease payments (e.g. changes to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset.

SHORT-TERM LEASES AND LEASES OF LOW-VALUE ASSETS

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

Biocartis as lessee before IFRS 16

Before the application of IFRS 16, the Group applied the accounting rules set out as follows. Assets held under financial leases are initially recognized as assets of the Group at their fair value or, if lower, at the present value of the minimum lease payments, each determined at the inception of the lease. Initial direct costs incurred in connection with the lease are added to the amount recognized as an asset. The corresponding liability to the lessor is included in the consolidated balance sheet as a financial liability. Lease payments are apportioned between financial charges and reduction of the lease liability so as to achieve a constant rate of interest on the remaining balance of the liability. Financial charges are charged directly in the income statement. If there is no reasonable certainty that the Group will obtain ownership by the end of the lease term, the asset shall be fully depreciated over the shorter of the lease term and its useful life. Payments made under operating leases are charged to the consolidated income statement on a straight-line basis over the period of the lease.

5.2.2.18 / BORROWING COSTS

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

5.2.3 / CRITICAL ACCOUNTING ESTIMATES, ASSUMPTIONS AND JUDGMENTS

5.2.3.1 / CRITICAL ACCOUNTING ESTIMATES, ASSUMPTIONS AND JUDGMENTS

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

CRITICAL JUDGMENTS

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 Company 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 Company 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 Company'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 Company 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 Company 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 Company.

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 5.2.2.7.

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

5.2.3.2 / 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 2019.

5.2.4 / REVENUE

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

In EUR 000	Years ended 31 December,			
	2019		2019	2018
	At a point in time	Over time		
Collaboration revenue				
R&D services	0	9,026	9,026	4,338
License fees	2,000	517	2,517	3,158
Milestones	908	0	908	833
	2,908	**9,542**	**12,451**	**8,329**
Product related revenue				
Idylla™ System Sales revenue	4,232	0	4,232	2,404
Idylla™ System Rental revenue	1,987	0	1,987	1,781
Cartridge revenue	18,004	0	18,004	14,658
	24,224	**0**	**24,224**	**18,843**
Service revenue				
Idylla™ System Service revenue	645	124	769	639
	645	**124**	**769**	**639**
Total	**27,777**	**9,666**	**37,443**	**27,811**

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

R&D service revenue is recognized over time as the services are rendered to the customer based on the progress over the activities i.e. a rato the services performed. Over the reporting period, the majority of the collaborations for which revenues were recognized, included a quarterly or monthly payment structure. Consequently, the Group recognized either an accrued income or deferred income on the balance sheet over the course of the reporting period.

In general, customers do not have a right-of return and/or are entitled to refunds in the context of product related sales.

The below table corresponds to the revenue expected to be recognized in the future relating to (partially) unsatisfied performance obligations. This table excludes potential future R&D service revenue of pending collaborations for which the associated services are performed on an hourly invoicing basis (IFRS 15.121).

The aggregate amount of the transaction price allocated to collaboration arrangements that are partially or fully unsatisfied as at 31 December 2019 is EUR 0.8m.

In EUR 000	Deferred income
2020	783
2021	24
2022	0
2023	0
2024	0
After 2024	0
Total	**807**

5.2.4.1 / 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 5.2.2.15.

AMGEN

Biocartis NV, a subsidiary of the Company, 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 the front of 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 2019.

EXACT SCIENCES

Biocartis and Exact Sciences (following the acquisition of Genomic Health, Inc.by Exact Sciences) have an exclusive agreement to develop an IVD version of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform which will provide Exact Sciences with exclusive worldwide rights to develop and commercialize its Oncotype DX Breast Recurrence Score® test on the Idylla™ platform, with the option to expand the collaboration to include additional tests in oncology and urology. Furthermore, Exact Sciences has certain urology field option rights for amongst others the development of urology tests on the Idylla™ platform. Payments by Exact Sciences to Biocartis will be made as certain developmental and commercial milestones will be achieved in the future. Upon commercialization of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform, Exact Sciences will make royalty payments to Biocartis based on net sales. Consequently, the elements included in this agreement consist of upfront license revenue, milestone revenue and R&D services as well as 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 several performance obligations: license to use IP, development activities, development services and the supply of Idylla™ assays.

- The transaction price is currently composed of a fixed part, being upfront fees, and a variable part, being development and commercial milestone payments, royalty payments and renewal fees. 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 obligation 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 start of the license period. Performance obligations relating to development activities and services are recognized over the estimated service period based on a pattern that reflects the transfer of the development activities. The milestone payments 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. The consideration received for initial first right period option is recognized straight-line over the option period as the services delivered by Biocartis in return for this first right period option are transferred over the option period. 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 over development components are transferred.

In 2019, the Group recognized milestone revenue, license fees, R&D service revenue and product related revenue in relation to the pending collaboration agreements with Exact Sciences. The recognized R&D service revenue mainly related to the billing of fixed amounts for each hour of service.

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 of which the objective is to register the Idylla MSI test as a companion diagnostic with the US FDA. The elements included in this CDx agreement 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.

WONDFO-CARTIS LTD. (JOINT VENTURE)

Biocartis and Wondfo Biotech HK Limited established a Hong Kong based joint venture for the commercialization of the Idylla™ platform in China. Both parties have made initial capital contributions to the joint venture. The joint venture entered into a license agreement with Biocartis in the context of the envisaged activities of the joint venture.

Based on the contractual dispositions, we assessed the following:

- The arrangement consists of the following performance obligations: license to use IP, 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 revenue based on the supply of Idylla™ assays and Idylla™ systems.
- 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 the supply of Idylla™ components are satisfied at a point in time, when the control over development components are transferred. Taking into consideration the 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 (IAS. 28.28).

In 2019, the Group has recognized license revenues (which was satisfied at a point in time) under the license agreement with the joint venture and product revenues.

5.2.4.2 / REVENUES BY MAJOR COUNTRIES AND CUSTOMERS

	Years ended 31 December,	
In EUR 000	2019	2018
Country of domicile	**756**	**765**
Belgium	756	765
Total all foreign countries, of which	**36,688**	**27,046**
United States of America	14,752	11,974
China	3,079	88
Spain	2,809	2,461
France	2,199	1,522
Rest of the world	13,850	11,002
Total	**37,444**	**27,811**

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

In 2019 there are no costumers representing at least 10% of the total recognized revenues, however the 5 largest clients together represent 33% of the revenue. In 2018 the Group did recognize revenues from two customers representing at least 10% of the total recognized revenues for EUR 7.3m.

5.2.5 / OTHER OPERATING INCOME

	Years ended 31 December,	
In EUR 000	**2019**	**2018**
R&D project support (IWT grants)	283	576
Other income	5	264
Total	**288**	**840**

Other operating income mainly consists out of grants that were awarded to support R&D activities. By the end of 2018 some grant programs ended and were fully recognized, for these grant programs no revenue was recognized in 2019.

5.2.6 / COST OF SALES

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

	Years ended 31 December,	
In EUR 000	**2019**	**2018**
Employee benefit expenses	-6,047	-4,573
Material, lab consumables & small equipment	-11,145	-7,302
Depreciation and amortization	-1,768	-1,302
Royalty expense	-1,290	-1,088
Facilities, office & other	-1,078	-1,084
Total	**-21,328**	**-15,349**

For the explanation on the increase of the cost of sales we refer to chapter 3, 'Business activities', 'Highlights and business review 2019'.

5.2.7 / RESEARCH & DEVELOPMENT EXPENSES

	Years ended 31 December,	
In EUR 000	**2019**	**2018**
Employee benefit expenses	-21,752	-19,671
R&D consultancy & subcontracting	-5,063	-4,540
Laboratory and cartridge costs	-2,355	-1,731
Quality, regulatory and intellectual property	-444	-636
Facilities, office & other	-1,509	-2,922
ICT	-1,333	-1,232
Travel, training & conferences	-742	-535
Depreciation and amortization	-6,645	-2,333
Impairment of assets	0	-3,242
Total	**-39,844**	**-36,842**

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 chapter 3, 'Business activities', 'Highlights and business review 2019'.

5.2.8 / SALES & MARKETING EXPENSES

In EUR 000	Years ended 31 December, 2019	2018
Employee benefit expenses	-11,126	-9,237
S&M consultancy & subcontracting	-1,259	-635
Sales and promotional expenses	-501	-420
Business development	-503	-697
Facilities, office & other	-854	-1,165
Travel, training & conferences	-2,701	-2,234
Depreciation and amortization	-810	-902
Impairment of receivables	-256	-59
Total	**-18,011**	**-15,349**

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 chapter 3, 'Business activities', 'Highlights and business review 2019'.

5.2.9 / GENERAL & ADMINISTRATIVE EXPENSES

In EUR 000	Years ended 31 December, 2019	2018
Employee benefit expenses	-8,778	-4,757
External advice	-927	-1,155
Facilities, office & other	-2,624	-816
Human resources	-1,027	-940
Travel, training & conferences	-444	-314
Depreciation and amortization	-351	11
Total	**-14,151**	**-7,971**

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 chapter 3, 'Business activities', 'Highlights and business review 2019'.

5.2.10 / EMPLOYEE BENEFIT EXPENSES

In EUR 000	Years ended 31 December, 2019	2018
Short term employee benefits	-45,509	-36,469
Post-employment benefit expenses	-471	-547
Termination benefits	-499	-157
Share-based payments	-1,225	-1,065
Total	**-47,704**	**-38,238**

Employee benefit expenses amounted to EUR 47.7m in 2019 compared to EUR 38.2m in 2018, a year-over-year increase of 25%. 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 2019	2018
Operations staff	120	119
Research and development staff	181	154
Marketing and sales staff	89	84
General and administrative staff	72	53
Total headcount	**462**	**410**
Average full time equivalents	465	394

5.2.11 / FINANCIAL INCOME AND EXPENSE

In EUR 000	Years ended 31 December, 2019	2018
Interest expense	-7,099	-1,358
Other financial expense	-401	-207
Total	**-7,500**	**-1,565**
Other financial result	-434	163
Total	**-434**	**163**
Financial result, net	**-7,934**	**-1,402**

Net financial expenses amounted to EUR 7.9m in 2019 compared to 1.4m in 2018 and included financial expenses in relation to the Company's convertible bond of EUR 5.7m (consisting of EUR 3.0m coupon payment and EUR 2.7m of debt appreciation), the Company's subordinated loan of EUR 1.1m and commitment fees for the multiple purpose credit lines.

5.2.12 / LOSS PER SHARE

The Company has stock option plans that may be settled in common shares of the Company 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 Company.

	Years ended 31 December,	
	2019	**2018**
Profit/loss for the period attributable to the owners of the Company (in EUR 000)	-64,068	-48,153
Weighted average number of ordinary shares for basic loss per share (in number of shares)	56,074,525	51,170,552
Basic loss per share (EUR)	**-1.23**	**-0.94**

5.2.13 / INTANGIBLE ASSETS

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

In EUR 000	**Patents and licenses**	**ICT software**	**Total**
Year ended 31 December 2018			
Opening carrying amount	10,018	249	10,267
Additions	200	57	257
Disposals	0	0	0
Disposal amortizations	0	0	0
Amortization expense	-558	-145	-702
Impairment	-3,242	0	-3,242
Closing carrying amounts	**6,419**	**161**	**6,579**
As at 31 December 2018			
Cost	11,992	1,629	13,621
Accumulated amortizations	-5,574	-1,468	-7,042
Carrying amount	**6,419**	**161**	**6,579**
Year ended 31 December 2019			
Opening carrying amount	6,419	161	6,579
Additions	300	94	394
Disposals	0	-1	-1
Disposal amortizations	0	0	0
Amortization expense	-567	-112	-679
Closing carrying amount	**6,151**	**143**	**6,294**
As at 31 December 2019			
Cost	12,292	1,722	14,014
Accumulated amortizations	-6,140	-1,580	-7,720
Carrying amount	**6,151**	**143**	**6,294**

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 2019 is EUR 5.0 (2018: EUR 5.5m). The remaining useful life is 9 years.

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

5.2.14 / PROPERTY, PLANT AND EQUIPMENT

The Group's property, plant and equipment comprise ICT equipment, laboratory equipment, manufacturing equipment, Idylla™ systems for internal use, furniture and fixtures, leasehold improvements, other property and equipment, equipment under construction, right-of-use assets and Idylla™ systems for rent. The carrying amounts 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
Year ended 31 December 2018												
Opening carrying amount	**499**	**618**	**854**	**2,687**	**407**	**979**	**225**	**17,099**	**265**	**2,566**	**0**	**26,199**
Additions	309	556	470	1,226	23	38	0	3,929	0	2,613	0	**9,164**
Disposals	-142	0	-55	-130	-22	0	-214	-638	0	-221	0	**-1,422**
Disposal depreciation	142	0	56	27	22	0	0	0	0	50	0	**297**
Depreciation charge of the period	-237	-369	-542	-1,217	-71	-392	-5	0	-283	-753	0	**-3,869**
Transfers gross carrying amount	0	0	0	0	0	0	0	-3,354	3,354	0	0	**0**
Transfers depreciations	0	0	0	0	0	0	0	0	0	0	0	**0**
Currency translation gross carrying amount	0	5	0	20	0	0	0	0	0	0	0	**25**
Currency translation depreciations	0	0	0	-3	0	0	0	0	0	0	0	**-3**
Closing carrying amount	**571**	**810**	**783**	**2,610**	**359**	**625**	**6**	**17,036**	**3,336**	**4,255**	**0**	**30,391**
As at 31 December 2018												
Cost	1,813	2,574	7,295	5,944	733	2,667	29	17,036	11,002	5,365	0	**54,458**
Accumulated depreciation	-1,242	-1,764	-6,512	-3,334	-374	-2,042	-23	0	-7,666	-1,110	0	**-24,067**
Carrying amount	**571**	**810**	**783**	**2,609**	**359**	**625**	**6**	**17,036**	**3,336**	**4,255**	**0**	**30,391**
Year ended 31 December 2019												
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	2,289	14,336	**16,626**
Additions	183	223	1,268	573	99	95	0	0	0	3,468	2,289	**5,909**
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**
Transfers 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**	**31,075**	**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**

The most significant addition to 'Property, plant and equipment' concerns the category 'Right-of-uses assets' and is related to the implementation of the new IFRS 16 standard, refer to note 5.2.2.2. Another large addition is related to the category 'Systems for Rent', which was driven to more operational reagent rentals placements.

The transfer from equipment under construction to manufacturing equipment and right-of-use assets is related to the second cartridge production line that became fully operational in 2019 and which was mainly funded for through lease financing.

The Right-of-use assets consist out of the following categories:

In EUR 000	As of 31 December 2019
Non-current assets	
Right-of-use assets - buildings	12,372
Right-of-use assets - manufacturing equipment	16,954
Right-of-use assets - cars	1,700
Right-of-use assets - office furniture	50
Total right-of-use assets	**31,076**

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

In EUR 000	For the year ended 31 December 2019
Depreciation expense per type right-of-use assets	
Buildings	1,739
Manufacturing equipment	2,482
Cars	752
Office furniture	15
Total depreciation expense	**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.

5.2.15 / 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.

5.2.16 / INVESTMENTS IN JOINT VENTURES

The Group holds an investment in one joint venture at the end of the reporting period:

Name of joint venture	Principal activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2019	2018
Wondfo-Cartis Ltd.	Commercialization	China	50%	0%

Wondfo-Cartis Ltd. was established in January 2019 for the commercialization of the Idylla™ platform. The Group's net investment amounted to EUR 2.4m. The joint venture is accounted for using the equity method in the consolidated financial statements as set out in the Group's accounting policies in note 5.2.2.5.

Summarized financial information of the joint venture is set out below. The summarized financial information below represents amounts in the joint venture's financial statements. They have been modified to reflect adjustments made by the entity when using the equity method, including fair value adjustments and adjustments for differences in accounting policy, but not adjusted for the Group's share. 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, 2019
Non-current assets	4,183
Current assets	4,971
Total assets	**9,154**
Non-current liabilities	0
Current liabilities	620
Total liabilities	**620**

Summarized statement of comprehensive income:

In EUR 000	Year ended 31 December, 2019
Operating income	156
Operating expenses	-1,526
Financial result, net	107
Income taxes	0
Result of the year	**-1,263**
Other comprehensive income	0
Total comprehensive income	**-1,263**
Share in total comprehensive income	**-631**

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 2018	**0**
Investments of the year	5,001
Share of the result of the year	-631
Share of the other comprehensive income	0
Dividends received	0
Elimination of unrealized gains and losses	-1,909
Foreign exchange differences	-103
As per 31 December 2019	**2,358**

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 has committed as of the date of this report to future capital contributions of EUR 2m.

5.2.17 / DEFERRED TAX ASSETS

Deferred taxes relate to the long-term portion of investment tax credit on research and development and amount to EUR 1.6m per 31 December 2019 (2018: EUR 6.6m). Recognized research and development tax credits in Belgium can be effectively repaid if the company has not been able to offset the tax credit against the corporation tax for the last five consecutive tax years. In 2019], EUR 5.2m of the Company's tax credit on research and development has become a short term receivable, see note 5.2.19.

	As of 31 December,	
In EUR 000	**2019**	**2018**
Tax credit research and development	1,594	6,559
Other	16	10
Total	**1,609**	**6,569**

5.2.18 / INVENTORIES

The inventory can be analyzed as follows:

	As of 31 December,	
In EUR 000	**2019**	**2018**
Inventory		
Raw materials	5,799	4,609
Semi-finished products	495	760
Finished products	7,867	6,550
Total	**14,161**	**11,919**
Amount recognized as an expense	**-21,328**	**-15,349**

Finished products include cartridges and systems held for expected commercialization, including systems placed under trial at customers under the Company's early adaptor program. As per 31 December 2019, EUR 1.0 m of the total inventory value was older than 12 months (2018: EUR 1.0m) for which EUR 0.3m impairment was recognized (2018: EUR 0.3m). It is the expectation that a significant part of the current inventory will be sold within the next 12 months.

5.2.19 / TRADE AND OTHER RECEIVABLES

Trade and other receivables can be analyzed as follows:

	As of 31 December,	
In EUR 000	**2019**	**2018**
Trade receivables	10,951	9,803
Allowance for doubtful receivables	-256	-59
Total	**10,695**	**9,744**

	As of 31 December,	
	2019	**2018**
VAT receivables	1,870	2,084
Tax credit research and development	5,242	223
Other receivables	1,528	1,444
Total	**8,640**	**3,751**

Trade receivables have increased from EUR 9.8m per 31 December 2018 to EUR 11.0m per 31 December 2019.

At the reporting date, the Group has approximately EUR 4.4m (2018: EUR 2.8m) trade and other receivables that were past due but were not impaired. In 2019 an allowance for doubtful receivables was recorded for EUR 0.3m (2018: EUR 0.6m) 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 2019 or 1 January 2019 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 5.2m (2018: EUR 0.2m) on research and development has been recognized in other receivables as this portion of the tax credit is to be received by the Company 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.

5.2.20 / OTHER CURRENT ASSETS

Other current assets can be analyzed as follows:

	As of 31 December,	
In EUR 000	**2019**	**2018**
Accrued grant income	347	192
Accrued collaboration income	627	169
Other accrued income	15	6
Deferred charges	1,419	1,464
Total	**2,407**	**1,830**

Other current assets include accrued income mainly related to Flemish government grants for EUR 0.3 m (2018: EUR 0.2m). The Group evaluates continuously if it fulfils the specific conditions as per specific grant agreements to justify that none of the grants receivables are to be impaired.

For more details on the revenues and collaboration agreements, please see note 5.2.4. Accrued partner income includes upfront payments from collaboration partners in relation to amongst others strategic licensing, development and/or commercialization collaborations.

	Accrued partner income
As per 31 December 2018	**169**
Invoiced	-1,047
Recognized in profit or loss	1,504
As per 31 December 2019	**627**

5.2.21 / CASH AND CASH EQUIVALENTS

The cash and cash equivalents can be analyzed as follows:

	As of 31 December,	
In EUR 000	**2019**	**2018**
Cash and cash equivalents		
Cash at bank and on hand	177,525	62,339
Total cash and cash equivalents	**177,525**	**62,339**
Total restricted cash	1,200	1,200
Total cash and cash equivalents for cash flow purposes	**178,725**	**63,539**

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.

5.2.22 / SHARE CAPITAL

ISSUED SHARE CAPITAL

As of 25 November 2014, the Company became the parent company and reporting entity of the Group. Previous to that date, Biocartis SA was the parent company and reporting entity.

The table below summarizes the share capital and the outstanding shares of the Company as at 31 December 2018 and 31 December 2019. 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 2017	**51,102,272**	**511**	**-221,232**	**-220,722**
Share issue - exercise of stock options on 5 April 2018	222,816	2		0
Share issue - exercise of stock options on 4 October 2018	29,500	1		64
Share issue - exercise of stock options on 20 December 2018	6,500	0		0
At 31 December 2018	**51,361,088**	**514**	**-221,232**	**-220,718**
Share issue - private placement 28 January 2019	5,000,000	50		50
Share issue - exercise of stock options on 4 April 2019	21,000	0		0
At 31 December 2019	**56,382,088**	**565**	**-221,232**	**-220,668**

The following capital transactions took place at the Company from 1 January 2019 until 31 December 2019:

- On 28 January 2019, the Company raised EUR 55,5m following a private placement, fully paid by an increase in share capital of EUR 0.05m and an increase in share premium of EUR 55.5m.
- On 4 April 2019, the Company raised EUR 0.2m following the exercise of 21,000 stock options. The amount is fully paid by an increase in share capital of EUR 0.0002m and an increase in share premium of EUR 0.17m.

VOTING RIGHTS

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

DIVIDENDS

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

5.2.23 / SHARE BASED PAYMENTS

The table below provides an overview of the movement in stock options since 1 January 2019:

		2008 Plan	2013 Plan	2015 Plan	2017 Plan	2018 Plan	Total
Total outstanding at 31 December 2017		**40,101**	**762,595**	**240,412**	**1,340,000**	**0**	**2,383,108**
Options granted	+	0	0	15,000	0	273,900	288,900
Options exercised	-	-21,000	-255,904	-2,912	0	0	-279,816
Options forfeited	-	0	-2,096	-2,512	0	1,000	-3,608
Options cancelled	-	0	0	0	0	0	0
Total outstanding at 31 December 2018		**19,101**	**504,595**	**249,588**	**1,340,000**	**274,900**	**2,388,184**
Options granted	+	0	0	0	0	278,550	278,550
Options exercised	-	0	-21,000	0	0	0	-21,000
Options forfeited	-	-19,101	-1,056	-40,370	0	-27,001	-87,528
Options cancelled	-	0	0	0	0	0	0
Total outstanding at 31 December 2019		**0**	**482,539**	**209,218**	**1,340,000**	**526,449**	**2,558,206**

2008 PLAN

The 2008 Plan is a non-dilutive stock option plan, implying that no new shares are issued upon the exercise of the respective stock options. The Company has signed shadow agreements with certain founders (shareholders) whereby, upon exercise of the stock options under the plan, these founders will transfer common shares held by them to the option holder.

In 2019, no warrants were exercised and 19,101 options were forfeited.

The key terms of the 2008 Plan are as follows:

- Options are granted for free
- Exercise price: CHF 4.14 (rounded)
- Option term: 10 years after the dates of the individual grants, expiry dates range between 2019 and 2020
- Vesting: time based vesting over 4 years (on a monthly basis; that is 1/48 per month)

The financial impact of the options granted under this plan is not material. The fair value of the options estimated by the Black-Scholes Merton model was EUR 0.1 per option.

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 2019.

In total 21,000 options were exercised in 2019 at an exercise price of EUR 8.1309 with a weighted average share price of EUR 11.80 at the moment of the exercise of the options. In 2019 1,056 options were forfeited. A total of 482,539 options are still outstanding per 31 December 2019 of which:

- 198,435 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

The weighted average remaining contractual life is 2.88 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 31/12/2019	0	0	0	0	19,881	171,875
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 2019, no options were granted and no options were exercised. In 2019 40,370 options were forfeited. A total of 209,218 options are still outstanding per 31 December 2019 and the weighted average remaining contractual life is 3.3 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 31/12/2019	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. No warrants were exercised nor were any warrants 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 (i.e., EUR 9.92),
- 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 assumptions:

	Grants December 2017
Number of warrants granted	1,340,000
Number of warrants not vested at 31/12/2019	865,975
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 2019, 278,550 warrants were granted. No warrants were exercised and 27,001 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 31/12/2019	133,562	97,500	76,228	65,000
Exercise price	EUR 11.95	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

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	2019	2018
Share based compensation	1,225	1,064
Total	**1,225**	**1,064**

5.2.24 / 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.

	Years ended 31 December,	
In EUR 000	**2019**	**2018**
Provisions for pensions and similar obligations	49	28
Total	**49**	**28**

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 2018	**28**
Service cost	471
Company contributions	-693
Actuarial gains/losses	243
As per 31 December 2019	**49**

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

	2019
Discount rate	1.30%
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:

	2019
Discount rate + 0.5%	28
Discount rate - 0.5%	-4

The plans assets are fully invested in assurance contracts with a guaranteed return, in terms of risk category these can be best described as bonds.

5.2.25 / FINANCIAL LIABILITIES

The financial liabilities can be analyzed as follows:

	Years ended 31 December,	
In EUR 000	2019	2018
PMV & FPIM loans	0	16,272
Lease liabilities	23,942	13,767
Bank borrowings	58	182
Convertible debt	136,158	0
Total non-current	**160,158**	**30,221**
PMV & FPIM loans	0	1,202
Lease liabilities	6,295	3,790
Bank borrowings	125	122
Total current	**6,420**	**5,114**
Total financial liabilities	**166,578**	**35,335**

The lease liabilities increased significantly due to the impact of IFRS 16, see note 5.2.2.2.
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 2019 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 2019 EUR 2.0m 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 1.865% and includes a purchase option of 1% of the financed amount. Per 31 December 2019 EUR 11.9m 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 2016, Biocartis NV and the Company also obtained a subordinated loan of EUR 15m provided by a consortium of PMV (Participatie Maatschappij Vlaanderen) and the Belgian 'Federal Holding and Investment Company' (FPIM). This loan carried a 7% interest (which is capitalized in the first three years) and had an initial maturity date a 30 September 2021 (except in case of extension of the loan upon the Company's request or voluntary or mandatory early repayment). In June 2019, this loan was fully redeemed based on the exercise of an early repayment option by Biocartis.

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 2019.

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%. As per 31 December 2019, EUR 0.7m has been withdrawn on this credit 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 135.7m per 31 December 2019.

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 2019, 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 2019.

The terms of the loans are summarized in the table below:

Loan	Year	Nominal amount (In EUR 000)	Secured (s) Non secured (s)	Interest rate	Maturity date
Lease company	2013	7,910	S	3.35%	31/05/2021
Lease company	2015	3,372	S	1.69%	1/12/2021
Bank	2015	600	S	1.93%	1/06/2021
Lease Company	2016	17,319	S	1.87%	1/12/2023
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, 2019		2018	
	Minimum lease payments	Present value of minimum lease payments	Minimum lease payments	Present value of minimum lease payments
Financial lease				
< 1 year	7,482	6,295	4,126	3,790
>1 and < 5 years	19,928	17,860	14,228	13,767
> 5 years	6,318	6,082	0	0
Total	**33,728**	**30,237**	**18,354**	**17,557**
Less interests	-3,250		-750	
Present value	**30,478**	**30,237**	**17,604**	**17,557**

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

In EUR 000	PMV & FPIM	Lease liabilities	Convertible debt	Bank
As per 31 December 2018	**17,474**	**17,556**	**0**	**305**
Changes from financial cash flows	-17,474	-6,142	133,490	-122
Changes arising from obtaining or losing control of subsidiaries or other business	0	0	0	0
Changes due to the effect of changes in FX rates	0	0	0	0
Changes in fair value	0	0	0	0
Accrued interest	0	0	2,668	0
Lease additions	0	18,823	0	0
As per 31 December 2019	**0**	**30,237**	**136,158**	**183**

Please see note 5.2.2.2 with respect to further details for lease liabilities such as interest expenses, expenses related to short term and low value leases and variable lease payments.

The Company's lease agreements do not include material restrictions or financial covenants.

5.2.26 / TRADE PAYABLES AND OTHER CURRENT LIABILITIES

	As of 31 December,	
In EUR 000	**2019**	**2018**
Trade payables	9,070	7,973
Total trade payables	**9,070**	**7,973**

	As of 31 December,	
In EUR 000	**2019**	**2018**
Provision vacation pay and end-of-year premium & other social debt	6,003	4,139
VAT payables	88	42
Other current liabilities	**6,091**	**4,181**

5.2.27 / DEFERRED INCOME

	Years ended 31 December,	
In EUR 000	**2019**	**2018**
Grants	859	987
Collaboration income	1,197	2,029
Total	**2,056**	**3,016**
Current	1,595	3,010
Non-current	461	6

For more details on the contract liabilities, we refer to note 5.2.4. Deferred partner income includes upfront payments from collaboration partners in relation to the strategic licensing, development and commercialization collaborations.

The deferred revenue per 31 December 2018 was EUR 2.0m, of which EUR 1.3m was recognized in revenue in 2019 and the remaining balance of EUR 0.7m is still outstanding and included in the deferred revenue balance of 31 December 2019.

	Deferred partner income
As per 31 December 2017	**1,574**
Invoiced	2,454
Recognized in profit or loss	-1,999
As per 31 December 2018	**2,029**
Invoiced	5,605
Recognized in profit or loss	-6,436
As per 31 December 2019	**1,197**

5.2.28 / ACCRUED EXPENSES

Accrued expenses primarily include accruals for rental charges.

5.2.29 / INCOME TAXES

5.2.29.1 / COMPOSITION OF TAX EXPENSE

	Years ended 31 December,	
In EUR 000	**2019**	**2018**
Current tax	-165	-112
Deferred tax	66	3
Income tax expense (profit) recognized in loss for the period	**-99**	**-109**

5.2.29.2 / TAX RECONCILIATION

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

	Years ended 31 December,	
In EUR 000	**2019**	**2018**
Loss before taxes	**-64,167**	**-48,262**
Income tax credit calculated at 29.58%	-18,981	-14,244
Effect of different tax rates	0	-76
Effect of income that is exempt from taxation	-4,631	-3,200
Effect of expenses that are non-deductible in determining tax profit	-169	566
Effect of unused tax losses and tax offsets not recognized as deferred tax assets	23,781	16,969
Effect of previously unrecognized and unused tax losses	0	0
Effect of tax credit for research and development	-311	-216
Effect of capital tax in Biocartis SA	178	103
Other	37	-8
	-96	**-106**
Adjustments recognized in the current year in relation to the current tax of prior years	-3	-3
Income tax expense (profit) recognized in loss for the period	**-99**	**-109**

5.2.29.3 / 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 341.1m (2018: EUR 309.0m). The tax losses of Biocartis NV for EUR 313.6m per 31 December 2019 (2018: EUR 254.1m) in Belgium will not expire as they can be carried forward indefinitely.

5.2.29.4 / RECOGNIZED DEFERRED TAX ASSETS

The Group has R&D tax credit carry-forwards in Belgium for a total amount of EUR 6.8m (2018: EUR 6.8m) for which a deferred tax asset of EUR 6.8m (2018: EUR 6.8m) has been recognized as the recognition criteria have been met as from 2014. Per 2019, EUR 5.2m of the total R&D tax credit has been classified as a current asset under 'other receivables'.

5.2.30 / FINANCIAL RISK MANAGEMENT

5.2.30.1 / 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.

5.2.30.2 / 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.

5.2.30.3 / 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 2019 and 2018.

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	2019	2018
Liabilities		
USD - United States	222	119
GBP - Great Britain	7	29
Assets		
USD - United States	3,487	3,565
GBP - Great Britain	372	98

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 2019 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 5.2.25. 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 2019, 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 2019. 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,					
	2019			2018		
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	9,070	6,668	6,091	7,972	5,114	4,181
1-3 years		11,804			24,351	386
3-5 years		156,113			5,870	360
5+ years		5,834			0	754
Total	**9,070**	**180,420**	**6,091**	**7,972**	**35,335**	**5,682**

The large increase in financial liabilities from EUR 35.3m in 2018 to EUR 180.4m in 2019 is related to the convertible bond on one hand and the implementation of IFRS 16.

5.2.31 / 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 2019 and 2018.

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 2019 and 2018.

Except for the borrowings (financial liabilities, see note 5.2.25), the carrying amount of the financial assets and liabilities approximate their fair values. The borrowings with a carrying amount of EUR 166.1m (2018: EUR 35.3m) have a fair value of EUR 165.3m (2018: EUR 35.1m).

5.2.32 / 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.

5.2.33 / COMMITMENTS

5.2.33.1 / 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 (2019: EUR 0.4m; 2018: EUR 0.6m). The group is also adding some office space for investments (lease hold improvements) will be made for EUR 0.3m (2018: EUR 0.6m). The Group had no other material commitments to capital expenditures on 31 December 2019.

5.2.33.2 / OPERATING COMMITMENTS

The Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 9.3m (2018: EUR 7.3m). It is expected that the majority of the commitments will be fulfilled in 2020.

5.2.33.3 / 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.

5.2.33.3.1 / REMUNERATION OF DIRECTORS AND MEMBERS OF THE EXECUTIVE MANAGEMENT

	Years ended 31 December,	
In EUR 000	**2019**	**2018**
Short-term employee benefits (salaries, social security bonuses and fringe benefits)	1,432	1,775
Post-employment benefits (Group insurance)	17	17
Share-based payment	841	762
Total	**2,290**	**2,554**

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 (2019: EUR 0.4m; 2018: EUR 0.6m). The group is also adding some office space for investments (lease hold improvements) will be made for EUR 0.3m (2018: EUR 0.6m). The Group had no other material commitments to capital expenditures on 31 December 2019.

5.2.33.3.2 / 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 2019	2,789	0	0	646	0	0
31 December 2018	0	0	0	0	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.

5.2.33.3.3 / SUBSIDIARIES

Details of the Company's subsidiaries at 31 December 2019 are as follows:

Name of subsidiary	Principal activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2019	2018
Biocartis NV	Develop and market diagnostic platforms	Generaal de Wittelaan 11 B 2800 Mechelen, Belgium	100%	100%
Biocartis US Inc.	Develop and market diagnostic platforms	2500 Plaza, 25th Floor, Suite 2547 Jersey City, NJ 07311 USA	100%	100%

There are no significant restrictions on the ability to access or use assets, and settle liabilities, of the Group, except for the debt service reserve account which is held as a security for the lease of the Idylla™ cartridge manufacturing line. This debt service reserve account has a carrying value of EUR 1.2m and is reflected under cash and cash equivalents.

5.2.34 / EVENTS AFTER THE BALANCE SHEET DATE

Seven important events were announced after the reporting date:

- **Achievement 2019 key business objectives** – On 9 January 2020, Biocartis announced to have achieved its latest key business objectives for 2019.
- **Partnership AstraZeneca** – On 22 January 2020, Biocartis announced that it entered into a master collaboration agreement with AstraZeneca, a global science-led biopharmaceutical company (LON/STO/NYSE: AZN). The scope of the new master collaboration agreement enables collaborative development and commercialization projects between Biocartis and AstraZeneca, such as but not limited to, CDx development projects that may cover any type of indication or biomarker. The first project to be initiated in that context is 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.
- **CFO resignation** – On 27 January 2020, Biocartis announced that Ewoud Welten, the Company's Chief Financial Officer ('CFO'), has decided to resign from Biocartis and to pursue an opportunity in the Netherlands, closer to his home and family. Biocartis has initiated a selection process to recruit a new CFO.
- **Limitation of the Executive Committee** – It has been decided that going forward the Company's executive management will be composed of the Chief Executive Officer (CEO), the Chief Financial Officer (CFO) and the Chief Operational Officer (COO).
- **New project under BMS immuno-oncology collaboration** – On 5 March 2020, Biocartis announced a new project under its existing immuno-oncology collaboration with Bristol-Myers Squibb Company. The new project pursues the registration of the Idylla™ MSI test as a companion diagnostic test in metastatic colorectal cancer in the People's Republic of China.

- **Impact COVID-19 outbreak** – On 5 March 2020, Biocartis announced its 2019 results and 2020 outlook. The outlook for 2020 assumes a moderate impact of the ongoing worldwide COVID-19 outbreak as well as a stabilization of the situation around the April 2020 time frame.

- **Co-commercialization SeptiCyte® RAPID Test on Idylla™ (CE-IVD) and update COVID-19 impact** – Biocartis announced on 26 March 2020 the expansion of its partnership with Immunexpress Pty Ltd ('Immunexpress') 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 Test, while Immunexpress will lead commercialization of the SeptiCyte® RAPID Test in the US. Furthermore, the Company announced in the context of the COVID-19 pandemic to expect that the current prolonged measures taken in many countries across the globe to contain the spreading of COVID-19 may potentially impact its 2020 outlook which initially assumed a normalization of activities around the April 2020 timeframe. The Company is monitoring the situation closely and will provide more information in due course.

There were no further important events between 31 December 2019 and the approval date of this annual report.

5.2.35 / RELEVANT STANDARDS AND INTERPRETATIONS PUBLISHED, BUT NOT YET APPLICABLE FOR THE ANNUAL PERIOD BEGINNING ON 1 JANUARY 2019

- Amendments to IAS 1 and IAS 8 Definition of Material (applicable for annual periods beginning on or after 1 January 2020)

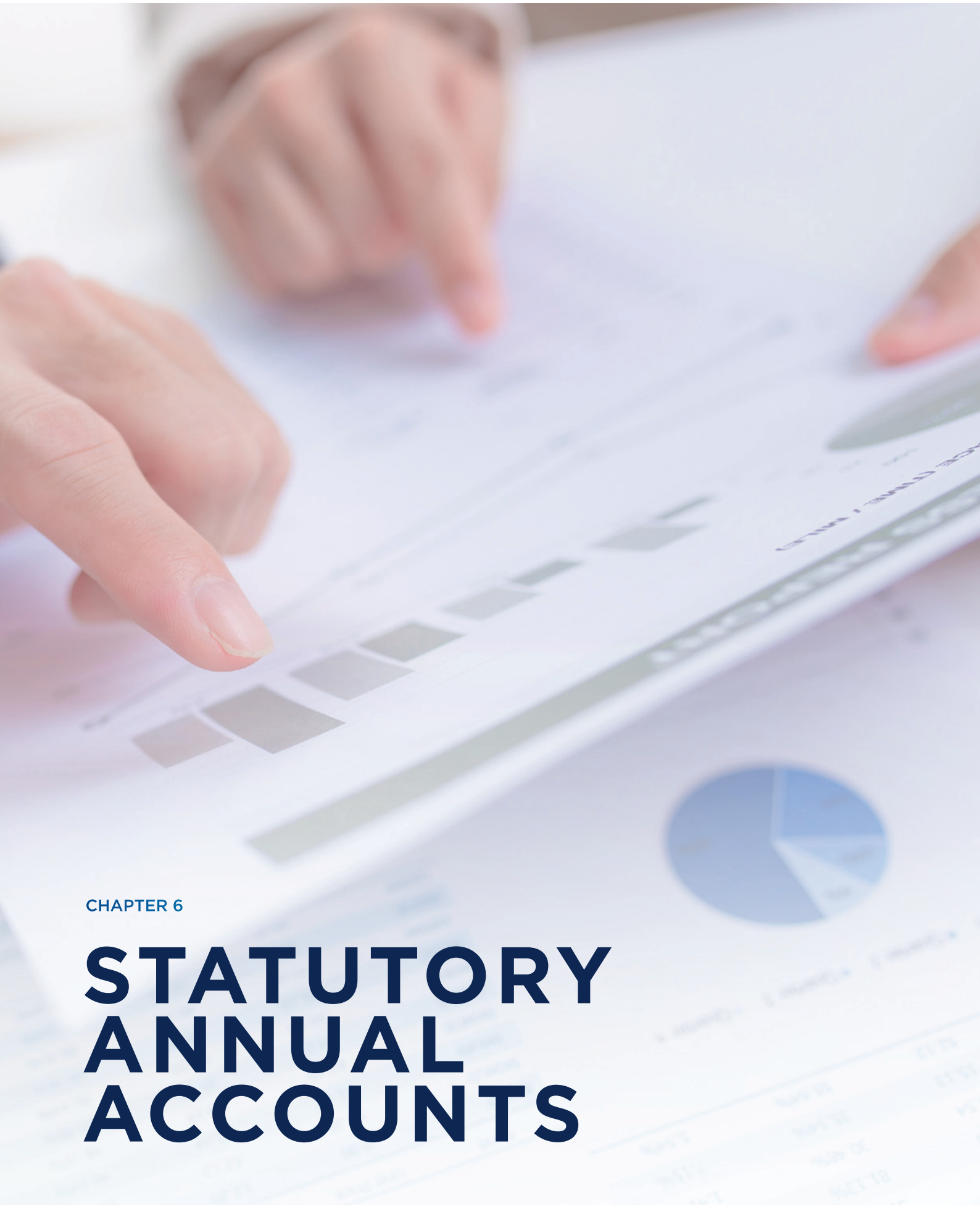
- Amendments to IFRS 3 Business Combinations (applicable for annual periods beginning on or after 1 January 2020, but not yet endorsed in the EU)

- Amendments to IFRS 9, IAS 39 and IFRS 7 Interest Rate Benchmark Reform (applicable for annual periods beginning on or after 1 January 2020)

- Amendments to references to the Conceptual Framework in IFRS standards (applicable for annual periods beginning on or after 1 January 2020)

- IFRS 17 Insurance Contracts (applicable for annual periods beginning on or after 1 January 2021, but not yet endorsed in the EU)

The Company currently beliefs that the above mentioned standards will not have a material impact on the consolidated financial statements of the Group.



CHAPTER 6

STATUTORY ANNUAL ACCOUNTS

6.1 / 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 Gert Vanhees, 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).

6.2 / 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.

6.3 / INCOME STATEMENT AND BALANCE SHEET BIOCARTIS GROUP NV

6.3.1 / INCOME STATEMENT

	Years ended 31 December,	
In EUR 000	**2019**	**2018**
Revenues	5,612	4,436
Other operating income	51	50
Total operating income	**5,663**	**4,486**
Services and other goods	-2,186	-1,426
Salaries, social security contributions and pensions	-3,683	-2,909
Other operating expenses	-4	-800
Operating expenses	**-5,873**	**-5,135**
Financial income	2,695	2,158
Financial expenses	-93,526	-1,218
Result from continuing operations	**-91,041**	**291**
Income taxes	27	0
Net result	**-91,014**	**291**

6.3.2 / BALANCE SHEET

In EUR 000	As of 31 December, 2019	2018
Financial fixed assets	450,116	235,933
Non-current assets	**450,116**	**235,933**
Trade receivables	0	0
Other receivables	8,777	200,032
Cash and cash equivalents	125,116	49,495
Deferred charges	41	17
Current assets	**133,934**	**249,545**
Total assets	**584,050**	**485,478**
Share capital	564	514
Share premium	535,301	479,680
Accumulated deficit	-104,071	-13,057
Total equity	**431,794**	**467,137**
Financial liabilities	150,000	16,272
Non-current liabilities	**150,000**	**16,272**
Financial liabilities	0	1,202
Trade payables	726	499
Provision taxes	0	16
Salaries, social security contributions and pensions	645	352
Accrued charges	885	0
Current liabilities	**2,256**	**2,069**
Total equity and liabilities	**584,050**	**485,478**

6.4 / DISCUSSION OF STATUTORY ACCOUNTS

6.4.1 / INCOME STATEMENT

Total operating income in 2019 amounted to EUR 5.7m (2018: EUR 4.5m) and consists mainly of expense recharges to the Biocartis Group NV subsidiaries. Operating expenses recorded in the period under review amounted to EUR 5.9m (2018 EUR 5.1m) and consist of salaries, social security contributions and pensions expenses for EUR 3.7m (2018: EUR 2.9m) and of expenses for services and other goods of EUR 2.2m (2018: EUR 1.4m). Services and other goods mainly consist of recurring general and administrative expenses.

Financial income amounted to EUR 2.7m (2018: EUR 2.2m) 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 93.5m (2018: EUR 1.2m) and relates to impairment losses on financial fixed assets, whereof EUR 5.0m was driven due to the full impairment that was taken on the Company's participation in MyCartis as a consequence of changed activities of MyCartis and realized valuation levels of recent capital increases. The financial expenses also contain EUR 76.8m which is related to the impairment of the Company's participation in Biocartis SA, due to the liquidation of Biocartis SA in 2019. The financial expenses also contains non-recurring expenses made in relation of the issuance of the convertible bond in May 2019 of EUR 4.3m and interest expenses related to this convertible bond of EUR 3.9m. The interest charges on the PMV & FPIM loan amounted to EUR 1.0m in 2019 (2018: EUR 1.2m).

The net result after taxes for the period ended 31 December 2019 amounts to EUR -91.0m (2018: EUR 0.3m).

6.4.2 / BALANCE SHEET

6.4.2.1 / ASSETS

The financial fixed assets consist of shares in the Biocartis Group NV subsidiaries for EUR 445.1m (Biocartis NV and Biocartis US Inc.) and of the China joint venture for EUR 5.0m. In 2018, Biocartis Group NV held a participation in Biocartis SA and not in Biocartis NV. Biocartis SA held a participation in Biocartis NV, due to the liquidation of Biocartis SA in 2019 the participation in Biocartis NV was transferred to Biocartis Group NV.

Other receivables amounted to EUR 8.8m (2018: EUR 200.0m) and mainly relate to receivables on the Biocartis Group NV subsidiaries, mainly related to financial advances. Cash and equivalents amounted to EUR 125.1m per 31 December 2019 (2018: EUR 49.5m). Deferred charges relate to prepaid expenses.

6.4.2.2 / EQUITY

Total equity per 31 December 2019 amounted to EUR 431.8m (2018: EUR 467.1m) and the legal share capital and share premium amount to respectively EUR 0.6m (2018: EUR 0.5m) and EUR 535.3m (2018: EUR 479.7m).

Following movements in equity were recorded during the reporting period:

- Capital increase by a private placement of 28 January 2019 for an amount of EUR 0.05m. The share premium account was increase with EUR 55,5m.
- Capital increase following the execution of stock options of 4 April 2019 for an amount of EUR 0.0002m. The share premium account was increased with EUR 0.17m.

6.4.2.3 / FINANCIAL LIABILITIES

In 2016, Biocartis Group NV obtained a loan of EUR 15m provided by a consortium of PMV (Participatie Maatschappij Vlaanderen) and the Belgian 'Federal Holding and Investment Company' (FPIM). Both PMV and FPIM granted a loan of EUR 7,5m each, bearing interest rate of 7% (which is capitalized in the first three years) and with a maturity date at 30 September 2021. In June 2019, this loan was fully redeemed based on the exercise of an early repayment option by Biocartis.

On 9 May 2019, Biocartis Group NV issued a convertible bond of EUR 150m, with a maturity date of 9 May 2024 and a coupon of 4%.

6.4.2.4 / OTHER LIABILITIES

As per 31 December 2019, trade payables amounted to EUR 0.7m (2018: EUR 0.5m), payables for salaries, social security contributions and pensions to EUR 0.6m (2018: EUR 0.4m) and transitory accounts to EUR 0.9m which mainly includes accrued interests for the interest coupon payment of the convertible bond.

6.4.2.5 / TOTAL ASSETS AND LIABILITIES

Total assets and on the other hand total liabilities amounted per 31 December 2019 to EUR 584.1m (2018: EUR 486.3m).

6.5 / APPROPRIATION OF RESULTS

The statutory accounts of the Company reported a net loss of EUR 91.0m for the year 2019. The Board of Directors proposes to carry forward the statutory net loss of EUR 91.0m of 2019 to the following financial year.

6.6 / 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 2019 as well as the expectations for 2020, 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 2021, and thus that the application of the valuation rules going concern is justified.

CHAPTER 7

AUDITOR'S REPORT

BIOCARTIS GROUP NV

STATUTORY AUDITOR'S REPORT TO THE SHAREHOLDERS' MEETING FOR THE YEAR ENDED 31 DECEMBER 2019 – CONSOLIDATED FINANCIAL STATEMENT

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 5 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 2019, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flow 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 268 323 (000) EUR and the consolidated statement of comprehensive income shows a loss for the year then ended of 64 068 (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 2019 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 2019 amounts to 37 444 KEUR and mainly consists of: → Product related revenues (24 224 KEUR) including various combinations of instruments and cartridges in multiple element sales agreements, operational reagent rental agreements and rental agreements; and → Collaboration revenues (12 451 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. The determination of revenue recognition for 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. The company's disclosures about revenue is included in note 5.2.2.15 Revenue recognition and 5.2.4 Revenue of the consolidated financial statements.	We considered the appropriateness of the Group's revenue recognition principles in accordance with the applicable IFRS standard. We obtained an understanding of the underlying processes and preventive and detective internal controls. We read the relevant agreements to assess whether the company correctly applied the Group's revenue recognition principles and we challenged the reasonableness of the judgements made by Management in determining the relevant assumptions utilized in calculating recognized revenue. We consulted with our IFRS specialists on aspects of the revenue recognition model that were particularly complex or judgmental in nature. 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

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[1].

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 governance 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.

[1] It is a copy of the text available in article 3:75 of the Code of companies and associations. We are aware of the inconsistency between the French version (referring to "l'étendue du contrôle legal") and the Dutch version (referring to "de wettelijke controle"). It has been decided however to stick to the text as provided by law. For the English version, we have opted to align the translation based on the French version.

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.

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, as well as to report on this matter.

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

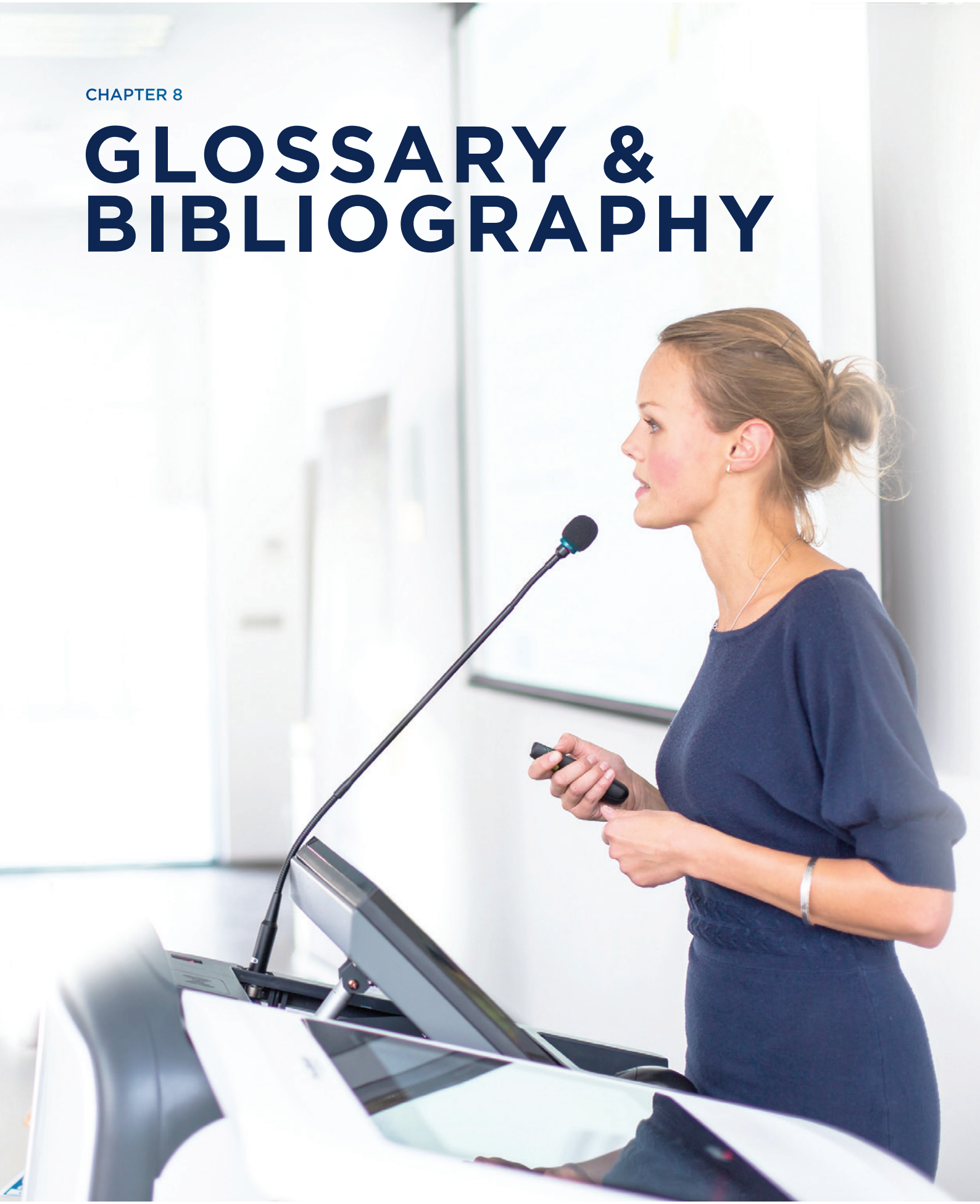
This report is consistent with our additional report to the audit committee referred to in article 11 of Regulation (EU) N°537/2014

Zaventem, 31 March 2020
The statutory auditor

DELOITTE BEDRIJFSREVISOREN/RÉVISEURS D'ENTREPRISES CVBA/SCRL
REPRESENTED BY GERT VANHEES

CHAPTER 8

GLOSSARY & BIBLIOGRAPHY



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.
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.
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.

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.
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.
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 antibodies produced by the bodies, which are detected by means of HCV or HIV antigens.
INFLUENZA	Also known as 'the flu' is a highly contagious respiratory tract infection caused by the family of influenza viruses.
IN VITRO DIAGNOSTICS OR IN VITRO DIAGNOSIS (IVD)	IVD is a diagnostic test outside of a living body in contrast to "in vivo", in which tests are conducted in a living body (for example an X-ray or CT-scan).
INVESTIGATIONAL USE ONLY (IUO)	An Investigational Use Only (IUO) product is an IVD product, in the testing phase of product development that is being shipped or delivered for product testing prior to full commercial marketing.
KIRSTEN RAT SARCOMA-2 VIRUS ONCOGENE (KRAS)	KRAS is a protein that, in humans, is encoded by the KRAS gene. Like other members of the Ras family, the KRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyse guanosine triphosphate), and is an early player in many signal transduction pathways. The protein product of the normal KRAS gene performs an essential function in normal tissue signalling, and the mutation of a KRAS gene is associated with the development of many cancers.
KOL	Key Opinion Leader.
MANUFACTURER	Natural or legal person responsible for the design, manufacture, fabrication, assembly, packaging or labelling of a medical device, for assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on their behalf by a third party.
MDSAP (MEDICAL DEVICE SINGLE AUDIT PROGRAM)	The MDSAP allows medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program's main mission is to "...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."

MEDICAL DEVICE	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of - diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of or compensation for an injury, - investigation, replacement, modification, or support of the anatomy or of a physiological process, - supporting or sustaining life, - control of conception, - disinfection of medical devices, - providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
METASTATIC COLORECTAL CANCER (mCRC)	Colorectal Cancer (CRC) is the second most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually. According to the International Agency for Research on Cancer, an estimated 694,000 deaths from CRC occur worldwide every year, accounting for 8.5% of all cancer deaths and making it the fourth most common cause of death from cancer.
MOLECULAR DIAGNOSTICS (MDx)	MDx is a form of diagnostic testing used to detect specific sequences in DNA or RNA that may or may not be associated with disease. Clinical applications of MDx include infectious disease testing, oncology, pharmacogenomics and genetic disease screening.
MICRO SATELLITE INSTABILITY (MSI)	MSI is a genetic hyper-mutability condition resulting from MMR that is functioning abnormally.
MULTIPLEXING	The simultaneous detection of more than one analyte or biomarker from a single sample.
NEUROBLASTOMA RAS VIRAL (V-RAS) ONCOGENE (NRAS)	NRAS is a protein that is encoded, in humans, by the NRAS gene. Like other members of the Ras family, the NRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyse guanosine triphosphate), and is an early player in many signal transduction pathways. The protein product of the normal NRAS gene performs an essential function in normal tissue signaling, and the mutation of a NRAS gene is associated with the development of many cancers.
NEXT-GENERATION SEQUENCING (NGS)	Sequencing is the process of determining the precise order of nucleotides within a DNA molecule. It includes any method or technology that is used to determine the order of the four bases—adenine, guanine, cytosine, and thymine—in a strand of DNA. The high demand for low-cost sequencing has driven the development of high-throughput sequencing technologies that parallelize the sequencing process, producing thousands or millions of sequences concurrently. High-throughput sequencing technologies are intended to lower the cost of DNA sequencing beyond what is possible with standard dye-terminator methods.
PERFORMANCE STUDY	Performance study means a study undertaken to establish or confirm the analytical or clinical performance of a device.
POLYMERASE CHAIN REACTION (PCR)	The specific and exponential amplification of DNA sequences by consecutive thermal cycling steps. Real-time PCR is a form of PCR whereby the amplified sequences are made visible by means of fluorescent labelling in real time, i.e., as they become synthesized. Real-time PCR can be used to estimate the quantity of target DNA sequences in a multiplexed way. PCR and real-time PCR can also be used to detect and quantify RNA sequences after a DNA copy has been made from the RNA sequence by means of a reverse transcriptase enzyme.
PROTEIN	Polypeptide chain built from the 20 natural amino acids. Proteins are synthesized from a messenger RNA copy of a gene and can have many functions in the cytoskeleton of the cell, enzymatic, messenger functions in cells and blood such as immune cytokines, DNA binding proteins that regulate expression, etc.

PROTOTYPE	(First) materialization of the intended product.
REGULATORY AUTHORITY	A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and can take legal action to ensure that medical devices marketed within its jurisdiction comply with legal requirements.
RESPIRATORY SYNCYTIAL VIRUS (RSV)	RSV is a major cause of lower respiratory tract infection that is a frequent infection in children.
RESEARCH USE ONLY (RUO)	This is a category of non-approved (i.e. no CE-marking and FDA approval) medical device products that can solely be used for research purposes. Many producers introduce their products first as RUO and/or IUO products, prior to obtaining 510(k) clearance or PMA approval.
RIBONUCLEIC ACID (RNA)	RNA, like DNA, is a nucleic acid molecule. RNAs have a variety of different functions in living cells. They can have a scaffolding role in the build-up of complexes (ribosomes, SNRPs), provide sequence recognition (translation, RNA spicing), have catalytic function (ribozymes), act as messengers for protein synthesis (mRNAs), regulate gene expression (miRNAs) or make up the genome of certain viruses.
RoW	RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan.
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.
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 mutationns 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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[1] Average FTE equals sum of the day-to-day FTE divided by the number of days. This average FTE is calculated on calendar year basis (January-December)

[2] Announced post-period. On 7 January 2019, Biocartis announced to have signed an agreement with Nichirei Bioscience, a leading supplier of biological and diagnostics products in Japan, for the product registration and exclusive distribution of Biocartis' molecular diagnostic (MDx) oncology tests in Japan, operating on the fully automated sample-to-result Idylla™ platform

[3] RUO = Research Use Only, not for use in diagnostic procedures

[4] Van Cutsem et al. (2016) ESMO Consensus Guidelines for the management of patients with mCRC. Annals of Oncology 27, 1386; NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Colon Cancer V.2.2018. Accessed 25 July 2018. To view the most recent and complete version of the guidelines, go online to NCCN.org; NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Rectal Cancer V.2.2018. Accessed 25 July 2018. To view the most recent and complete version of the guidelines, go online to NCCN.org; NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Uterine Neoplasms V.2.2018. Accessed 25 July 2018. To view the most recent and complete version of the guidelines, go online to NCCN.org

[5] The European Society for Medical Oncology ('ESMO') congress that took place between 27 September and 1 October 2019 in Barcelona (Spain)

[6] The American Society of Clinical Oncology ('ASCO') Annual Meeting took place between 30 May and 4 June 2019 in Chicago (IL), US

[7] The Association for Molecular Pathology ('AMP') conference took place between 7 and 9 November 2019 in Baltimore, Maryland, US

[8] Nichirei Biosciences Inc. is a leading supplier of biological and diagnostic products in Japan

[9] Source: ASCO guidelines, www.asco.org/endorsements/HereditaryCRC

[10] Including insertions and deletions in exon 18, 19, 20 and 21 in the EGFR gene

[11] See product labelling on https://www.yervoy.com

[12] Treatment with fluoropyrimidine, oxaliplatin and irinotecan

[13] Genomic Health was acquired by Exact Sciences Corp. (NASDAQ: EXAS) on 8 November 2019

[14] In June 2017, Biocartis announced a partnership with LifeArc to develop selected molecular diagnostic tests for use on the Idylla™ platform. 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. More info on www.biocartis.com/partners

[15] Formalin fixed, paraffin embedded

[16] Huang et al. J Mol Diagn. 2019 Sept

[17] The use of the Idylla™ ctKRAS Mutation Assay directly on pancreatic cyst fluid was researched as a solution for direct, rapid KRAS mutation testing, which is especially helpful in cases where cellular content and fluid volume of pancreatic cysts are suboptimal for other routine testing (Al-Turkmani M et al. Pancreatic cyst fluid harboring a KRAS mutation. Cold Spring Harb Mol Case Study 5.(2) Apr 2019. Available online on https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6549572/)

[18] Huang et al. J Mol Diagn. 2019 Sept

[19] The Idylla™ BRAF Assay and the Idylla™ NRAS-BRAF Assay (RUO) were used to research the direct use of thyroid FNA samples as a Rapid On site Molecular Evaluation (ROME) solution for the rapid and easy detection of NRAS and BRAF mutations without having to send out the samples to specialized, centralized labs (De Luca C et al. Rapid On-site Molecular Evaluation in thyroid cytopathology: A same-day cytological and molecular diagnosis. Diagn Cytopathol. 6 January 2020, doi: 10.1002/dc.24378. Epub ahead of print. Available online on https://www.ncbi.nlm.nih.gov/m/pubmed/31904908/)

[20] See list of publications on www.biocartis.com/publications

[21] The Idylla™ MSI Test is intended for the qualitative detection of a novel panel of seven monomorphic homopolymer biomarkers for identification of colorectal cancers (CRC) with microsatellite instability (MSI)

[22] Two of which the epub version was published in 2019, ahead of the print version in 2020

[23] The European Society for Medical Oncology ('ESMO') congress that took place between 27 September and 1 October 2019 in Barcelona (Spain)

[24] The American Society of Clinical Oncology ('ASCO') Annual Meeting took place between 30 May and 4 June 2019 in Chicago (IL), US

[25] The Association for Molecular Pathology ('AMP') conference took place between 7 and 9 November 2019 in Baltimore, Maryland, US

[26] Immuno-histochemistry is often used to assess the MSI status. MSI is useful for screening patients for Lynch syndrome, and has become a predictive marker for response to immunotherapy.

[27] Next-Generation Sequencing or NGS is a technology for determining the sequence of DNA or RNA to study for example specific genetic alterations in patients with cancer. Source: NCBI, Jan-Dec 2018, last consulted on 17 February 2020

[28] We refer to the abstracts for more details on https://doi.org/10.1016/S1525-1578(19)30391-5

[29] Incl. (un)extracted FFPE tissue, cytologic material, blood, bone marrow, aspirate smears and touch preparation tissue samples as well as NGS pre-capture libraries

[30] Bratzman SV et al. Expert Rev Mol Diagn. 2015; 15(6): 715—719, Siravegna G and Bardelli A. Genome Biol. 2014; 15(8): 449.

[31] Janku F et al. Oncotarget. 2015; 6(29): 26886—2689; Sam SS et al. Pathol Res Pract. 2015. pii: jclinpath-2015—203345; Colling R et al. J Clin Pathol. 2015. pii: jclinpath-2015—203345

[32] ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016; NCCN Clinical Practice Guidelines in Oncology – Melanoma - Version 3.2016; NCCN Clinical Practice Guidelines in Oncology – NSCLC – Version 6.2017; Novello S. et al. Metastatic non-small-cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up Annals of Oncology 2016; AACR 2016: 5-Year Survival Rates for Patients With Metastatic Melanoma Treated With Nivolumab Much Higher Than Historical Rates. http://www.ascopost.com/News/39500

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

[34] CAGR = Compound Annual Growth Rate. Source: Market Insights Reports, https://www.marketwatch.com/press-release/oncology-molecular-diagnostics-market-size-status-global-outlook-2019-to-2025-2019-10-18?mod=mw_quote_news, last consulted on 20 January 2020

[35] Source: Fortune Business Insights, https://www.marketwatch.com/press-release/oncology-molecular-diagnostics-market-size-share-and-worldwide-trend-analysis-forecast-2019-2026-2019-09-24?mod=mw_quote_news, last consulted on 20 January 2020

[36] Source: M. Rabie Al-Turkmani, PhD, "The Promise of Extreme Molecular Diagnostics", August 2019, AACC.org, available online on https://www.aacc.org/publications/cln/cln-daily/2019/the-promise-of-extreme-molecular-diagnostics, last consulted on 20 January 2020

[37] Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482)

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

[39] These linkages are based on a more detailed analysis available on the SDG Compass website: www.sdgcompass.org

[40] Source: https://www.globalreporting.org/standards/

[41] US FDA, https://www.fda.gov/

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

[43] Source: MedTech Europe, https://www.medtecheurope.org/news-and-events/default/funding-and-reimbursement/

[44] Source: NILA USA, https://www.nila-usa.org/nila/PAMA.asp

[45] Source: Pacific Bridge Medical, https://www.pacificbridgemedical.com/publication/ivd-registration-reimbursement-china/

[46] 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

[47] 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.

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

[49] World Cancer Research Fund International, https://www.wcrf.org/dietandcancer/cancer-trends/colorectal-cancer-statistics, last consulted on 11 February 2020

[50] Jean-Yves Douillard, M.D., Ph.D., et al. Panitumumab–FOLFOX4 Treatment and RAS Mutations in Colorectal Cancer. N Engl J Med 2013;369:1023-34

[51] Jean-Yves Douillard, M.D., Ph.D., et al. Panitumumab–FOLFOX4 Treatment and RAS Mutations in Colorectal Cancer. N Engl J Med 2013;369:1023-34

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[55] http://www.amp.org/committees/clinical_practice/CRCOpenComment.cfm

[56] At a sensitivity of 5% in RAS genes exon 2 (codons 12 and 13), exon 3 (codons 59 and 61) and exon 4 (codons 117 and 146)

[57] ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016

[58] ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016

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[75] The Idylla™ MSI Test is intended for the qualitative detection of a novel panel of seven monomorphic homopolymer biomarkers for identification of colorectal cancers (CRC) with microsatellite instability (MSI)

[76] Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey

[77] Genomic Health was acquired by Exact Sciences Corp. (NASDAQ: EXAS) on 8 November 2019

[78] And some European countries

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[81] Two of which the epub version was published in 2019, ahead of the print version in 2020

[82] The European Society for Medical Oncology ('ESMO') congress that took place between 27 September and 1 October 2019 in Barcelona (Spain)

[83] The American Society of Clinical Oncology ('ASCO') Annual Meeting took place between 30 May and 4 June 2019 in Chicago (IL), US

[84] The Association for Molecular Pathology ('AMP') conference took place between 7 and 9 November 2019 in Baltimore, Maryland, US

[85] Immuno-histochemistry is often used to assess the MSI status. MSI is useful for screening patients for Lynch syndrome, and has become a predictive marker for response to immunotherapy.

[86] Next-Generation Sequencing or NGS is a technology for determining the sequence of DNA or RNA to study for example specific genetic alterations in patients with cancer. Source: NCBI, Jan-Dec 2018, last consulted on 21 October 2019

[87] We refer to the abstracts for more details on https://doi.org/10.1016/S1525-1578(19)30391-5

[88] Incl. (un)extracted FFPE tissue, cytologic material, blood, bone marrow, aspirate smears and touch preparation tissue samples as well as NGS pre-capture libraries

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Ref: BC_AR_2019 / Design: gpm.digital