# ANNUAL REPORT 2018

NOTHING IS SIMPLE
IN ONCOLOGY.

## NOTHING BUT THIS.


**Idylla™, leading a new global community of easy & rapid molecular diagnostics**

High Precision Diagnostics
for Personalized Medicine

BIOCARTIS

# CONTENTS

CHAPTER 1

# INTRODUCTION

## 1.1/
# BIOCARTIS AT A GLANCE

WE AIM
TO PROVIDE
**DIRECT ACCESS**
TO PERSONALIZED
MEDICINE FOR
PATIENTS
WORLDWIDE


**BIOCARTIS IS AN INNOVATIVE MOLECULAR DIAGNOSTICS COMPANY COMMITTED TO REVOLUTIONIZE MOLECULAR ONCOLOGY DIAGNOSTICS WITH ITS UNIQUE PROPRIETARY IDYLLA™ PLATFORM**

Biocartis provides next generation diagnostic solutions 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**

**394 EMPLOYEES[1]**

## 2018 HIGHLIGHTS

- Installed base of over **970 Idylla™ instruments** and **133,000 cartridges** sold in 2018, **+ 87%** versus 2017
- EUR **18.8m** product revenues (+**46%** compared to 2017)
- Operating income increased by **24%** to EUR **28.7m**
- Completion of a global commercial footprint with successful initial Idylla™ roll-out in the US, joint venture with **Wondfo in China**, selection of distribution partner with **Nichirei Bioscience** in Japan[3]
- Launch of the innovative **Idylla™ MSI Assay** (RUO[2])
- Expansion of partnership with **Genomic Health** into the urology space and announcement of agreement with pharmaceutical partner **AstraZeneca** in the lung cancer domain
- **394** employees[1], **21** 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, CEO Biocartis*

*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 2018 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 119 of the Belgian Companies Code, 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 English version shall prevail. An electronic version of the annual report 2018 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 2018 and 31 December 2018.

### FORWARD-LOOKING STATEMENT

Certain statements, beliefs and opinions in this report are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this report regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this report, those results or developments may not be indicative of results or developments in future periods. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this report as a result of

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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 trademark and logo and the 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

# 2018 PERFORMANCE

# 2.1/ MESSAGE FROM THE CHAIRMAN & CEO

## IDYLLA™, LEADING A NEW GLOBAL COMMUNITY OF EASY AND RAPID MOLECULAR DIAGNOSTICS

*"The global cancer diagnostics market is the fastest growing diagnostics market. Cancer incidence is rising everywhere in the world. It can hit anyone at any time. Early screening and getting the right treatment on time remains a real challenge. Rapid access to accurate data about relevant cancer mutations and treatment resistance is therefore vital. Current molecular oncology technologies are complex, require a lot of hands-on time and are often difficult to implement in the local laboratory. Biocartis wants to change this. Our unique approach is centered around the Idylla™ technology, enabling easy, rapid and highly accurate molecular diagnostics closer to the point of need."*

*Herman Verrelst, CEO Biocartis*

In 2018, we worked hard on strengthening our foundations aimed at creating a global community around easy and rapid molecular diagnostics with Idylla™, which will enable access to better treatments for patients across the world.

### MSI AS PROOF OF AN INNOVATIVE TEST MENU WITH LARGE MARKET POTENTIAL

During 2018, significant further investments were made in menu expansion. On 17 July 2018, earlier than expected due to high market demand, Biocartis launched its highly innovative Idylla™ MSI Assay (RUO[4]) that provides information on the MSI status (i.e. MSI-High or Microsatellite stable) of a tumor within approx. 150 minutes from just one slice of FFPE[5] tumor tissue, without requiring a reference sample. This assay, based on a novel set of seven exclusively licensed MSI biomarkers from VIB, the life sciences research institute in Flanders (Belgium), is a highly performant assay: several multi-center studies comparing to the standard methods showed a >95% concordance between results as well as a significantly lower failure rate[6]. Biocartis sees great potential here, as MSI over the last years has shown to be associated with response to immunotherapy in a very broad range of tumors[7], adding significant potential to MSI testing in cancer. MSI testing is currently cumbersome and is vastly underused compared to guideline recommendations. Therefore, fast and easy access to MSI testing using the Idylla™ technology could contribute to the success of immunotherapies.

## NEXT STEPS FOR A GLOBAL FOOTPRINT: US & CHINA

We also further strengthened our global expansion. 2018 was the first full commercial year in the US, the largest MDx market in the world. Idylla™ showed strong commercial traction with over 100 placements in the US. This was supported by several Idylla™ studies that were performed by leading KOLs, including the Memorial Sloan Kettering Cancer Center in New York and the Dartmouth-Hitchcock Medical Center in New Hampshire. Idylla™ also set its first steps in China, one of the fastest growing MDx markets in the world, with the joint venture we established there with fast growing diagnostics leader Wondfo.

## PARTNERSHIPS AS A KEY STRATEGIC LEVER

In 2018, the Idylla™ ecosystem was reinforced with several new partnerships, among which the partnership with Genomic Health Inc. which expanded into the field of urology with the development of an in vitro diagnostic (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. Once available, the Idylla™ Oncotype DX GPS test can support pathology labs and also local urology centers across the world in making better informed treatment decisions for patients with prostate cancer. Additionally, Biocartis announced a partnership with AstraZeneca, a global science-led biopharmaceutical company (LON: AZN), aimed at obtaining faster lung cancer molecular diagnostic biomarker results in Europe. Being already the third partnership with a global oncology treatment pharmaceutical company, this again demonstrates the positive impact of delivering highly accurate biomarker results in a fast and easy way, to the benefit of the patients.

## HIGH IDYLLA™ TEST PERFORMANCE HIGHLIGHTED IN VARIOUS NEW STUDIES

Finally, the collaborations of Biocartis with a wide range of KOLs translated in 2018 into 16 Idylla™ abstracts and posters and 11 publications in key journals, all demonstrating the quality and high performance of the Idylla™ products. Highlights here were the eight Idylla™ performance study abstracts[8] that were selected for presentation at the Association for the Molecular Pathology Conference (AMP), the leading meeting of professionals in the field of molecular diagnostics in the US, which took place between 1-3 November 2018 in San Antonio, Texas (US). The studies were performed by renowned US oncology key opinion leaders from the Memorial Sloan Kettering Cancer Center, Dartmouth–Hitchcock Medical Center, AstraZeneca and the University of Alabama, which truly strengthen Idylla™'s market adoption in the US. Another key study was published in June 2018 in the Journal of Clinical Pathology[9]. It concerned a study that reviewed a vast amount of 2,500 Idylla™ tests performed across 18 performance studies, showing Idylla™ generates valid results in 98.1% of the cases and as such outperforms over currently used reference methods. The Idylla™ data generated by all studies in this review proves the high accuracy of the Idylla™ platform to test for actionable mutations in different cancers, underlining the cost-effectiveness of Idylla™ testing compared to other molecular methods.

All of this indicates that Idylla™ today - thanks to the efforts of all of our stakeholders (employees, customers, shareholders, business partners, suppliers and others) - is taking the lead in a new global community of easy and rapid highly accurate molecular diagnostics. We are very much looking forward to further growing the Idylla™ community together in the times to come.

*Herman Verrelst, CEO Biocartis*

*Christian Reinaudo, Chairman of the Board of Directors*

2.2/

# 2018 HIGHLIGHTS AND BUSINESS REVIEW


## 2.2.1/ COMMERCIAL HIGHLIGHTS

### Installed base

The installed base of Idylla™ instruments increased to 973 as per year-end as a result of by 326 new installations in 2018. The majority of new placements in 2018 were realized in the European and US market. Post-period, driven by continued installed base growth, predominantly in the US market, the total installed base of Idylla™ instruments as per the date of this announcement amounts to over 1,000.

### Cartridge volume

In 2018, Biocartis realized a commercial volume of approx. 133k Idylla™ cartridges, a year-over-year increase of approx. 87%. The European and RoW markets contributed most to the absolute volume growth.

### European commercialization

Over 2018, European direct markets showed an increase in installed base that was above expectation as well as a strong ramp-up of commercial cartridge volumes. This performance was the consequence of an increased usage of Idylla™ in first line testing by customers in key European markets, a strong overall contribution from pharmaceutical collaborations and the launch of the Idylla™ MSI Assay (RUO).

## US commercialization

2018 was the first full year of commercialization in the US during which the US direct sales team, in combination with the Fisher Healthcare sales team, realized a promising initial US installed base and was able to attract high profile customers such as Memorial Sloan Kettering Cancer Center and Dartmouth-Hitchcock Medical Center. Furthermore, and as part of the aim to accelerate market adoption several US based studies[10] of Idylla™ assays were published of which eight were presented at the Association for Molecular Pathology Conference in the US in November 2018.

## RoW distribution markets

RoW realized a strong ramp-up in cartridge volumes in 2018, mainly driven by the 57 new market authorizations for Idylla™ products that Biocartis added in 2018 across 18 geographies. The increase in RoW performance was also the result of the strategy focused on those geographies that are of interest to pharmaceutical partners.

## China commercialization

On 3 September 2018, Biocartis and Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, announced entering into a joint venture aimed at the commercialization of the Idylla™ platform in mainland China, within the field of oncology. The joint venture is 50% owned by Biocartis and 50% owned by Wondfo. The initial activities of the joint venture are focused on the local manufacturing, commercialization and registration with the Chinese Regulatory Authorities (CFDA) of the existing Idylla™ molecular oncology assays for amongst others colorectal and lung cancer. This is a first important step in unlocking Idylla™'s commercial potential in the Chinese molecular diagnostics market, being one of the fastest growing in the world and expected to reach a total value of USD 1.5bn by the end of 2022[11].

## Japan commercialization

In 2018, Biocartis selected its commercialization partner for Japan, resulting into signing of a distribution agreement with Nichirei Bioscience as announced post the reporting period (see below), on 7 January 2019.

2.2.2/

# MENU AND PARTNERSHIP HIGHLIGHTS


## COLORECTAL CANCER MENU

### Launch Idylla™ MSI Assay (RUO)

On 17 July 2018, Biocartis launched its innovative Idylla™ MSI Assay (RUO) that provides information on the MSI status (i.e. MSI-High or Microsatellite stable) of a tumor within approximately 150 minutes from just one slice of FFPE[12] tumor tissue, without requiring a reference sample and based on a novel set of seven exclusively licensed MSI biomarkers. Several multi-center studies comparing the Idylla™ MSI Assay to the standard methods showed a >95% concordance between results as well as a significantly lower failure rate[13]. Once validated for diagnostic use, targeted for in Q1 2019, the test is expected to significantly strengthen Biocartis' colorectal cancer test menu. Since MSI is an independent factor that may predict a patient's response to certain immunotherapies, it provides Biocartis with further opportunities to enter into the field of immuno-oncology.

### EGFR ectodomain mutations

On 28 August 2018, Biocartis announced that it has obtained exclusive worldwide license rights for highly innovative EGFR ectodomain mutations that have been shown to determine response to targeted therapy for patients with metastatic colorectal cancer (mCRC).

# LUNG CANCER MENU

## Collaboration AstraZeneca

On 29 November 2018, Biocartis announced to have entered into an agreement with AstraZeneca, a global science-led biopharmaceutical company (LON: AZN), aimed at obtaining faster lung cancer molecular diagnostic biomarker results in Europe. Pursuant to the agreement, a prospective lung cancer study with the Idylla™ EGFR Mutation Test (CE-IVD) will be conducted in selected European countries.

## ctEGFR

During 2018, Biocartis further progressed the development of the liquid biopsy version of the Idylla™ EGFR Mutation Assay (RUO).This test is an important addition to Biocartis' lung cancer menu as liquid biopsy EGFR testing is included in guidelines for situations where no tumor tissue is available for testing.

## Idylla™ GeneFusion Panel

During 2018, Biocartis in concertation with its network of Key Opinion Leaders (KOLs) finalized the panel composition of the Idylla™ GeneFusion Panel. This panel is intended for the qualitative detection of different gene fusions (e.g. ALK and ROS1) in human non-small cell lung cancer FFPE[14] tissue samples. Together with the Idylla™ EGFR Mutation Test (CE-IVD), the Idylla™ GeneFusion Panel will cover the majority of actionable lung cancer mutations, making the GeneFusion Panel as such a key addition to Biocartis' lung cancer menu.

# BREAST CANCER MENU

On 3 June 2018, Biocartis' partner Genomic Health, Inc. (NASDAQ: GHDX) announced the results of the long-awaited TAILORx study, the largest ever breast cancer treatment trial, which provided definitive evidence that the Oncotype DX Breast Recurrence Score® test identified the vast majority of early stage breast cancer patients who receive no benefit from chemotherapy, and can be effectively treated with endocrine therapy alone. Additionally, the trial established that chemotherapy may provide life-saving benefit to an important minority of patients. These results are expected to be an important driver in the market adoption and reimbursement of the future Oncotype DXi IVD Breast Recurrence Score™ test in Europe. During 2018, Genomic Health and Biocartis reached an important milestone in the development of that test by demonstrating feasibility on the Idylla™ platform. Furthermore, early access sites to initiate validation studies were selected, in the second half of 2019 and to launch the Oncotype DXi IVD Breast Recurrence Score™ test in 2020, beginning in France and Germany.

## PROSTATE CANCER MENU

On 3 December 2018, Biocartis and Genomic Health announced to have expanded their exclusive collaboration into the field of urology aimed at the development of an in vitro diagnostic (IVD) version of the Oncotype DX Genomic Prostate Score® (GPS™) Test[15] on the Idylla™ platform and potentially additional cancer tests that can be performed locally by laboratory partners and in hospitals around the world. Post the reporting period, on 5 February 2019, Genomic Health also announced the publication of results from a multi-center, prospective validation study of the Oncotype DX® Genomic Prostate Score® (GPS™) Test in newly diagnosed men with clinically low-risk prostate cancer who elected immediate radical prostatectomy after receiving the test. Published in Urology[16], the study results prospectively validated the GPS test as an independent predictor of adverse pathology at the time of surgery as a measure of disease aggressiveness for men with clinically low- or intermediate-risk prostate cancer.

## PERFORMANCE STUDIES

**During 2018, Biocartis announced the publication of several studies demonstrating the high performance of Idylla™ and its oncology molecular diagnostic tests, among which:**

Eight Idylla™ performance study abstracts[17] were selected for presentation at the Association for the Molecular Pathology Conference (AMP), the leading meeting of professionals in the field of molecular diagnostics in the US, which took place between 1-3 November 2018 in San Antonio, Texas (US). The studies were performed by renowned US oncology key opinion leaders from the Memorial Sloan Kettering Cancer Center (New York), Dartmouth–Hitchcock Medical Center (New Hampshire), AstraZeneca and the University of Alabama.

Two performance studies on Idylla™ MSI Biomarkers[18] selected for publication at the American Society of Clinical Oncology (ASCO) Annual Meeting conference, taking place between 1-5 June 2018, Chicago (IL), US[19].

Studies[20] on the Idylla™ MSI Assay (RUO) and the Idylla™ RAS liquid biopsy tests[21] were presented at the European Society for Medical Oncology (ESMO) congress, 19-23 October 2018 in Munich, Germany.

A study[22] published on 14 June 2018 in the Journal of Clinical Pathology reviewing 2,500 performed Idylla™ tests across 18 performance studies showed the generation of valid results in 98.1% of the cases and outperformance over currently used reference methods. The 1.9% invalid results generated with Idylla™ is approx. 40% lower than the results of the included reference methods, which showed invalid results in 3.1% of the cases.

Other studies included a study abstract[23] on the performance of the Idylla™ ctRAS liquid biopsy tests which was selected for oral presentation at the 2018 American Association for Cancer Research (AACR) Annual Meeting taking place between 14-18 April 2018 in Chicago (US), a study demonstrating the ability of the Idylla™ EGFR Mutation Test (CE-IVD) to produce a result in 80% of failed Next Generation Sequencing Lung Cancer Tests was published in the Journal of Clinical Pathology on 24 May 2018[24], and a study abstract on the performance of the Idylla™ RAS tests[25] was selected for oral presentation at the 70th AACC Annual Scientific Meeting in Chicago, IL (US) on 31 July 2018.

2.2.3/

# ORGANIZATIONAL AND OPERATIONAL HIGHLIGHTS

## New board composition

Following the annual general shareholders' meeting (AGM) held on 11 May 2018, five new independent board members[26] were appointed and three board members whose mandate expired at the closing of the AGM, were re-appointed[27]. The new board composition allows for a transition towards a board of directors consisting predominantly of independent directors and consists of: CRBA Management BVBA (represented by Christian Reinaudo), chairman of the board, Ann-Christine Sundell, Scientia II LLC (represented by Harry Glorikian), CLSCO BVBA (represented by Leo Steenbergen), Luc Gijsens BVBA (represented by Luc Gijsens), Peter Piot, Hilde Windels BVBA (represented by Hilde Windels), Roald Borré and Herman Verrelst (CEO of Biocartis).

## US R&D center

On 1 March 2018, Biocartis announced to have established an R&D center in the US as the result of a transfer of R&D staff members and Idylla™ related assay development assets and tests of Janssen Diagnostics (a division of Janssen Pharmaceuticals, Inc.). With the establishment of this US R&D center, Biocartis supports the execution of its strategy to accelerate test menu expansion on the Idylla™ platform through predominantly companion diagnostics collaborations and assay content partnerships.

## Cartridge manufacturing

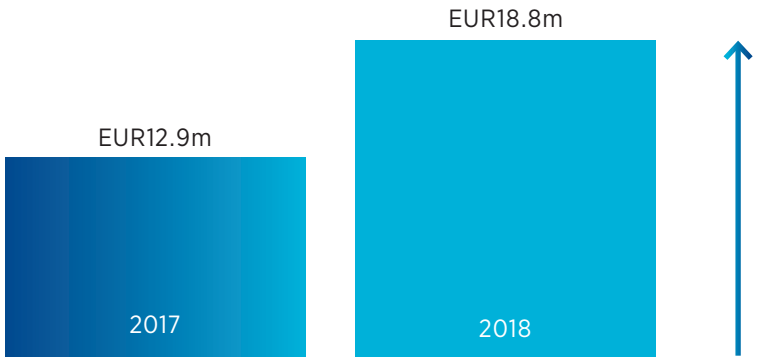
During 2018, Biocartis completed the construction and validation of its second cartridge manufacturing line that should provide for an additional annual cartridge capacity of over 1 million Idylla™ cartridges. Currently, Biocartis is in the process of transferring the commercial production of its high volume tests to this new cartridge manufacturing line.

## Contract terminations

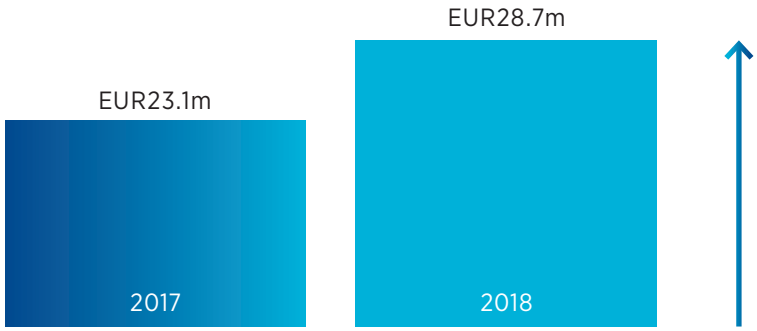
During H2 2018, a review of infectious disease oriented collaborations and license agreements was conducted, which resulted in the termination of certain collaborations that were no longer of strategic importance to Biocartis. As part of this review, the agreement with Koninklijke Philips N.V., under which Biocartis had gained access to certain patent rights and know-how, in relation to an ancillary platform for selective enrichment of pathogen DNA for use with bloodstream infection tests, has been terminated. The underlying patent rights are being returned to Philips and the related book value has been fully impaired, resulting in EUR 3.2m non-cash impairment.

## 2.2.4/
# FINANCIAL HIGHLIGHTS

### Product sales revenues
Total product sales increased year-over-year with 46% to EUR 18.8m in 2018 (EUR 12.9m in 2017), as the consequence of higher Idylla™ cartridge sales (year-over-year growth of 76%) due to increased cartridge volumes partially offset by lower Idylla™ platform sales (year-over-year decline of 9%) as more instruments are now being placed under leasing contracts.




### Total operating income
Total operating income amounted to EUR 28.7m in 2018, representing a year-over-year growth of 24% due to higher Idylla™ product sales, collaboration revenues and service revenues partially offset by lower grant income.




**63.5m**

### Cash position
Biocartis' cash position as per 31 December 2018 amounted to EUR 63.5m compared to EUR 112.8m as per 31 December 2017. Please see the paragraph post-period events on the equity raise completed in January 2019.

### OPEX
Total operating expenses (including cost of sales) amounted to EUR 75.5m, a year-over-year increase of 13% due to higher cost of sales, sales and marketing expenses and general and administrative expenses partially offset by lower research and development expenses.

### Operational cash flow
Total operational cash flow amounted to minus EUR 42.0m in 2018 versus minus EUR 41.4m in 2017.

Additional details – see 'key figures for 2018' below for more details on the 2018 financials.


## 2.2.5/
# SUMMARY IDYLLA™ TEST MENU STRATEGY

The oncology MDx market that Biocartis operates in, is growing rapidly and is continuously evolving according to the ever-increasing pace of scientific and technological progress. Biocartis therefore continuously monitors the trends affecting its core markets with the aim to strengthen Idylla™'s competitive position and to identify new segments where the platform has unique value.

With respect to Biocartis' internally developed Idylla™ assay menu, the focus going forward is on three key strategic building blocks: targeted therapies (assays focused on cancer specific therapies as well as pan-cancer applications), immunotherapy (assays focused on immune checkpoint inhibitors and cell-based therapies) and liquid-biopsy based monitoring applications (assays focused on on-therapy and post-therapy monitoring).

Furthermore, Biocartis is envisioning additional collaborations with partners who own validated, proprietary, high-value oncology gene signatures that can be ported onto the Idylla™ platform. This is expected to result in the addition of cancer franchises for Idylla™, and the expansion of the platform into new customer segments within the oncology MDx market.

The Biocartis Idylla™ menu strategy is indicative and subject to change driven by amongst others commercial, partnering, financial and operational considerations. More details on the long term Idylla™ test menu strategy can be found under chapter 3, section 'strategy' and in Biocartis' corporate presentation available on www.biocartis.com under 'investors'.

## 2.2.6/
# FINANCIAL REVIEW 2018

The tables below show an overview of the key figures and a breakdown of operating income for 2018. 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) | 2018 | 2017 | % Change |
|---|---|---|---|
| **Total operating income** | **28,651** | **23,110** | **24%** |
| Cost of sales | -15,349 | -8,673 | 77% |
| Research and development expenses | -36,842 | -39,594 | -7% |
| Sales and Marketing expenses | -15,349 | -11,600 | 32% |
| General and administrative expenses | -7,971 | -6,832 | 17% |
| **Operating expenses** | **-75,511** | **-66,699** | **13%** |
| **Operational result** | **-46,860** | **-43,589** | **8%** |
| Net financial result | -1,402 | -1,736 | -19% |
| Income tax | 109 | 3,365 | -97% |
| **Net result** | **-48,153** | **-41,960** | **15%** |
| Cash flow from operating activities | -41,993 | -41,405 | 2% |
| Cash flow from investing activities | -5,820 | -4,320 | 30% |
| Cash flow from financing activities | -1,508 | 75,256 | -102% |
| **Net cash flow** | **-49,320** | **29,531** | **-267%** |
| **Cash and cash equivalents**[1] | **63,539** | **112,765** | **-44%** |
| Financial debt | 35,335 | 35,388 | 0% |

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

| Operating income (EUR 1,000) | 2018 | 2017 | % Change |
|---|---|---|---|
| **Collaboration revenue** | **8,329** | **7,739** | **8%** |
| Idylla™ System sales | 4,185 | 4,620 | -9% |
| Idylla™ Cartridge sales | 14,658 | 8,316 | 76% |
| **Product sales revenue** | **18,843** | **12,936** | **46%** |
| **Service revenue** | **639** | **282** | **127%** |
| **Total revenue** | **27,811** | **20,957** | **33%** |
| Grants and other income | 840 | 2,153 | -61% |
| **Total operating income** | **28,651** | **23,110** | **24%** |

| Product sales revenue by type (EUR 1,000) | 2018 | 2017 | % Change |
|---|---|---|---|
| Commercial revenue | 17,843 | 12,748 | 40% |
| Research & Development revenue | 1,000 | 187 | 434% |
| **Total product sales revenue** | **18,843** | **12,936** | **46%** |

# INCOME STATEMENT

## OPERATING INCOME

Collaboration revenue increased year-over-year with 8% to EUR 8.3m in 2018 driven by proceeds from R&D services that increased with over 6 times to EUR 4.3m which was partially offset by lower upfront license revenues (EUR 3.2m) and milestone revenues (EUR 0.8m).

Total product sales amounted to EUR 18.8m in 2018 (EUR 12.9m in 2017), representing a year-over-year growth of 46%, and included Idylla™ cartridge sales of EUR 14.7m (EUR 8.3m in 2017) and Idylla™ system revenues of EUR 4.2m (EUR 4.6m in 2017). The decrease in Idylla™ system revenues was driven by lower Idylla™ system sales (EUR 2.4m in 2018 versus EUR 3.4m in 2017), partially offset by higher Idylla™ system rental revenue (EUR 1.8m in 2018 versus EUR 1.2m in 2017).

Service revenue increased year-over-year with over 2 times to EUR 0.6m in 2018 as the consequence of the increased customer base. Recognized grants and other income amounted to EUR 0.8m in 2018 (EUR 2.2m in 2017) and consisted of R&D project support grants and training subsidies related to the establishment of a second cartridge manufacturing line.

Driven by the above Biocartis' total operating income in 2018 amounted to EUR 28.7m versus EUR 23.1m in 2017, representing an increase of 24%.

## OPERATING EXPENSES

Total operating expenses in 2018 amounted to EUR 75.7m versus EUR 66.7m in 2017, an increase of 13%. This included cost of sales of EUR 15.3m in 2018 compared to EUR 8.7m in 2017 as the consequence of an overall increase in commercial product volumes as well as higher operational costs for cartridge manufacturing due to the expansion of night and weekend shifts. Operating expenses excluding cost of sales amounted to 60.2m in 2018 versus EUR 58.0m in 2017 as the result of a decrease in research and development ('R&D') expenses that was offset by higher expenses for sales and marketing ('S&M') and general and administrative expenses ('G&A').

R&D expenses amounted to EUR 36.8m in 2018 versus EUR 39.6m in 2017 which represents a year-over-year decrease of approx. 7%. This was predominantly driven by lower platform and cartridge prototype costs, subcontracting expenses (i.e. outsourced R&D activities) and allocated depreciation and amortization expenses which was partially offset by an one-off (non-cash) impairment expense related to patent rights that are being returned to Philips (see the paragraph 'Organizational and operational highlights' above) as well as higher employee benefit expenses and consultancy costs. Sales and marketing expenses amounted to EUR 15.3m in 2018 compared to EUR 11.6m in 2017, a year-over year increase of 32%. 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, mainly in the US, and higher allocated depreciation and amortization expenses. G&A expenses amounted to EUR 8.0m in 2018 compared to EUR 6.8m in 2017 being a year-over-year increase of approx. 17% as a result of higher costs for staffing (including non-cash share based payment expenses), human resources and external advice.

## OPERATING RESULT

The above resulted in an operational result for the period of EUR -46.9m, compared to EUR -43.6m in 2017, a year-over-year change of approx. 8%. Excluding one-off impairment losses, the 2018 operating result would have amounted to EUR -43.7m (i.e. a similar level as compared to 2017).

## NET FINANCIAL RESULT AND INCOME TAXES

Net financial expenses amounted to EUR 1.4m in 2018 compared to 1.7m in 2017 and predominantly include financial expenses in relation to the Company's subordinate loan and commitment fees for the multiple purpose credit lines. As the Company had no taxable income in 2018, income tax expenses consists of recognized research and development tax credits in Belgium. Please note that the recognized tax credits for 2017 included a one-off adjusted fiscal treatment of certain historical intellectual property (IP) investments.

## NET RESULT

As a result of the foregoing, the net result for the year 2018 amounted to EUR -48.2m (EUR -45.0m excluding one-off impairment losses) compared to EUR -42.0m in 2017.

# BALANCE SHEET

## NON-CURRENT ASSETS

Intangible assets predominantly consist of patents and licenses on third-party intellectual property and decreased from EUR 10.3m in 2017 to EUR 6.6m in 2018 driven by additions of EUR 0.3m and amortization and impairment expenses of EUR 3.9m, of which the latter predominantly related to the impairment mentioned under the paragraph 'Organizational and operational highlights' above.

During 2018, property plant & equipment increased with EUR 4.2m to EUR 30.4m driven by additions of EUR 9.2m and depreciation charges for the period of EUR 5.0m. Additions predominantly consisted of new manufacturing equipment for cartridge manufacturing as well as capitalization of instrumentation placed at clients under leasing or rental contracts as well as instrumentation held for internal needs.

Per 31 December 2018, a financial participation of EUR 5.1m was included on the balance sheet in relation to a 7.1%participation in MyCartis NV. Deferred tax assets per 31 December 2018 amounted to EUR 6.6m and relate to tax credits for research and development in Belgium.

## CURRENT ASSETS

Inventory amounted to EUR 11.9m as per end 2018 compared to EUR 9.1m as per end 2017. This year-over-year increase was driven by higher inventory levels of finished products and raw materials. Trade receivables increased to EUR 9.7m as per year-end 2018 (EUR 9.9m end of 2017) as a consequence of higher overall commercial volumes as well as amongst others invoicing to strategic partners in Q4 in light of collaboration activities. Other receivables relate to VAT and capital grant receivables and amounted to EUR 3.8m as per end of 2018 versus EUR 2.9m as per end of 2017. Other current assets include accrued operating grant income and deferred charges and decreased in 2018 to EUR 1.8m from EUR 1.5m as per end of 2017.

The Company's cash and cash equivalents end of 2018 amounted to EUR 63.5m compared to EUR 112.8m end of 2017.

## EQUITY

Biocartis' total equity end of 2018 amounted to EUR 87.4m compared to EUR 132.2m end of 2017. This decrease was driven by the negative operating result for 2018 that was partially offset by proceeds from warrants exercises as well as a correction for non-cash share-based payment expenses.

## FINANCIAL DEBT

Total financial debt amounted to EUR 35.3m as per end of 2018 versus EUR 35.4m as per end of 2017 as a consequence of a decrease in lease financing that was offset by the addition of capitalized interest to the Company's subordinated loan.

## OTHER LIABILITIES

Trade payables end of 2018 amounted to EUR 8.0m, representing an increase of EUR 2.4m compared to the EUR 5.6m that was outstanding end of 2017. Deferred income increased in 2018 to EUR 3.0m (EUR 2.8m end of 2017) as a consequence of payments received from collaboration partners, partially offset by the revenue recognition of received grant payments. Accrued charges as of 31 December 2018 decreased to EUR 1.5m and predominantly consisted of accruals for rental charges. Other current liabilities increased from EUR 3.4m per end of 2017 to EUR 4.2m per end 2018 and consist predominantly of provisions for vacation pay and for variable compensation schemes.

## BALANCE SHEET TOTAL

Biocartis' balance sheet total amounted to EUR 139.4m as per end of 2018.

## CASH FLOW STATEMENT

### CASH FLOW FROM OPERATING ACTIVITIES

The cash flow from operating activities amounted to EUR –42.0m in 2018 which was slightly lower compared to 2017 (EUR -41.4m) driven by a lower net result for 2018 and increased investments in working capital that were to a large extent offset by increased (non-cash) adjustments due to the 2018 impairment losses as well as the one-off income statement impact in 2017 due to the adjusted fiscal treatment of certain historical IP investments.

### CASH FLOW FROM INVESTING ACTIVITIES

The cash flow from investing activities in 2018 amounted to EUR –5.8m compared to EUR -4.3m in 2017 and included predominantly capitalization of Idylla™ instrumentation as well as investments in laboratory and manufacturing equipment.

### CASH FLOW FROM FINANCING ACTIVITIES

The cash flow from financing activities in 2018 amounted to EUR –1.5m (EUR 75.3m in 2017, driven by the capital raise of EUR 80m in November 2017) and predominantly consisted of repayments on borrowings that were partially offset by proceeds from the exercise of warrants.

### TOTAL NET CASH FLOW

Driven by the aforementioned, the total net cash flow in 2018 amounted to EUR -49.3m compared to EUR 29.5m in 2017.

## 2.2.7/ IMPORTANT EVENTS AFTER THE REPORTING DATE

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

CHAPTER 3

# BUSINESS ACTIVITIES


IDYLLA™
Powered by Biocartis
IDYLLA™
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IDYLLA™
Powered by Biocartis
IDYLLA™

## 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[28] 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[29]. 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[30]. 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[31]. 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 USD 233 bn by 2025 at an annual growth rate[32] of 7.2%, according to a report by Grand View Research, Inc[33]. Rising cancer incidence is triggering the demand for cancer screening tests[34] and are pushing laboratories to improve their oncology screening technologies. In terms of geographies, North America dominates the global space with the largest revenue share of more than 41% already in 2016. Asia Pacific is expected to emerge as the fastest growing region, amongst others due tothe growing patient pool in India, China, and Japan, the support in diagnostic process at comparatively lower prices, and a favorable regulatory framework[35].**

**In terms of technologies, Polymerase Chain Reaction or PCR, the technology on which Idylla™ tests are based, is the most widely used technology in molecular diagnostics[36].**

## 3.2/
# MISSION

Biocartis aims to make **personalized cancer medicine an everyday reality**, by providing easy and direct access to MDx information close to the clinical decision-making point and without the need for complex laboratory infrastructure. With Idylla™, a fully automated, sample-to-result PCR based molecular diagnostics system that provides same-day results, allows multiple sample types, including solid and liquid biopsies, and use in virtually any laboratory setting, Biocartis aims to establish a new gold standard in molecular diagnostic testing.

# 3.3/ HISTORY

**2007** Biocartis was founded in Switzerland.

**2010** Acquisition of 'Apollo' (now Idylla™) from Koninklijke Philips NV. Strategic licensing, development and commercialization agreement with Johnson & Johnson to co-develop tests.

**2011** R&D activities move to Mechelen (Belgium). Biocartis received the prestigious 2012 Technology Pioneer Award by the World Economic Forum.

**2012** Collaboration with Philips, Genome Research Limited and the Wellcome Trust to develop a technology for an automated blood-based test system to monitor tumor load.

**2013** Biocartis' MDx platform is named Idylla™. New collaborations and license agreements with Hospital del Mar (Spain) and the Flemish Institute for Biotechnology (VIB, Belgium) to develop tests for several cancers using new biomarkers.

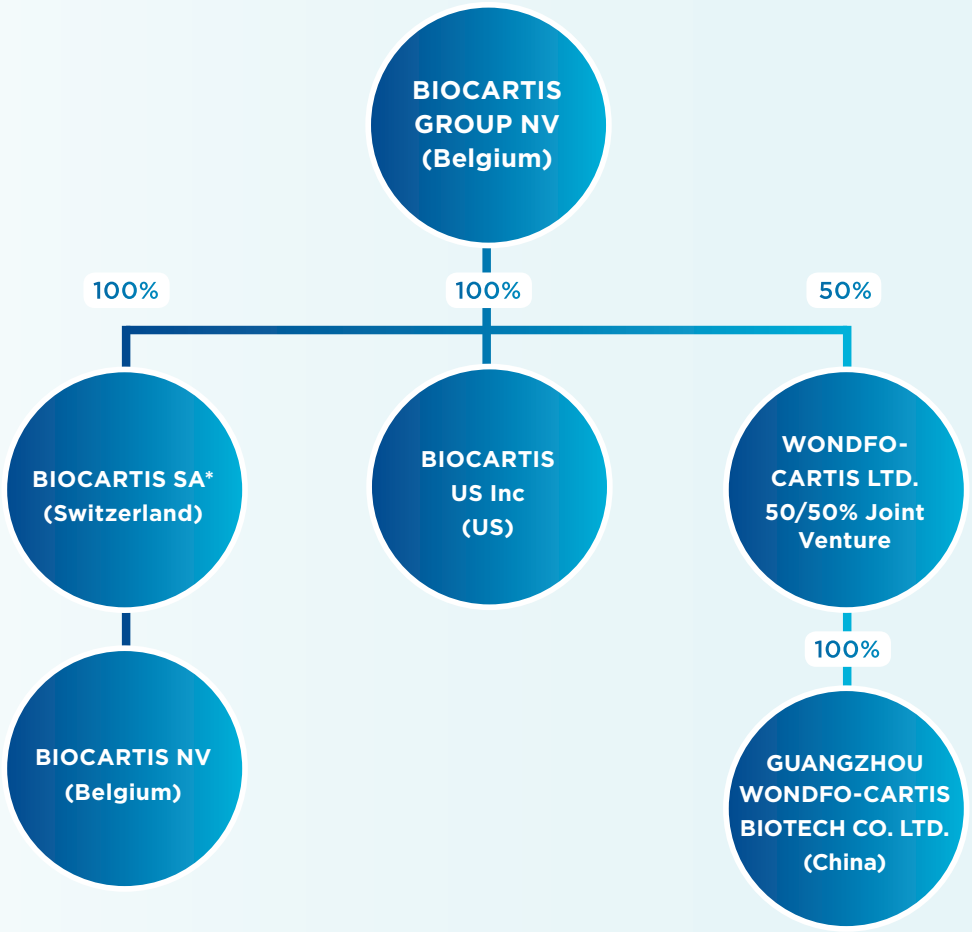
**2014** Establishment of Biocartis Group NV as the group's new holding company.

**2015** Biocartis raised EUR 115m in its IPO in April 2015 on Euronext Brussels. Launch of three new oncology tests of which the first liquid biopsy test. Outsourcing of the Idylla™ Instrument and Idylla™ Console to a renowned Contract Manufacturing Organization (CMO).

**2016** First commercial collaboration agreements signed with pharmaceutical oncology treatment companies Merck KGaA (Darmstadt, Germany) and Amgen. Distribution partnership signed with Thermo Fisher Scientific Inc. for the US market. Launch of three new oncology tests. Successful equity placement of EUR 32.7m and securing of EUR 55m of non-dilutive financing.

**2017** Biocartis Inc. established in the US. Launch of four new tests, including the first CE-marked IVD liquid biopsy tests developed under partnership with Merck KGaA (Darmstadt, Germany) and launch of the first CE-IVD marked lung cancer test, the Idylla™ EGFR Mutation Test. Successful equity placement of EUR 80m.

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 2018 is as follows:




*After the balance sheet date, Biocartis SA was dissolved and put into liquidation.

Biocartis' headquarters 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. 6,800 sq m). In addition, Biocartis operates a US R&D Center in Raritan (New Jersey, US) and certain US commercialization activities that are supported by Biocartis US Inc. Furthermore, Biocartis' joint venture , Wondfo-Cartis Ltd., was established in the 2nd half of 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 enabling molecular testing in virtually any lab setting
- Allows for a reduction of time-to-results from weeks to hours
- Offers sample-to-result (i.e. full automation) capabilities for solid biopsies (i.e. FFPE, FNA** (Fine Needle Aspirates), fresh samples**) and liquid biopsies (plasma*, whole blood**, urine**)

* Validated sample type ** Research Use Only

Biocartis' menu strategy for the Idylla™ platform is driven by several key 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:

1. **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 in an efficient 2-cartridge menu. 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-cancer applications.
2. **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.
3. **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.
4. **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 the addition of 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.

*Herman Verrelst, CEO Biocartis*

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

# 3.5/ SUSTAINABILITY

In defining its sustainability approach and material sustainability disclosures, Biocartis has taken into account the Sustainable Development Goals[38] (SDG) as well as the Global Reporting Initiative (GRI) guidelines. The 17 SDG's 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[39]. 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: ACCESS TO MDX TESTING FOR ALL CANCER PATIENTS WORLDWIDE

Sustainability is in the DNA of Biocartis, since our products focus is on improving the lives of cancer patients across the globe by enabling easy and rapid access to MDx testing and as such access to more optimal cancer treatments, while lowering 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.

## HOW WE CREATE VALUE FOR SOCIETY

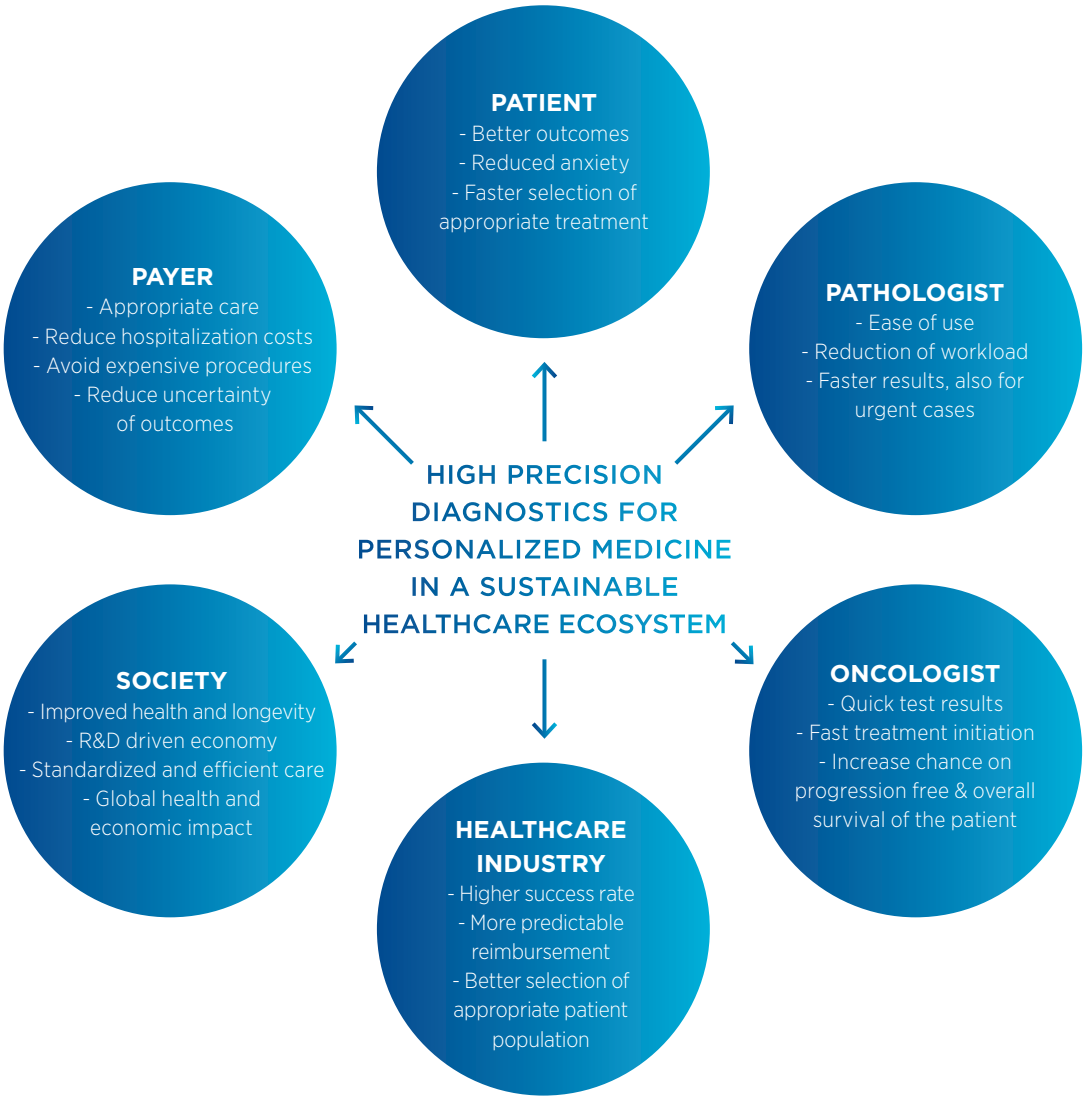
Biocartis creates value for society with Idylla™ products that allow as fast, easy and highly accurate molecular information enabling fast and more efficient treatment decisions for cancer patients worldwide. This contributes to a more sustainable healthcare model:

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 are 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 2018

In 2018, 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.

| | | |
|---|---|---|
| **Enabling personalized medicine for cancer patients worldwide through rapid, easy & highly accurate MDx testing** | • Broad menu of Idylla™ tests supporting patients worldwide<br>• Installed base of over 970 Idylla™ instruments in 2018<br>• Cartridge volume in 2018 to 133,000 cartridges |  |
| **Building an Idylla™ ecosystem with partners globally** | • +8% collaboration revenues in 2018<br>• Several new oncology partnerships<br>• 1 new partnership in infectious diseases<br>• Annual fundraising actions by employees supporting 7 different non-profit organizations in the area of cancer and health |  |
| **Caring for the environment** | • Energy consumption audit in our headquarters and cartridge production site to map improvement actions<br>• New cartridge manufacturing line 'ML2' taking into account the best solutions in terms of energy efficiency<br>• Refurbishing of Idylla™ instruments and Idylla™ consoles |  |
| **Delivering growth** | • +46% product revenues<br>• +87% cartridge volume<br>• +326 Idylla™ instruments added to the installed base |  |
| **A safe & healthy workplace** | • 394 employees[1]<br>• 50%-50% balanced gender diversity<br>• 21 nationalities<br>• No lethal accidents or accidents causing disability on the workplace |  |

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 also strives to act responsibly as a company with the social and environmental resources it uses. Information on this topic can be found throughout this report. It covers different aspects, of which the main ones and their references in this report are listed as follows:

**We integrate sustainability in the governance of our organization.**
Sustainability is the responsibility of our board and executive management. Sustainability related improvement plans are regularly discussed. Furthermore, Biocartis also integrates feedback from SRI investors. In 2018, this led to the decision to the adoption of a new Code of Conduct which now includes several ethical business measures to avoid corruption, bribery & fraud, as well as an ethics hotline ('whistleblowing') for Biocartis employees worldwide and diversity & inclusiveness principles. We refer to the chapter 4 'Corporate Governance' for more information.

**We strive to 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 is 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 work on having 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 MDx market access. 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.

## PRODUCTS

### EU: CE-MARKING

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

**Regulatory body?** Review by a Notified Body is required for a majority of medical device products prior to launch, as well as further on-market validation efforts to ensure devices continue to perform as expected. On 5 April 2017, two new EU regulations on medical devices were adopted: the regulation on medical devices and the regulation on in vitro diagnostic 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 in vitro diagnostic medical devices (May 2022). The new regulations aim for a consistent disclosure across medical devices on quality and performance. Its increased transparency as such aims to allow for a better performance comparison of similar medical devices across the EU.

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

### US: PMA OR 510(K)

**What?** The US requires more rigorous product clearance efforts before market access is granted. Based on the risk class of the medical device, either a 510(k) clearance or a more stringent Pre-Market Approval (PMA) is required.

**Regulatory body?** The Food and Drug Administration (FDA or US FDA) is a 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 amongst others food safety, pharmaceutical drugs and medical devices[40].

**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[41].

### 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.

### CHINA

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

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

## DATA PRIVACY

As a company increasing managing large amounts of data both internally as well as with regards to its products, Biocartis is fully committed to protecting and safeguarding personal data. Biocartis takes privacy seriously and continuously works on improving the privacy and security framework. In 2018, several actions were taken around the EU General Data Protection Regulation (GDPR), which was enforced on 25 May 2018 and is considered to be the most important change in data privacy legislation in the past 20 years:

Biocartis established a personal data protection governance structure, which includes officially appointed Data Protection Officer (DPO).

All policies, procedures, transparency statements and contracts were updated to meet new legislative requirements.

Every Biocartis staff member who is exposed to personal data management was trained appropriately.

A GDPR Awareness Program was put in place to ensure all employees are continuously updated.

General policy integration: when developing its products and services, Biocartis always takes into consideration the data protection principle and rights of the individuals.

# 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 price.

Today, most Idylla™ assays in Biocartis' product offer 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 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[42].

## US

In the US, reimbursement is typically higher since the reimbursement 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[43].

## 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[44].

## 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 of 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 2018 included:

- The re-certification of the ISO 13485:2016 standard and the obtaining of a MDSAP certificate (Medical Device Single Audit Program) for Australia, Brazil, Canada and US, covering the design and development activities, manufacturing and testing activities and customer related processes in Mechelen (Belgium). The MDSAP allows medical device manufacturers to 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." This will allow Biocartis to sell the Idylla™ platform and its oncology assays in the respective countries, once regulatory clearance is granted for the individual products.
- Implementation of the requirements of the US FDA QSR 21 CFR part 820 (Quality System Regulation) to comply with the US FDA regulations governing IVD devices.

## 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 directive regarding the Restriction of Hazardous Substances in electrical and electronic equipment.
- The WEEE directive (Waste of Electrical and Electronic Equipment) 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[45].

In the context of the WEEE directive, Biocartis refurbishes its equipment where possible and as such refurbished several Idylla™ instruments and Idylla™ consoles in 2018.

## Environmental impact of our activities as a company

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

- The Contained Use Directive aimed at limiting contact of the environment with genetically modified and infectious microorganisms.
- The Biocidal Products Directive 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.

The main results of the environmental actions Biocartis took in 2018 were:

1. The installation of a new, energy efficient **Idylla™ cartridge production line** (see text box)
2. The setup of a selective **Waste Handling & Recycling Program** together with the Belgian environmental non-profits Renewi, Val-i-pac, Bebat and Recupel, leading to an improved waste management and several recycling actions, inc. the refurbishing of Idylla™ instruments and Idylla™ consoles.
3. An **Energy Efficiency Audit**, leading to several energy efficiency improvement actions, including the installations of energy consumption meter devices for an improved energy monitoring going forward.
4. An **Employee Mobility Guide** to stimulate employees to choose a sustainable way of transport to and from work.

**Energy efficient new Idylla™ cartridge production line**

**During the design and construction of the second Idylla™ cartridge manufacturing line 'ML2', several energy efficiency studies were implemented, leading to the best solution in terms of total installed power, heat recovery and minimal environmental impact for the ventilation, cooling and lightning systems of the ML2 production area. Additionally, the ML2 production equipment was designed to generate a maximum assembly yield while ensuring a minimal of production waste.**

## 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 overlooked 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 25 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

## THE IDYLLA™ PLATFORM

*"We develop fully integrated and broadly applicable molecular diagnostics. Our platform can be used in a wide variety of healthcare settings to enable rapid and high-quality care close to patients."*


The Idylla™ platform was launched end of 2014 as a CE-marked product. It 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:

**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.

**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.

**Step 3:** The patient sample is added into the cartridge. By closing the lid, the cartridge is hermetically sealed to prevent contamination of the instrument or laboratory.

**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.

# MENU OF IDYLLA™ ONCOLOGY MOLECULAR DIAGNOSTIC TESTS

As per end 2018, Biocartis offered tests supporting melanoma, colorectal and lung cancer.

## FFPE - SOLID BIOPSY TESTS

### Diagnostic products (CE IVD)

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

### Research products (RUO)

Idylla™ MSI Assay
Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay

## PLASMA – LIQUID BIOPSY TESTS

### Diagnostic products (CE IVD)

Idylla™ ctKRAS Mutation Test
Idylla™ ctNRAS-BRAF Mutation Test

### Research products (RUO)

Idylla™ ctBRAF Mutation Assay
Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay


## METASTATIC COLORECTAL CANCER (MCRC)

Colorectal cancer is the third most common cancer worldwide, with nearly 1.4 million new cases diagnosed in 2012[46]. About 46% of all metastatic colorectal tumors harbor KRAS gene mutations[47] and about 5% of all metastatic colorectal tumors harbor NRAS gene mutations[48]. According to ESMO[49], NCCN[50] , ASCO[51] and CAP/AMP/ASCO[52] guidelines, genotyping of clinically actionable mutations[53] 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[54].

About 46% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the *KRAS* gene[55]. Several studies are ongoing to define the predictive impact of KRAS mutations on therapy decision for non-small-cell lung cancer (NSCLC) patients[56]. Currently there is evidence that KRAS in lung cancer has a prognostic value, indicating poor survival for patients with NSCLC, compared to the absence of KRAS mutations[57].

Using 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.

The Idylla™ KRAS Mutation Test, Idylla™ NRAS-BRAF Mutation Test and Idylla™ NRAS 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[58] and ESMO[59]. The ability of Biocartis' RAS test offering to enable same-day results can now open routes towards faster treatment selection for mCRC patients.

### Idylla™ KRAS Mutation Test (CE IVD, diagnostic use)

- Approx. 120 minutes sample-to-result
- 21 mutations, directly on FFPE tissue sections (5-10µm) from mCRC
- < 2 minutes hands-on time
- Mutation detection for baseline treatment

### Idylla™ ctKRAS Mutation Assay (CE IVD, diagnostic use)

- Approx. 130 minutes sample-to-result
- 21 mutations, directly on 1 ml plasma from mCRC patients
- 1 minute hands-on time
- Mutation detection for baseline treatment

### Idylla™ NRAS-BRAF Mutation Test (CE IVD, diagnostic use)

- Approx. 120 minutes sample-to-result
- 18 NRAS mutations and 5 BRAF mutations, directly on FFPE tissue sections (5-10µm) from mCRC
- < 2 minutes hands-on time
- Mutation detection for baseline treatment

### Idylla™ NRAS Mutation Test (CE IVD, diagnostic use)

- Approx. 120 minutes sample-to-result
- 18 NRAS mutations, directly on FFPE tissue sections (5-10µm) from mCRC
- < 2 minutes hands-on time
- Mutation detection for baseline treatment

### Idylla™ ctNRAS-BRAF Mutation Test (CE IVD, diagnostic use)

- Approx. 110 minutes sample-to-result
- 18 NRAS mutations and 5 BRAF mutations, directly on directly on 1 ml plasma from mCRC patients
- < 1 minutes hands-on time
- Mutation detection for baseline treatment

## IDYLLA™ MSI DETECTION ON SOLID BIOPSIES

Microsatellite instability (MSI) is defined as a length variation of DNA repeat regions found in microsatellites or homopolymers. MSI 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[60]. MSI can be sporadic or hereditary. 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[61]. Clinical trials and pathophysiological studies indicate a wide distribution of MSI-H across tumor types[62]. In addition to CRC, high incidences are observed in endometrial cancer (20-30%), and gastric cancer (15-20%)[63]. Guidelines recommend assessing the MSI status for all patients with colorectal or endometrial carcinomas for screening for Lynch syndrome as well as for prognostic stratification and 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 Assay (RUO, not for diagnostic use)

- Approx. 150 minutes sample-to-result
- 7 novel MSI Biomarkers: ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2
- Directly on 1 FFPE tissue section (5µm). No need for normal tissue sample
- < 2 minute hands-on time
- Useful in multiple cancers harboring MSI mutations

*Sarah L. McCarron,*
*Cancer Molecular Diagnostics,*
*St. James' Hospital, Dublin, Ireland*

*"We are delighted with the performance of the Idylla™ MSI Assay providing high quality results from minimal amount of tissue. The ease of use allows even laboratories with minimal histopathology experience to perform MSI testing in-house."*

## 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 Assay (CE IVD, diagnostic use)

- Approx. 150 minutes sample-to-result
- 51 mutations, directly on 1 FFPE tissue section (5µm) from metastatic non-small cell lung cancer
- < 2 minutes hands-on time
- Mutation detection for treatment assessment

*Prof. Giancarlo Troncone*
*University of Napoli Federico II,*
*Naples, Italy*

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

## MELANOMA CANCER

Activating mutations in the BRAF occur in about 8% of all cancers[68] and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics. Cancers in which BRAF mutations are observed include: melanoma, colorectal cancer, thyroid cancer, lung cancer, hairy cell leukemia and ovarian cancer. BRAF testing is recommended in all patients with metastatic melanoma and metastatic colorectal cancer (mCRC). About 50% of all metastatic melanoma patients harbor mutations in the BRAF gene, making them eligible for BRAF or BRAF/MEK inhibitor therapy[69]. 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%[70].

### Idylla™ BRAF Mutation Test (CE IVD, diagnostic use)

- Approx. 90 minutes sample-to-result
- 7 mutations, directly on FFPE tissue sections (5-10µm) from metastatic melanoma
- < 2 minutes hands-on time
- Mutation detection for baseline treatment

### Idylla™ ctBRAF Mutation Assay (RUO, not for diagnostic use)

- Approx. 85 minutes sample-to-result
- 7 mutations, directly on 1 ml plasma
- < 1 minute hands-on time
- Useful in multiple cancers harboring BRAF mutations

*Prof. B. Neyns, M.D., Ph.D,*
*Medical Oncology,*
*UZ Brussels, Belgium*

*"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."*

# 3.12/ STAKEHOLDERS

## 3.12.1/ PARTNERS

Partnerships are a cornerstone in Biocartis' Idylla™ platform and test menu expansion strategy. In 2018, Biocartis expanded its number of partnerships. End of 2018, Biocartis had the following partnerships in place:

**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 assays. 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. The first assay selected for development under the new partnership is a fully automated solid biopsy assay, operating directly from FFPE tumor tissue and aimed at supporting optimal therapy selection for Her2-targeted therapies, hormone receptor therapies, as well as some novel targets for breast cancer patients.

**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[71], the partnership was expanded in December 2016 to up to 10 European countries and in 2017 to the field of CDx development.

**ASTRAZENECA:** On 29 November 2018, Biocartis and AstraZeneca, a global science-led biopharmaceutical company (LON: AZN), announced their agreement aimed at obtaining faster lung cancer molecular diagnostic biomarker results in Europe. As part of the collaboration, a prospective lung cancer study will be conducted at more than a dozen sites in Belgium, France, Germany and Italy. The study is aimed at demonstrating how the unique features of the Idylla™ platform can overcome the current complexity and long turnaround time for lung cancer patients by delivering accurate biomarker results faster and easier with the Idylla™ EGFR Mutation Test (CE-IVD).

**GENOMIC HEALTH INC.:** On 13 September 2017, Biocartis and Genomic Health Inc. announced to have signed an exclusive agreement to develop on the Idylla™ platform an IVD version of the Oncotype DX Breast Recurrence Score® test 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 in vitro diagnostic (IVD) version of the Oncotype DX Genomic Prostate Score® (GPS™) Test on the Idylla™ platform 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. Parties will co-develop the SeptiCyte™ Idylla™ test, whereas Immunexpress will take the lead in the commercialization with an initial focus on the US and the European markets.

**JOHNSON & JOHNSON – JANSSEN PHARMACEUTICA:** Janssen Pharmaceutica NV (JPNV) signed a strategic partnership with Biocartis in December 2010 to co-develop assays for the Idylla™ platform and collaborate commercially. Tests developed under the partnership include the Idylla™ Respiratory (IFV-RSV) Panel[72] and the Idylla™ Ebola Virus Triage Test[73] .

**LIFEARC:** On 7 June 2017, Biocartis announced its agreement with LifeArc, a medical research charity, for the development of selected MDx tests for Idylla™. This partnership marked an important first step in the breast cancer menu that Biocartis is developing. 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. The first test to be developed under the partnership will be a liquid biopsy test aimed at monitoring of metastatic breast cancer patients for resistance to hormone therapy.

**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 Test and the Idylla™ ctNRAS-BRAF Mutation Test were launched as Biocartis' first CE marked liquid biopsy tests in November 2017 for in vitro diagnostic use to detect RAS and BRAF mutations in patients with metastatic colorectal cancer (mCRC). Both companies are now collaborating to make the tests commercially available to medical centers[74].

**NICHIREI BIOSCIENCE:** Post the reporting 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 Idylla™ oncology tests in Japan. Under the terms of the agreement, Nichirei Bioscience will seek the regulatory approval of Idylla™ MDx oncology tests with the Japanese Ministry of Health, Labor and Welfare. Upon successful registration, Nichirei Bioscience's sales force plans to distribute Biocartis' Idylla™ platform across its commercial network of some 2,000 pathology laboratories in Japan.

**THERMO FISHER SCIENTIFIC:** Biocartis announced its partnership with Fisher Healthcare (part of Thermo Fisher Scientific Inc.) in November 2016 for the distribution of its Idylla™ platform and oncology assays. In the US, Biocartis has installed a hybrid sales model, whereby Biocartis is both operating through its own US sales and via Thermo Fisher Scientific. More information can be found under 'Customers & patients' below.

**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 will be 50% owned by Biocartis and 50% owned by Wondfo. The initial activities of the joint venture will be focused on the local manufacturing, commercialization and registration with the Chinese Regulatory Authorities (CFDA) of the existing products in the Idylla™ MDx oncology test menu for amongst others colorectal and lung cancer.

3.12.2/
# CUSTOMERS & PATIENTS

## GO-TO-MARKET STRATEGY

### THE PATHOLOGIST AND ONCOLOGIST AS KEY IDYLLA™ STAKEHOLDERS

Oncology MDx testing today is performed by pathologists who determines the molecular changes present in tumors for diagnostic, prognostic or predictive purposes. They often operate within central, highly skilled laboratories, running a high volume of tests. Pathologists increasingly also 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. On the other side of the spectrum, in the hospital setting, the oncologist is in contact with the patient and a key user of MDx information to determine the best treatment plan for each individual patient. Obtaining fast test results and in future potential monitoring of the treatment efficiency by means of liquid biopsy tests is therefore 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 larger 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 mid and 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 Inc. partnership which expanded in 2018 to the domain of urological cancer testing. Here, the 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 2018, Biocartis was active in over 70 countries through a combination of direct sales and (distribution) partners.

**Direct sales strategy:** In Europe, Biocartis has a direct sales force covering all key European countries.

**Hybrid sales strategy:** In the US, Biocartis implements a hybrid model consisting of direct sales and sales through its distribution partner Fisher Healthcare (part of Thermo Fisher Scientific Inc.)[75]. Fisher Healthcare has exclusive distribution rights on the Biocartis Idylla™ tests and non-exclusive distribution rights on the Idylla™ instruments. In 2018, Biocartis expanded its US sales team which is supporting the Fisher Healthcare team, and is also selling directly in the US market.

**Distributor sales strategy RoW:** In RoW countries[76], 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 extensive product trainings for new distributors, regular distributor update meetings, 24/7 access to an online marketing platform, a one-stop-shop for all product marketing materials, joining international and local congresses and joint visits to key accounts. On 7 January 2019, post the reporting period, 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.

**Pharmaceutical and (test) content partners:** Partnerships with pharmaceutical oncology treatment companies such as the ones 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 benefit from an accelerated global roll-out of their test content, cost efficiencies and faster customer adoption since no platform education is needed.

## 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[77]. 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 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[78].

The first go-to-market focus in the US is on **the large 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 will target the smaller laboratories and hospitals that do not yet perform MDx testing.

*Alexander C. Mackinnon, Jr., MD, PhD, Associate Professor of Pathology, Medical College of Wisconsin (US), providing care to more than 500,000 patients*

*"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."*

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

### Teams:

**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. In 2018, the Biocartis sales team counted some 60 people.

**Dedicated team of Customer support and Customer service employees.**

### Customer trainings & meetings:

As a minimum, every customer receives the Idylla™ User training at the moment of the instrument placement. In 2018, Biocartis organized seven customer events, including Idylla™ User meetings, Idylla™ Technician Training Day and a Metastatic Colorectal Cancer Academy in Vienna.

### Communications:

**New website:** End of 2018, the Biocartis website was renewed with a targeted messaging addressing the different Idylla™ stakeholders, including pathologists, oncologists and pharmaceutical oncology treatment partner companies. The new website also includes a new 'publications' section focusing on all Idylla™ publications.

**Regular direct customer communications:** On the product menu and commercial activities.

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 2018 consisted of:

**Abstracts and publications:** Biocartis collaborated with KOLs on innovative research and clinical data that translated into 16 abstracts/posters presented at national and international conferences and 11 publications in key journals demonstrating the quality and high performance of the Idylla™ products.

**Key Expert Meetings:** In 2018, Biocartis organized two KOL meetings with experts to assess current trends and market opportunities in oncology MDx testing. The first one, on 15 June 2018, was on the topic of breast cancer. The second one took place in during the ESMO meeting in Munich, Germany on 18 October 2018 and focused on colorectal and lung cancer in connection to the future Idylla™ product portfolio. In total, 12 key experts from key European countries attended to share their insights and knowledge on current trends in oncology molecular diagnostic testing.

## SCIENTIFIC ADVISORY BOARD

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 made up in order to avoid or mitigate potential internal and external threats (IT, power outage, fire, terrorist attacks, ….)

**Agreements:** Various agreements (quality, manufacturing, distribution, …) are made with suppliers outlining Biocartis' expectations in terms of technical specifications, quality, safety and environment.

**Performance audits:** Every year, an audit plan is 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 or exceed the required performance , e.g. product specification documents and audit action plans.

**Key supply chain focus areas in 2018 were:**

**1.** Maximizing and sustaining the cartridge manufacturing output on the first manufacturing line (ML1), expand the capacity by designing and installing a smart second automated manufacturing line (ML2) which would allow for a standardization of future upscaling.

**2.** Implement a Quality Readiness program with an Electronic Batch Record system and prepare Manufacturing and Supply Chain for US FDA audit inspections.

**3.** Secure a reliable and cost effective supply chain with BCP (Business Continuity Plan) for critical suppliers, develop strategic partnerships and implement quality supplier programs.

**4.** Build the right organizational capabilities to facilitate smart automated upscaling.

### MEMBERSHIPS AND SUPPLY CHAIN LEARNING PROGRAMS

Biocartis was nominated 'Finalist' in the VIB-PICS 2018 Supply Chain Awards.

Biocartis is an active member of EGN (Executives Global Network, www.egn.com), VIB (Vereniging voor Inkoop en Bedrijfslogistiek, www.bevib.be) and PICS (a professional association for logistics services, www.picsbelgium.be) to stimulate peer-to-peer and best practice learning within supply chain.

Biocartis actively partners with Belgian universities (KU Leuven, Artevelde Ghent, Thomas Moore) to provide internships for future supply chain talents.

## 3.12.4/ EMPLOYEES

*Susy Spruyt,*
*Head of People & Organization*
*Biocartis*

*"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."*

### HR STRATEGY

Employees are essential to our success. We are dedicated to building a diverse, global team of talented people that contribute to our organizational success. We operate through a team-based, horizontally focused structure that stimulates cross-company collaboration. Our HR strategy is built on six strategic pillars which were reinforced in 2018 through various actions:

**1) Organizational structure:** In 2018 the organizational structure was improved to better support Biocartis' size allowing it to scale further as a customer-focused organization. A key initiative in this respect was the reshaping towards a matrix organization composed of four functional business units: Create (R&D), Make (production), Sell (sales & marketing) and Foundations (general support & administration) with a cross-functional project/team focus. Furthermore, in the US, a particular investment was made to establish a larger direct sales & marketing team and to set up a US-based R&D (Create) team to support local partnership collaborations.

**2) Workforce planning, recruitment & selection:** As a fast-growing company, Biocartis' recruitment strategy evolved towards increased team diversity e.g. levels of experience (junior vs senior), international experience, and expert vs managerial capabilities. In 2018, actions were implemented with respect to a.o. expanding the team of production operators and additional shifts, the integration of a competency framework that supports the identification of certain workforce gaps and the roll-out of a company-wide introduction program for new employees.

**3) Compensation & benefits:** Biocartis' compensation & benefits framework is fair, consistent and competitive. The total rewards offering is benchmarked on a regular basis and covers basic pay and potentially other employee benefits such as pension schemes and hospitalization plans, flexible work schemes, sales incentives for sales teams, short-term incentives (cash bonus) and long-term incentives (warrants). Each job in Biocartis is positioned into a job & level grid, based on six parameters: job impact, job complexity, communication, people management, resource responsibility and knowledge/skills/expertise. Salaries are reviewed annually through the merit review process. Key compensation & benefit actions in 2018 included the roll-out of a new employee warrant plan. More information can be found in the remuneration report below.

**4) Employee performance & engagement:** Biocartis is committed to continuously support its employees to be fully engaged and passionate in working for Biocartis, its purpose and strategy. This is done through continuous feedback and coaching and participative and coaching leadership, which requires a different skills set whereby development of leadership capabilities is essential. In this respect, Biocartis initiated several actions to update its performance management system emphasizing employee engagement, contribution and satisfaction, based on a more collaborative and outcome-driven goal setting.

**5) Leadership at all levels:** Development of leadership capabilities is a key focus in Biocartis' HR strategy. In 2018, several actions were initiated in this respect including personal leadership styles trainings, workshops on active listening, management by objectives, etc.

**6) Standardization & automation:** In its efforts to keep a healthy balance between growth & stability & scalability, in 2018, special efforts went out to the further standardization and automation.

## DIVERSITY & INCLUSIVENESS

With 394 employees[1] at work end of 2018 in a company active in over 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 potential assessment, 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 2018, the Biocartis workforce of 394 employees[1] counted.

21 different nationalities

A balanced level of gender diversity of 50% male and 50% female, stable since 2016.

Approx. 90% of the Biocartis employees worked full-time, stable since 2016

### NATIONALITIES IN 2018

21

### GENDER DIVERSITY

50/50

### WORKFORCE EVOLUTION

2015
270

2016
308

2017
318

2018
394

## TRAINING & DEVELOPMENT

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

**1) 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

**2) Continuous learning:**

At the start of his/her employment, each employee is offered an onboarding program 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 2018, 23 Welcome Days and four Induction sessions were held for all new employees to provide them with all the info they need within the first months joining Biocartis. All new employees receive a Welcome Package which contains a wide range of corporate information and policies.

A mix of corporate training programs are offered throughout the year, including on for example project management, business acumen, soft skills trainings, IT, etc.

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 School' lunch learning sessions, or ad hoc expert speaker sessions from e.g. KOLs.

In 2018, the Biocartis workforce followed over 11,000 training hours.

## HEALTH, SAFETY AND EMPLOYEE WELLBEING

### HEALTH & SAFETY

Biocartis is committed to a safe and healthy work environment for all of its employees, contractors and visitors worldwide by:

Ensuring compliance with the most recent global Environment, Health and Safety (EHS) legislation through permanent advice by an internal and external prevention advisor, an environmental coordinator, a biosafety advisor and an EHS Committee

Keeping legal permits up to date with the actual business situation

Continuous risk evaluation of all EHS aspects, resulting in a business-wide EHS improvement action list

EHS strategy definition and prioritization through monthly EHS steering team meetings

Involvement of employees in the EHS policy through monthly participative round table meetings

Taking into account EHS requirements in every new business initiative, infrastructural as well as organizational

In 2018:

- Key EHS projects related to the design of a safe and ergonomic-friendly new production line ('ML2') and the expansion of the EHS policy covering the global reach of Biocartis
- 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 were caused. Six accidents occurred during commuting to & from the workplace

**WORKPLACE ACCIDENTS**

**0**

**ACCIDENTS DURING TRAVEL TO & FROM WORK**

**6**

## EMPLOYEE WELLBEING

The constantly changing environment, information overload and the always-connected work environment sometimes overwhelm employees and if not addressed properly, could undermine productivity and employee engagement.

Biocartis' main focus to address employee wellbeing was the implementation of its cross-functional matrix structure with clear roles and responsibilities for every employee. Other initiatives in 2018 included:

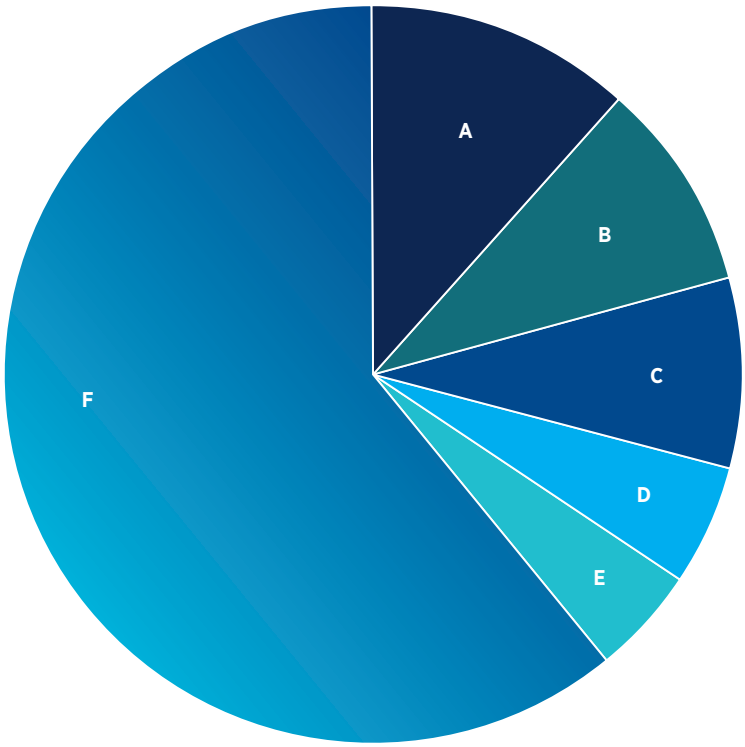
- Encouraging cross-functional teamwork inc. shared responsibilities in smaller, more agile teams
- Flexible working schedules where possible
- Celebrating big & small successes, through regular employee events such as a Spring BBQ or an annual Corporate or Family Day at Biocartis
- Other wellbeing initiatives Biocartis offers include sports events, fresh fruit delivery once a week, start to relax initiation course, locked bicycle storage to promote sustainable commuting, etc.

In November and December 2018, Biocartis employees organized several fundraising actions for the 'Music for Life' campaign, as such raising over EUR 3,700 and supporting seven different non-profit organizations in the area of cancer and health

# 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 more local retail investors. Based on the number of shares as at 31 December 2018 and the transparency notifications received until that date, the shareholder structure of the Company was as follows as per 31 December 2018:




| | |
|---|---|
| **A:** Johnson & Johnson Innovation – JJDC, Inc.[1]: | 11.5% |
| **B:** OppenheimerFunds[2]: | 9.4% |
| **C:** Debiopharm Innovation Fund S.A.[3]: | 8.3% |
| **D:** Sycomore Asset Management[4]: | 5.2% |
| **E:** ParticipatieMaatschappij Vlaanderen NV (Flemish Region)[5]: | 4.6% |
| **F:** Other institutional and retail investors: | 61% |

[1] Johnson & Johnson Innovation-JJDC, Inc., is a wholly owned subsidiary of Johnson & Johnson. Johnson & Johnson is not a controlled entity.
[2] OppenheimerFund, Inc. Is not a controlled entity
[3] Debiopharm Innovation Fund S.A. (formerly Debiopharm Diagnostics S.A.)[79] is controlled by Debiopharm Holding S.A., which is controlled by Thierry Mauvernay.
[4] Sycomore Asset Management is not a controlled entity.
[5] 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 2018, the share capital of the Company amounted to EUR 513,610.88 represented by 51,361,088 shares. In addition, as at such date, 3,441,603 shares could still be issued by the Company as follows:

- 516,755 shares can be issued upon the exercise of 516,755 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;
- 250,422 shares can be issued upon the exercise of 250,422 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;
- 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; and
- 1,334,426 shares can be issued upon the exercise of 1,334,426 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.

The total number of fully diluted shares consequently amounted to 51,361,088 as of 31 December 2018. More information on the Company's stock options and warrants can be found below and in the Remuneration Report.

## STOCK BASED INCENTIVE PLANS AND CONVERSION OPTION AGREEMENT

### STOCK BASED INCENTIVE PLANS

The Company currently has four stock based incentive plans:

- The 2008 Plan
- The 2013 Plan
- The 2015 Plan
- The 2018 Plan

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

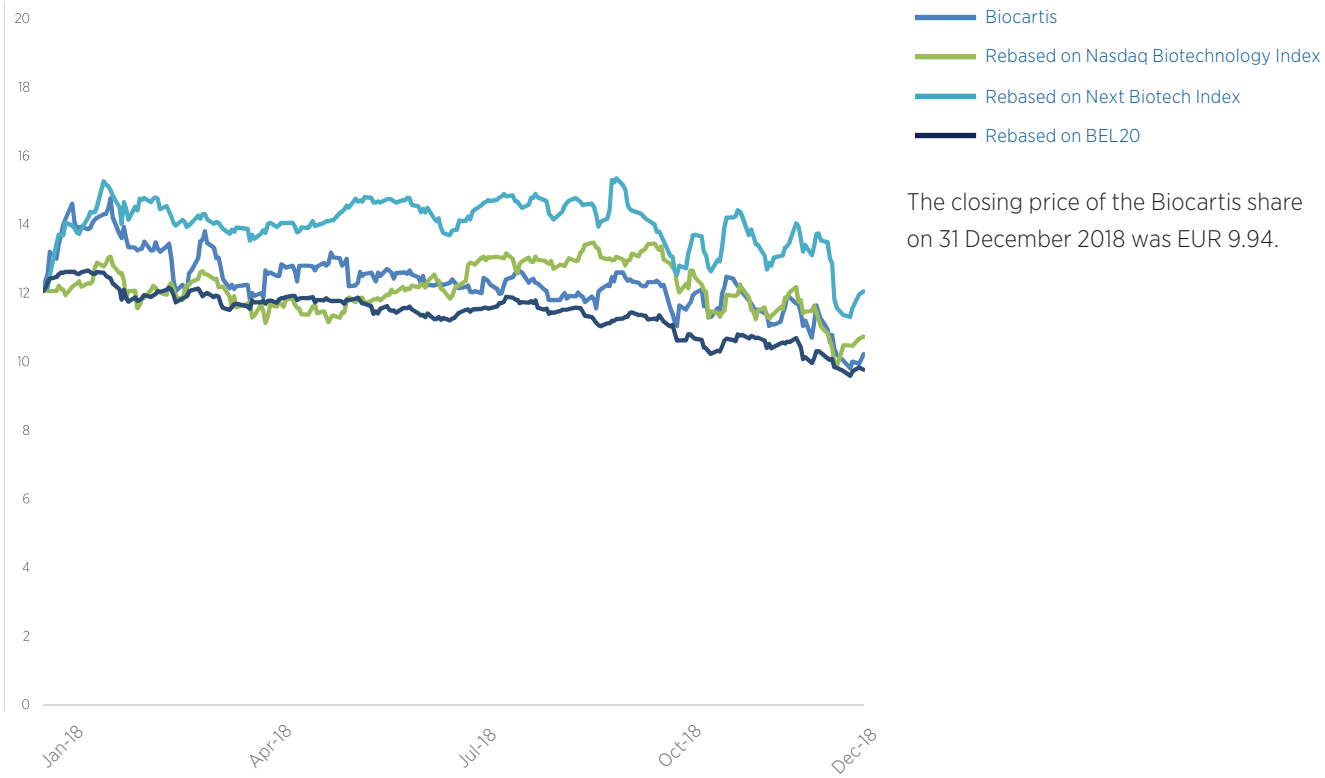
## SHARE PERFORMANCE

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)




The closing price of the Biocartis share on 31 December 2018 was EUR 9.94.

* Rebased at Biocartis share price on 2 January 2019 / Source: Bloomberg

## TRADING VOLUME

Below is a summary of the 2018 trading volumes of Biocartis' share.

| BCART | 2018 | 2017 | % |
|---|---|---|---|
| **Average daily volume** | 75,903 | 77,210 | -2% |
| **Average daily value** | 12.36 | 10.7 | 13% |
| **Total traded volume** | 19,355,234 | 19,688,660 | -2% |
| **Total traded value** | 487,298,753 | 218,354,801 | 55% |

Source: Bloomberg

## ANALYST COVERAGE

The Biocartis share was covered by six brokers end of 2018:

| BROKER | ANALYST | RATING END 2018 | TARGET PRICE END 2018 |
|---|---|---|---|
| **Berenberg** | Michael Ruzic-Gauthier | Buy | EUR 16.50 |
| **Degroof Petercam** | Stéphanie Put | Buy | EUR 17.00 |
| **KBC Securities** | Lenny Van Steenhuyse | Buy | EUR 16.00 |
| **Kempen & Co** | Alexandru Cogut | Buy | EUR 21.00 |
| **Kepler-Cheuvreux** | Kris Kippers | Buy | EUR 15.70 |
| **NIBC** | Dylan van Haaften / Anita Yé | Buy | EUR 15.90 |

## FINANCIAL CALENDAR 2019

| | |
|---|---|
| **28 February 2019** | Full year results 2018 |
| **4 April 2019** | Publication Annual Report 2018 |
| **25 April 2019** | Q1 2019 Business Update |
| **10 May 2019** | Annual General Meeting Biocartis Group NV |
| **5 September 2019** | H1 2019 results |
| **14 November 2019** | Q3 2019 Business Update |

## INVESTOR RELATION DETAILS

For any investor relation related questions, please contact:
Renate Degrave, Biocartis, Generaal de Wittelaan 11 B, 2800 Mechelen (Belgium),
tel. +32 15 631 729, rdegrave@biocartis.com.

# 3.13 / RISKS RELATED TO OUR BUSINESS

The following risk factors may affect the future operating and financial performance of Biocartis. 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 in four categories: strategic and commercial risks, operational risks, regulatory risks and financial risks.

## STRATEGIC AND COMMERCIAL RISKS

### THE MDX INDUSTRY IS HIGHLY COMPETITIVE AND SUBJECT TO RAPID TECHNOLOGICAL CHANGES.

The 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. 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. Biocartis faces intense competition from a number of companies that offer solutions and technologies in its target markets. The Idylla™ platform is a sample-to-result platform, and several other companies have brought such platforms to the market or aim to do so. Some competitors have substantially greater financial resources and larger, more established marketing, sales and service organizations than those of Biocartis.

### THE COMMERCIAL SUCCESS OF BIOCARTIS WILL DEPEND ON COMMERCIAL MARKET ACCEPTANCE OF THE IDYLLA™ PLATFORM AND ITS MENU OF TESTS.

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. Since that date, Biocartis and/or its partners have launched several additional tests, but so far Biocartis has only generated limited revenue. There can be no assurance that these products or any further products launched by Biocartis will gain acceptance by the market as many factors, of which many outside the control of Biocartis, can influence market acceptance.

### BIOCARTIS FACES UNCERTAINTIES OVER THE REIMBURSEMENT FOR ITS PRODUCTS BY THIRD PARTIES AND MAY BE SUBJECT TO STRICT PRICE CONTROLS.

The commercial success of Biocartis' Idylla™ platform and menu of tests depends, in part, on the degree to which they are reimbursed by public health administrations, private health insurers, managed care organizations and other organizations in the countries in which Biocartis operates. Although Biocartis' first wave of tests predominantly involve biomarkers for which reimbursement is already established, 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. As a result, Biocartis will need to continue to expend significant effort and expense to establish, and may never succeed in establishing, widespread or systematic reimbursement arrangements for its products. Furthermore, reimbursement levels are set by parties outside the control of Biocartis and they may change over time. A reduction in reimbursement levels may affect the price that Biocartis is able to obtain for the Idylla™ platform and tests.

# OPERATIONAL RISKS

## DELAYS IN THE DEVELOPMENT OF TESTS MAY OCCUR RESULTING IN A SLOWER AVAILABILITY OF A BROAD AND CLINICALLY RELEVANT MENU OF TESTS.

To date, the Idylla™ platform has been commercialized on the basis of a limited number of tests 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 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. Furthermore, Biocartis may experience unexpected delays or difficulties in the development and commercialization of tests (both on a standalone basis and together with partners), which may jeopardize and/or delay market acceptance of the Idylla™ platform, could jeopardize Biocartis' ability to enter into additional partnerships for the development and commercialization of tests and could consequently affect future revenue growth. Such delays may occur due to a variety of factors, of which many outside the control of Biocartis.

## 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. In addition, 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 the Company's installed base and could result in a loss in revenues. Furthermore, Biocartis will need to continue to build a maintenance and service organization in order to ensure adequate installation and servicing of its installed base.

## 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. The manufacturing or assembly of the instrument and the console has been outsourced to a contract manufacturing partner (CMO). The manufacturing or assembly of the cartridge is currently performed in-house at Biocartis' facilities in Mechelen (Belgium). In order to meet future expected demand, Biocartis has constructed a more automated and higher volume production line for Idylla™ cartridges in its Mechelen facilities. Biocartis is currently in the process of transferring its commercial volume to this new production line. There can be no assurance that such assay 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. This could affect Biocartis' ability to continue supply to its customers which could result in potential financial and reputational damages.

## 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 few components Biocartis is exposed to single source risk. There can be no assurance that Biocartis' suppliers will at all times be able 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 potential financial and reputational damages. If Biocartis needs alternative sources for key components, for any reason, these alternative component parts 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.

## BIOCARTIS FACES AN INHERENT RISK OF PRODUCT LIABILITY CLAIMS.

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 has entered into product liability insurance with an overall cover that it believes to be market conform.

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

Biocartis' MDx products are designed solely to detect the levels of certain specified biomarkers and are not designed to specify the treatment necessary for each patient, which remains the responsibility of relevant medical personnel. Although Biocartis makes this very clear when it markets its products and on its labelling (which indicates, among other things, the relevant test's accuracy rate), Biocartis cannot provide assurance that patients, hospitals, surgeons 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.

## 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 rights form the basis of its products and technologies. Biocartis invests in different forms of intellectual property 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. In addition to patents, Biocartis also relies on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements and other contractual provisions and technical measures. Protecting the intellectual property rights may be critical to Biocartis' success, but will depend on a number of complex legal and factual questions.

## BIOCARTIS IS DEPENDENT ON (SUB)LICENSES FOR KEY TECHNOLOGIES FROM THIRD PARTIES AND MAY REQUIRE ADDITIONAL LICENSES.

Biocartis relies on key technologies from third parties and has entered into (sub)license agreements with a number of (sub) licensors. Various license agreements impose on Biocartis various development obligations, payment of royalties and fees obligations, as well as other obligations. If Biocartis fails to comply with any of its obligations under these agreements, the (sub)licensor may have the right to terminate the (sub) license. In addition, if the sublicensor fails to comply with its license or the licensor fails to enforce its intellectual property, the (sub)licensed rights may not be adequately

maintained. The termination of any (sub)license agreements, or the failure to adequately protect the intellectual property rights which are the subject matter of such (sub)license agreements, could prevent Biocartis from commercializing products covered by the (sub)licensed intellectual property or have another negative impact on such commercialization. In addition, Biocartis may require access to additional third-party technologies for which an additional (sub)license, or (sub)licenses, needs 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. Finally, certain technologies and patents have been developed with collaboration partners, and Biocartis may be limited by restrictions on this jointly developed intellectual property.

## 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 thus 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. 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.

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

Competition for skilled personnel 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. Attracting, retaining and training personnel with the requisite skills is therefore challenging. If, at any point, Biocartis is unable to hire, train and retain a sufficient number of qualified employees to match its growth, this could have a material adverse effect on its ability to implement its business strategy.

## A BREACH OF SECURITY IN BIOCARTIS' PRODUCTS OR COMPUTER SYSTEMS MAY COMPROMISE THE INTEGRITY OF BIOCARTIS' PRODUCTS, HARM BIOCARTIS' REPUTATION, CREATE ADDITIONAL LIABILITY AND HAVE A MATERIAL ADVERSE IMPACT ON BIOCARTIS' RESULTS OF OPERATIONS.

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 and Biocartis' customers serve.

## POTENTIAL LIABILITY RELATED TO THE PRIVACY AND SECURITY OF PERSONAL INFORMATION BIOCARTIS COLLECTS.

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 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.

### BREXIT

The manufacturing or assembly of the Idylla™ instrument and the console has been outsourced to a contract manufacturing partner 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 may be 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, a potential Brexit remains an unprecedented situation with a lot of uncertainty that may have negative impact on Biocartis' logistic streams from and to the UK and hence on the availability of its products and components.

## REGULATORY RISKS

### FAILURE TO COMPLY WITH REGULATIONS OF THE MDX MARKET.

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 or advertising restrictions, Biocartis may become subject to significant fines and/or other liabilities, including being prohibited from importing into these markets.

### 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.

### BIOCARTIS' BUSINESS COULD BE SIGNIFICANTLY AND NEGATIVELY AFFECTED BY SUBSTANTIAL CHANGES IN GOVERNMENT REGULATIONS, PARTICULARLY IN (BUT NOT LIMITED TO) THE EU AND THE US.

In line with its strategy, Biocartis launched its Idylla™ platform and its first tests, for commercial sale in the EU and countries recognizing CE-marked IVD devices. Biocartis has begun expanding to the US market, and has taken initiatives to prepare for launch in Japan and China in the coming 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 government regulation 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, reporting of certain product failures and distribution. 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.

### HEALTHCARE POLICY CHANGES 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.

## 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. 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.

### 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. 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. Biocartis is subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing 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. Furthermore, Biocartis' increasing international business may make it subject to income tax and other taxes in countries where it was previously not the case.

## BIOCARTIS MAY FACE RISKS ASSOCIATED WITH PREVIOUS OR FUTURE ACQUISITIONS AND DISPOSALS OF COMPANIES, ASSETS, SOLUTIONS AND TECHNOLOGIES.

Since its incorporation, Biocartis has grown through significant 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, 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.

## BIOCARTIS HAS NO FIXED DIVIDEND POLICY.

Biocartis has not declared or paid dividends on its shares to date, and it is not expected that Biocartis will declare or pay dividends in the near future. In the future, Biocartis' dividend policy will be determined and may change from time to time upon proposal of Biocartis' board of directors. Any declaration of dividends will be based upon Biocartis' 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 Biocartis to declare dividends.

Further financial risks are identified in the IFRS financial notes under 'Financial Risk Management'.

CHAPTER 4

# CORPORATE GOVERNANCE

# 4.1/ INTRODUCTION

The Company applies the Belgian Code on Corporate Governance as published on 12 March 2009 (the 'Corporate Governance Code'), which can be consulted on the website of the Belgian Corporate Governance Committee (www.corporategovernancecommittee.be). In accordance with the 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 Company's corporate governance charter was last updated at the meeting of the board of directors held on 22 May 2018. The articles of association and the corporate governance charter are available on the Company's website www.biocartis.com under 'investors'.

The Company strives to comply with the rules of the Corporate Governance Code as much as possible. Nonetheless, the board of directors is of the opinion that certain deviations from the provisions of the Corporate Governance Code are 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 'Remuneration of the Directors'.

# 4.2/ BOARD OF DIRECTORS

## COMPOSITION

The board of directors is composed of nine directors. The table below gives an overview of the members of the Company's board of directors as at 31 December 2018.

| Name | Position | Start of term | 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 |
| **Peter Piot** | Non-executive, independent director | 2015 | 2019 |
| **Hilde Windels**[(5)] | Non-executive director | 2015 | 2019 |
| **Roald Borré** | Non-executive director | 2016 | 2019 |

Notes:
(1) Permanently representing CRBA Management BVBA.
(2) Permanently representing Luc Gijsens BVBA.
(3) Permanently representing CLSCO BVBA.
(4) Permanently representing Scientia II LLC.
(5) Permanently representing Hilde Windels BVBA. Hilde Windels BVBA, represented by Hilde Windels, was an executive director until 11 May 2018.

**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 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 currently serves as chairman of the board of Oy Medix Biochemica group Ab and Serres Oy and is a board member of Blueprint Genetics Oy, Immunovia Ab, Ledil Group Oy, Ledil Oy, Raisio Oyj, Revenio Group Oyj, Committee Member of Raisio Oyj's Research Foundation, member of the nomination and remuneration committee of Raisio Oyj 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 currently serves on the board of GeneNews Ltd. and serves on the advisory board of Evidation Health 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.

**Peter Piot** is director at the London School of Hygiene & Tropical Medicine. He was the founding executive director of UNAIDS and under secretary-general of the United Nations from 1995 until 2008, and was an associate director of the Global Program on AIDS of the WHO. Under his leadership, UNAIDS became the chief advocate for worldwide action against AIDS, also spearheading UN reform by bringing together 10 UN systems organizations. In 1976 he co-discovered the Ebola virus in Zaïre. Mr. Piot also led research on HIV/AIDS, sexually transmitted diseases and women's health and has held positions as professor of microbiology and of public health at various institutions. Mr. Piot has received numerous scientific and civil awards and has published over 550 scientific articles and 16 books. He holds among others an M.D. from the University of Ghent, Belgium and a Ph.D. in microbiology from the University of Antwerp, Belgium. Furthermore, he is a member of the US National Academy of Medicine and the UK Academy of Medical Sciences and was elected a 2014 TIME Person of the Year.

**Hilde Windels** has close to 20 years of experience in biotech with a track record of building and structuring organizations, private fundraising, M&A, public capital markets and business and corporate strategy. She joined Biocartis as CFO mid-2011 and transitioned in the role of deputy CEO as of September 2015 and to the role of CEO (ad interim) between March 2017 and August 2017. From 2009 to mid-2011, she worked as independent CFO for several private biotech companies. From 1999 to 2008, Mrs. Windels was CFO of publicly-listed DevGen. She also served on the boards of DevGen and FlandersBio and currently serves as a board member of MDxHealth, VIB, Erytech SA, MyCartis NV and Celyad SA. Mrs. Windels holds a Masters in economics from the University of Leuven, Belgium.

**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 amongst its shareholders, directors, managers or employees 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 dismiss the directors at any time.

## CHANGES TO THE COMPOSITION OF THE BOARD OF DIRECTORS

The annual shareholders' meeting held on 11 May 2018 appointed CRBA Management BVBA, represented by Christian Reinaudo, as director of the Company for a term of three years, and appointed Ann-Christine Sundell, Harry Glorikian, CLSCO BVBA, represented by Leo Steenbergen, and Luc Gijsens BVBA, represented by Luc Gijsens, as directors of the Company for a term of two years. The annual shareholders' meeting also reappointed Hilde Windels BVBA, represented by Hilde Windels, Roald Borré, and Peter Piot as directors of the Company for a term of one year. The meeting of the board of directors held on 21 June 2018 coopted Scientia II LLC, represented by Harry Glorikian, as director of the Company, replacing Harry Glorikian.

The board mandates of Gengest BVBA, represented by Rudi Mariën, Valetusan Ltd., represented by Rudi Pauwels, Shaffar LLC, represented by Mark Shaffar, and Be@dvised BVBA, represented by Renaat Berckmoes, expired on 11 May 2018. Citros vof, represented by Hilde Eylenbosch, resigned as director of the Company with effect as of 11 May 2018, but remained active within the Company as chief commercial officer.

The mandates of Hilde Windels BVBA, represented by Hilde Windels, Roald Borré and Peter Piot will end after the annual shareholders' meeting of 10 May 2019. The proposal of the board of directors to the annual shareholders' meeting regarding the (re-)appointment of directors will be included in the convening notice of the annual shareholders' meeting.

## DIVERSITY

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

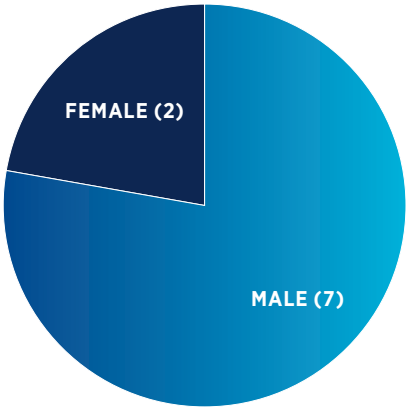
| Name | Functional background and expertise | Gender | Age | Nationality |
|---|---|---|---|---|
| **Christian Reinaudo**[1] | • ehealth & digital imaging solutions<br>• Managing companies<br>• International business | Male | 64 | France |
| **Herman Verrelst** | • Molecular diagnostics<br>• Software solutions<br>• Entrepreneurship | Male | 45 | Belgium |
| **Luc Gijsens**[2] | • Finance<br>• Capital markets<br>• Corporate and investment banking | Male | 65 | Belgium |
| **Leo Steenbergen**[3] | • Finance<br>• General management<br>• Accounting and auditing | Male | 66 | Belgium |
| **Ann-Christine Sundell** | • Life sciences<br>• Diagnostics<br>• Strategy and operations | Female | 54 | Finland |
| **Harry Glorikian**[4] | • Life sciences and healthcare<br>• Diagnostics<br>• Private equity | Male | 53 | United States |
| **Peter Piot** | • Microbiology<br>• Infectious diseases<br>• International institutions | Male | 70 | Belgium |
| **Hilde Windels**[5] | • Finance<br>• Biotech<br>• Molecular diagnostics | Female | 53 | Belgium |
| **Roald Borré** | • Corporate finance and M&A<br>• Investment funds<br>• Accounting and auditing | Male | 46 | Belgium |

Notes:
[1] Permanently representing CRBA Management BVBA; [2] Permanently representing Luc Gijsens BVBA; [3] Permanently representing CLSCO BVBA; [4] Permanently representing Scientia II LLC; [5] Permanently representing Hilde Windels BVBA.

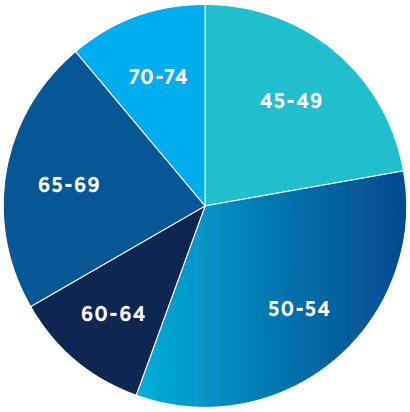
The board is well aware of the provisions of Article 518bis of the Belgian Companies Code that require at least one third of the directors to be of a different gender than the other directors. The rules on gender diversity set out in Article 518bis of the Belgian Companies Code will apply to the Company as from 1 January 2021, being the first day of the sixth financial year after the Company's IPO in 2015. Currently, the Company has two female directors on its board of directors on a total of nine 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.

The board of directors will 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. In order to ensure compliance with the provisions of Article 518bis of the Belgian Companies Code, the board of directors will make every effort to propose female candidate directors for nomination by the general shareholders' meeting going forward.

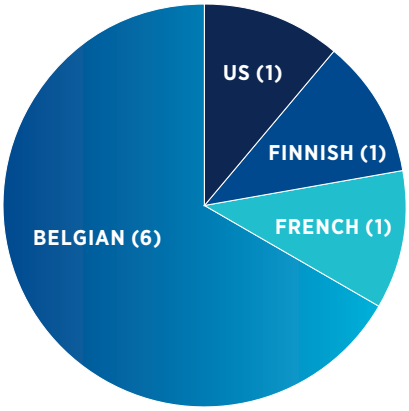
**GENDER**




**AGE**




**NATIONALITY**




## ACTIVITY REPORT

In 2018, the board of directors held eight 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 2018 was 100%, save for Hilde Windels BVBA (permanently represented by Hilde Windels) who was excused during one board meeting, and Peter Piot who was excused during two board meetings.

During the meetings of the board of directors, the board among others reviewed the Group's strategy and operations, discussed business development opportunities, discussed and approved the Company's new debt financing, discussed various corporate governance matters and adopted a new version of its corporate governance charter, prepared the appointment of five new board members, approved the warrant plan 2018, discussed the regular updates of the financial performance and approved the budget for the financial year 2019. The board further reviewed the development of the different activities of the Group (research & development, manufacturing and commercial) on the basis of reports prepared by the executive management team. 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 carried out an internal evaluation relating to its size, composition, performance and interaction with the executive management team and the board committees in accordance with provision 4.11 of the Corporate Governance Code by way of a questionnaire. It intends to repeat the evaluation in 2019 given the changes to the board composition in 2018.

## OTHER BOARD MANDATES

Apart from their mandate within Biocartis, the directors of the Company hold the following board mandates (directly or via a management company):

| | | |
|---|---|---|
| **Christian Reinaudo** | CRBA Management BVBA<br>Agfa Gevaert NV<br>Domo Chemicals GmbH | |
| **Herman Verrelst** | South Bay Ventures (SBV) BVBA<br>Opdorp Finance BVBA<br>Icometrix | FlandersBio VZW<br>Fox Biosystems NV |
| **Luc Gijsens** | Luc Gijsens BVBA<br>Arvesta NV<br>PMV NV | |
| **Leo Steenbergen** | CLSCO BVBA<br>Metallum Holdings BV | LEDSky BVBA<br>Antwerp Metals NV |
| **Ann-Christine Sundell** | Medix Biochemica Group Oy<br>Serres Oy<br>Revenio Group Oyj<br>Raisio Oyj<br>Immunovia AB | Ledil Group Oy<br>Ledil Oy<br>Blueprint Genetics Oy<br>AConsult |
| **Harry Glorikian** | GeneNews Ltd. | |
| **Peter Piot** | None | |
| **Hilde Windels** | Hilde Windels BVBA<br>MDxHealth NV<br>Erytech | VIB<br>MyCartis NV<br>Celyad SA |
| **Roald Borré** | High Wind NV<br>FNG Group NV<br>miDiagnostics NV<br>Capricorn Cleantech Fund NV<br>Laboratoria Smeets NV<br>Newtech Group NV | Newtec Cy NV<br>Innovation Fund NV<br>Kebony AS<br>Media Invest Vlaanderen NV<br>Comics Station NV |

## 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 conflicting financial interest as envisaged by Article 523 of the Belgian Companies Code with respect to any matter or decision of the board of directors must inform his or her fellow directors and the statutory auditor thereof and may not take part in the deliberations or voting related thereto. The Company's corporate governance charter contains the procedure for transactions between Biocartis and directors which are not covered by the legal provisions on conflicts of interest.

The conflict of interest procedure pursuant to Article 523 of the Belgian Companies Code was applied four times in 2018. The extract of the minutes of those meetings is as follows:

The conflict of interest procedure pursuant to Article 523 of the Belgian Companies Code was applied for the first time during the board meeting held on 27 February 2018:

*"Prior to discussing the next item, Mr. Herman Verrelst, director of the Company, and Mrs. Hilde Windels and Mrs. Hilde Eylenbosch, permanent representatives and shareholders of respectively Hilde Windels BVBA and Citros vof, directors of the Company, declared that they have 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 their respective variable remuneration regarding performance year 2017, the determination of the maximum amount and underlying KPIs for their respective variable remuneration packages regarding performance year 2018 and, as far as Herman Verrelst is concerned, the KPIs relating to the vesting of the performance-based warrants under the warrant plan 2017 for performance year 2018.*

*In accordance with Article 523 of the Belgian Companies Code, Mr. Herman Verrelst, Mrs. Hilde Windels and Mrs. Hilde Eylenbosch have decided that they will refrain from taking part in the deliberations and from voting on the matters for which they have 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 members of the executive management relating to performance year 2017 and assessed the degree to which these goals were achieved in 2017. The Board was of the opinion that overall 72% of the company goals were achieved and resolved to approve the amount of the variable remuneration for each member of the executive management relating to performance year 2017 on this basis.*

*B. Following the recommendations of the Remuneration and Nomination Committee, the Board of Directors discussed and deliberated on the variable remuneration for the executive management (excluding CEO) for 2018.*

*a) For the CCO, the proposal is to fix the maximum variable remuneration to 36% (rounded)(1) of her annual fixed remuneration for 2018. In order to measure the performance of the CCO, the proposal is to link rewards to KPIs which can be grouped into three categories: sales and revenues (60%, of which 40% commercial product revenues and 20% non-commercial revenues and grants), overall company goals as set out under C. below (20%) and Board discretion (20%).*

*b) For the other members of executive management, the proposal is to fix the maximum variable remuneration to 20% of their respective annual fixed remuneration for 2018. In order to measure the performance of these members of executive management, the proposal is to link rewards to company goals (80%) and individual goals (20%). The same company goals apply as for the CEO as described under C. below. The individual goals relate to business critical objectives that the respective members of the executive management, from a company perspective, would most attribute to given among others their respective focus areas and leadership position.*

*The Board considered the proposed variable remuneration mechanism and the KPIs that will be used to measure and determine the variable remuneration for these members of executive management for 2018 to be fully in line with the Company's interests. Therefore, after discussion, the Board resolved to approve the variable remuneration mechanism for these executives for 2018 as discussed.*

*C. Following the recommendations of the Remuneration and Nomination Committee, the Board of Directors discussed and deliberated on the variable remuneration for the CEO for 2018. The proposal is to fix the maximum variable remuneration to 50% of his annual fixed remuneration for 2018. In order to measure the performance of the CEO, the proposal is to link rewards to company goals (100%) which can be grouped into five categories: sales and revenues (35%, of which 25% commercial product revenues and 10% non-commercial revenues), production and supply chain (20%), menu development (15%), market expansion, including partnering, portfolio and global expansion (10%) and Board discretion (20%). 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 for 2018 as discussed.*

*Subsequently, and following the recommendations of the Remuneration and Nomination Committee, the Board discussed the KPIs relating to the vesting of maximum 167,500 warrants under the warrant plan 2017 for the CEO for performance year 2018. The proposal is that the KPIs for this purpose can be grouped into three categories: sales and revenues (60%, of which 40% commercial product revenues and 20% non-commercial revenues and grants), menu development and expansion, including CDx and content partner projects (20%) and Board discretion (20%). The Board considered the KPIs to be fully in line with the Company's interests. Therefore, after discussion, the Board resolved to approve the KPIs relating to the vesting of maximum 167,500 warrants under the warrant plan 2017 for the CEO for performance year 2018 as discussed."*

(1) This percentage was later reduced to 25% of the annual fixed remuneration. More information on the remuneration of Herman Verrelst, Hilde Windels BVBA and Citros vof in 2018 can be found in the Remuneration Report below.

The conflict of interest procedure pursuant to Article 523 of the Belgian Companies Code was applied a second and third time during the board meetings held on 21 June 2018 and 10 September 2018 (the latter meeting was held before a notary)[1]:

*"Prior to the deliberation and resolutions by the board of directors, each of the independent directors of the Company, notably: (i) CRBA Management BVBA, represented by its permanent representative Christian Reinaudo, (ii) Ann-Christine Sundell, (iii) Scientia II LLC, represented by its permanent representative Harry Glorikian, (iv) CLSCO BVBA, represented by its permanent representative Leo Steenbergen, (v) Luc Gijsens BVBA, represented by its permanent representative Luc Gijsens, and (vi) Peter Piot, (hereinafter jointly, the "Independent Directors") made the following declaration:*

*The Independent Directors informed the meeting that the agenda refers to the issuance of the Warrants in the framework of the Warrant Plan 2018, and that the independent directors of the Company form a category of Beneficiaries under the Warrant Plan 2018 as a result of which the Company might grant Warrants to one or more independent directors of the Company.*

*The Independent Directors informed the meeting that, as a result, they might have a conflict of interest within the meaning of Article 523 of the Belgian Companies Code in relation to the resolutions to be passed by the board of directors with respect to the proposed issuance of the Warrants and the Warrant Plan 2018.*

*Subsequently, the Independent Directors no longer took part in the further deliberation and resolutions of the board of directors with respect to the Warrant Plan 2018."*

(1) The annual shareholders' meeting held on 11 May 2018 resolved that each of the independent directors of Biocartis is entitled to receive up to 15,000 warrants of Biocartis.

The conflict of interest procedure pursuant to Article 523 of the Belgian Companies Code was applied a fourth time during the board meeting held on 20 November 2018:

*"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 his variable remuneration. Herman Verrelst and the Biocartis attendees who were present left the meeting.*

*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 included in the annual report of the Board of Directors.*

*Following the recommendations of the Remuneration and Nomination Committee, the Board of Directors discussed and deliberated on the 2-year and 3-year KPIs for the CEO.*

*The proposal is to use total revenue and gross margin on product revenues as the two KPIs for both the 2-year target (for 2019) and 3-year target (for 2020). Both the 2-year target and 3-year target will be applied for 25% of the on-target bonus for the relevant performance year (i.e. 2019 and 2020, respectively). Both KPIs will have equal weight for the determination of the on-target bonus for performance years 2019 and 2020, respectively. In case of achievement of the KPIs relating to a certain performance year of 75% or more, the corresponding percentage of the variable remuneration will be payable (e.g., if 80% of the KPIs are achieved, 80% of the variable remuneration to which the KPIs relate shall be payable), provided that the maximum amount payable shall be equal to 100%. In case of an achievement of less than 75% of a certain KPI, no variable remuneration to which such KPI relates shall be payable.*

*The level of achievement of the KPIs relating to a certain performance year shall be determined by the Board of Directors, upon recommendation of the Remuneration and Nomination Committee, at the occasion of the first Board meeting in the calendar year immediately following the relevant performance year.*

*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 in line with the Company's interests. Therefore, after discussion, the Board resolved to approve the variable remuneration mechanism for the CEO as discussed, using the figures as proposed by the Remuneration and Nomination Committee."*

The procedure pursuant to Article 524 of the Belgian Companies Code was not applied in 2018.

# 4.3/ COMMITTEES OF THE BOARD OF DIRECTORS

The board of directors has established two board committees: the audit committee which has been established in accordance with Article 526bis of the Belgian Companies Code and provision 5.2 of the Corporate Governance Code, and the remuneration and nomination committee which has been established in accordance with Article 526quater of the Belgian Companies Code and provisions 5.3 and 5.4 of the Corporate Governance Code. The terms of reference of these board committees are set out in the Company's corporate governance charter.

## AUDIT COMMITTEE

### COMPOSITION

According to Article 526bis of the Belgian Companies Code, 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 BVBA, permanently represented by Luc Gijsens (chairman), Roald Borré, and CLSCO BVBA, 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 2018, the audit committee held five meetings which were attended by all members, resulting in a 100% attendance rate for the audit committee meetings. During its meetings, the audit committee among others reviewed and discussed the financial reporting process and the internal control processes. The audit committee also assessed the declarations regarding internal control and risk management in the annual report 2017. It also discussed the cooperation with the external auditor of the Company, Deloitte Bedrijfsrevisoren BV ovve CVBA, represented by Gert Vanhees, and proposed to reappoint 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 2018 during the last meeting of the audit committee held in 2018. The audit committee reported systematically to the board of directors and ensured the co-operation of the executive management team and the finance department of the Company where required.

## REMUNERATION AND NOMINATION COMMITTEE

### COMPOSITION

The remuneration and nomination committee consists of three directors: CRBA Management BVBA, permanently represented by Christian Reinaudo (chairman), CLSCO BVBA, 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 2018, 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 was involved in the search for the new board members who were appointed by the shareholders' meeting in May 2018. It also discussed the composition of the executive management team. Furthermore, the committee prepared the remuneration report, approved the warrant plan 2018, discussed the HR and operational strategy and the process for board evaluation going forward, and reviewed and discussed the remuneration of the members of board, the board committees and the executive management team. The remuneration and nomination committee reported systematically to the board of directors and ensured the co-operation of the executive management team and the HR department of the Company where required.

# 4.4/ EXECUTIVE MANAGEMENT

## COMPOSITION

Biocartis' executive management is composed of the chief executive officer and the other C-levels. On 31 December 2018, the executive management team was composed as follows[1]:

| Name | Age | Function |
|---|---|---|
| **Herman Verrelst** | 45 | Chief executive officer (CEO) |
| **Ewoud Welten** | 35 | Chief financial officer (CFO) |
| **Hilde Eylenbosch[2]** | 55 | Chief commercial officer (CCO) |
| **Benoit Devogelaere** | 38 | Chief technology officer (CTO) |

Notes:
[1] Beginning of 2018, the board of directors decided to limit the composition of the executive management team to the C-levels only. Biocartis appointed Piet Houwen as chief operating officer effective as of April 2019.
[2] Permanently representing Citros vof.

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

**Ewoud Welten** is the chief financial officer (CFO). 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.

**Hilde Eylenbosch** is the chief commercial officer (CCO). Mrs. Eylenbosch is a senior business executive with over 25 years of experience in marketing, product innovation, cross functional businesses and organizational leadership in the life sciences industry. Prior to joining Biocartis, she held the roles of chief commercial officer at Alere Inc. and was president of Alere International, reporting to the COO. Mrs. Eylenbosch holds a degree as Medical Doctor (University of Ghent, Belgium) and successfully completed the General Management Program at Harvard Business School.

**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

In 2018, the executive management team consisted of the CEO, CFO, CCO 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 team. Biocartis appointed Piet Houwen as COO effective as of April 2019 in order to bring additional expertise to the team, mainly in manufacturing, process engineering, project management and people management.

# 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 team 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 team 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, and
- 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. In addition, the independent directors are entitled to warrants which are not linked to any performance criteria. The directors who are also a member of the executive management team 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 team consists of:

- An annual fixed base salary,
- A variable remuneration (cash bonus),
- Participation in warrant 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 team 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 2018:

- 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 CCO could be maximum 25% of her annual fixed remuneration.
- The variable remuneration of the CFO and CTO could be maximum 20% of their respective annual fixed remuneration.

In addition, the members of the executive management team participate in warrant plans 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 warrants granted under the 2013 Plan, 2015 Plan and 2018 Plan are not linked to any performance criteria, except for the warrants granted to Benoit Devogelaere, CTO of Biocartis, of which 50% are not linked to any performance criteria (time-based vesting), while the other 50% will vest if and to the extent certain objective and verifiable key performance indicators are achieved.

50% of the warrants 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. The warrants are not considered as variable remuneration, nor as fixed remuneration or annual remuneration pursuant to Articles 520ter, 524bis, 525 and 554 (as applicable) of the Belgian Companies Code. More information can be found under 'Characteristics of the stock option and warrant plans'.

## REMUNERATION POLICY FOR THE NEXT TWO FINANCIAL YEARS (2019-2020)

The Company currently has no plans to substantially deviate from the general principles of the remuneration policy used in 2018, as described in this Remuneration Report, in the next two financial years.

# REMUNERATION OF THE DIRECTORS

## PRINCIPLES

The remuneration of the non-executive directors is composed of a fixed fee and an attendance fee[(1)]. 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.

Notes:
(1) The annual shareholders' meeting held on 12 May 2017 resolved that Valetusan Ltd., permanently represented by its permanent representative Rudi Pauwels, was entitled to a fixed fee of EUR 87,500 per annum for its role as director and chairman of the strategy committee but not to any (other) fixed fees or attendance fees. Valetusan Ltd. performed such mandate until the annual shareholders' meeting held on 11 May 2018.

### Annual Fixed Fees

| | Prior to 2018 annual shareholders' meeting | As from 2018 annual shareholders' meeting held on 11 May 2018 |
|---|---|---|
| **Chairperson of the board** | EUR 14,000 | EUR 36,000 |
| **Chairperson of the audit committee** | EUR 12,000 | EUR 18,000 |
| **Chairperson of the remuneration & nomination committee** | EUR 10,000 | EUR 14,000 |
| **Other non-executive directors** | EUR 8,500 | 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. The aforementioned amounts are applicable as from the annual shareholders' meeting held on 11 May 2018.

### 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 is entitled to receive up to 15,000 warrants. Part of the warrants under the 2018 Plan is used for this purpose. In accordance with the decision of the general shareholders' meeting of 11 May 2018, the warrants under the 2018 Plan can, as the case may be, 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 Article 520ter of the Belgian Companies Code. The granting of warrants to independent directors is contrary to provision 7.7 of the Corporate Governance Code that provides that non-executive directors should not be entitled to performance related remuneration such as among others stock related long-term incentive schemes. The Company justifies this as it allows 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 warrants is limited. The board of directors is of the opinion that the granting of warrants has no negative impact on the functioning of the 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 2018

Based on what is set out above, the remuneration of the directors for the performance of their director mandate in 2018 is as follows:[1]

| Name | Annual fixed fees | Attendance fees | Total |
|---|---|---|---|
| **Directors in office as at 31 December 2018** | | | |
| CRBA Management BVBA, represented by Christian Reinaudo | EUR 31,712 | EUR 15,000 | EUR 46,712 |
| Luc Gijsens BVBA, represented by Luc Gijsens | EUR 11,416 | EUR 16,500 | EUR 27,918 |
| CLSCO BVBA, represented by Leo Steenbergen | EUR 7,693 | EUR 18,000 | EUR 25,693 |
| Ann-Christine Sundell | EUR 7,693 | EUR 21,000 | EUR 28,693 |
| Scientia II LLC, represented by Harry Glorikian | EUR 7,611 | EUR 19,500 | EUR 27,111 |
| Peter Piot | EUR 10,744 | EUR 9,000 | EUR 19,744 |
| Hilde Windels BVBA, represented by Hilde Windels | EUR 7,693 | EUR 10,500 | EUR 18,193 |
| Roald Borré[2] | EUR 10,744 | EUR 25,500 | EUR 36,244 |
| **Directors whose mandate terminated in 2018** | | | |
| Gengest BVBA, represented by Rudi Mariën | EUR 8,614 | EUR 7,000 | EUR 15,614 |
| Be@dvised BVBA, represented by Renaat Berckmoes | EUR 4,307 | EUR 7,000 | EUR 11,307 |
| Shaffar LLC, represented by Mark Shaffar | EUR 3,051 | EUR 7,000 | EUR 10,051 |
| Valetusan Ltd., represented by Rudi Pauwels | N/A | N/A | EUR 31,404 |

Notes:
[1] Amounts of annual fixed fees are pro rated taking into account the changes to the composition of the board and its committees with effect as from the annual shareholders' meeting dated 11 May 2018.
[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 warrants held by the directors as at 31 December 2018:

| Name | Granted and accepted in 2018 | Exercised in 2018 | Null and void in 2018 | Total held as at 31 December 2018 | Plan |
|---|---|---|---|---|---|
| **Directors in office** | | | | | |
| CRBA Management BVBA | 15,000 | 0 | 0 | 15,000 | 2018 |
| Luc Gijsens BVBA | 10,000 | 0 | 0 | 10,000 | 2018 |
| CLSCO BVBA | 10,000 | 0 | 0 | 10,000 | 2018 |
| Ann-Christine Sundell | 10,000 | 0 | 0 | 10,000 | 2018 |
| Scientia II LLC | 10,000 | 0 | 0 | 10,000 | 2018 |
| Peter Piot | 5,000 | 0 | 0 | 20,000 | 2015, 2018 |
| Hilde Windels BVBA | 0 | 82.500 | 0 | 17.500 | 2013 |
| **Directors whose mandate terminated in 2018[1]** | | | | | |
| Be@dvised BVBA | 5.000 | 0 | 0 | 15.000 | 2015 |
| Shaffar LLC | 5.000 | 0 | 0 | 15.000 | 2015 |

Notes:
(1) Only including those directors who were granted warrants in the framework of their mandate as director of the Company and whose mandate terminated during 2018. The information on Citros vof, permanently represented by Hilde Eylenbosch, is set out below under 'Remuneration of the members of the executive management team'.

## REMUNERATION OF THE MEMBERS OF THE EXECUTIVE MANAGEMENT TEAM

### PRINCIPLES

The remuneration of the members of the executive management team 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 warrant plans
- Group and hospitalization insurance
- Other components

For 2018, 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 CEO was structured so as to link rewards 100% to 1-year company goals (no individual goals) grouped into five categories:

- Sales and revenues (35%, of which 25% commercial product revenues and 10% non-commercial revenues),
- Production and supply chain (20%),
- Menu development (15%),
- Market expansion, including partnering, portfolio and global expansion (10%) and
- Board discretion (20%).

In 2018, the Board also defined for the first time a 2-year target (for 2019) and a 3-year target (for 2020). It resolved that total revenue and gross margin on product revenues will be the two KPIs for both the 2-year target (for 2019) and 3-year target (for 2020). Both the 2-year target and 3-year target will be applied for 25% of the on-target bonus for the relevant performance year (i.c. 2019 and 2020, respectively). Both KPIs will have equal weight for the determination of the on-target bonus for performance years 2019 and 2020, respectively. In case of achievement of the KPIs relating to a certain performance year of 75% or more, the corresponding percentage of the variable remuneration will be payable (e.g., if 80% of the KPIs are achieved, 80% of the variable remuneration to which the KPIs relate shall be payable), provided that the maximum amount payable shall be equal to 100%. In case of an achievement of less than 75% of a certain KPI, no variable remuneration to which such KPI relates shall be payable. In 2019, the 2-year targets will be applied for 25% of the on-target bonus for performance year 2019 while 75% will relate to 1-year targets. In 2020, the 1-year targets will only account for 50% of the on-target bonus while the 2-year and 3-year targets will each account for 25% of the on-target bonus.

The KPIs used in 2018 to determine the vesting of maximum 167,500 warrants under the warrant plan 2017 for the CEO for performance year 2018 was grouped into three categories:

- Sales and revenues (60%, of which 40% commercial product revenues and 20% non-commercial revenues and grants),
- Menu development and market expansion, including CDx and content partner projects (20%) and
- Board discretion (20%).

For 2018, the variable remuneration of the CCO could be maximum 25% of the annual remuneration. The variable remuneration of the CCO was structured so as to link rewards to KPIs which can be grouped into three categories:

- Sales and revenues (60%, of which 40% commercial product revenues and 20% non-commercial revenues and grants),
- Overall company goals as set out for the CEO above (20%), and
- Board discretion (20%).

The variable remuneration of the CFO and CTO could be maximum 20% of their respective annual fixed remuneration. The variable remuneration of these executives was structured so as to link rewards to company goals (80%) and individual goals (20%).The same company goals apply as for the CEO as described above. The individual goals relate to business critical objectives that the respective members of the executive management, from a company perspective, would most attribute to given among others their respective focus areas and leadership position.

The members of the executive management team were also eligible to participate in the warrant 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 group insurance, hospitalization plan, company car with fuel card, meal vouchers, mobile phone and laptop.

## REMUNERATION OF THE MEMBERS OF THE EXECUTIVE MANAGEMENT TEAM IN 2018

The following remuneration and compensation was paid to the CEO and the other members of the executive management with respect to 2018:

| Amounts in EUR[1] | Herman Verrelst | Other executives |
|---|---|---|
| **Annual base salary** | EUR 375,000.00 | EUR 615,944.57 |
| **Variable remuneration** | EUR 135,000.00 | EUR 121,994.77 |
| **Company Car** | - | EUR 26,491.92 |
| **Group insurance[2]** | - | EUR 17,281.92 |
| **Other elements[3]** | - | EUR 6,921.57 |
| **Total** | EUR 510,000.00 | EUR 788,634.75 |

Notes:
[1] The column 'Other executives' captures the remuneration of the CFO, CCO and CTO. Hilde Windels BVBA, represented by Hilde Windels, was part of the executive management team until 11 May 2018 for which period she received a remuneration equal to EUR 5,280.00. The amounts mentioned in the table include both (proportional) gross salaries (excluding employer social security contributions) and compensation paid to the self-employed members of the executive management team. Employer social security contributions amounted to EUR 56,323.76.
[2] The Biocartis group insurance package 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.

The table below provides an overview of the number of warrants held by the members of the executive management team as at 31 December 2018:

| Name | Granted and accepted in 2018 | Exercised in 2018 | Null and void in 2018 | Total held | Plan |
|---|---|---|---|---|---|
| **Herman Verrelst** | 0 | 0 | 0 | 1,340,000 | 2017 |
| **Ewoud Welten** | 0 | 0 | 0 | 62,500 | 2015 |
| **Citros vof, represented by Hilde Eylenbosch** | 10,000 | 0 | 0 | 72,500 | 2015, 2018 |
| **Benoit Devogelaere** | 0 | 0 | 0 | 187,500 | 2013 |

For an overview of the features of the stock options and warrants, see also 'Characteristics of the stock option and warrant plans'.

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

The CEO and CCO 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 service contract of the CCO was entered into for an indefinite period of time and can be terminated by either the CCO 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 CCO 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

There are no contractual provisions in place between the Company and the CEO or the other members of the executive management team 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

In 2018, no members of the executive management team left Biocartis. The executive mandate of Hilde Windels BVBA, permanently represented by Hilde Windels, terminated with effect as of 11 May 2018. No severance payment was made to any executives.

## CHARACTERISTICS OF THE STOCK OPTION AND WARRANT PLANS

Biocartis currently has five outstanding stock based incentive plans, namely (i) the 2008 stock option plan (the '2008 Plan'), (ii) the 2013 warrant plan (the '2013 Plan'), (iii) the 2015 warrant plan (the '2015 Plan'), (iv) the 2017 warrant plan (the '2017 Plan'), and (v) the 2018 warrant plan (the '2018 Plan'), the main characteristics of which are described below.

### 2008 PLAN

On 2 July 2008, the board of directors of Biocartis SA approved the 2008 Plan, enabling it to grant certain stock options to selected staff members (consisting of employees, consultants and members of the management). On 26 June 2012, the board of directors of Biocartis SA amended and restated certain clauses of the 2008 Plan. On 25 November 2014, the 2008 Plan was rolled up in order to relate to the shares of the Company instead of the shares of Biocartis SA.

The 2008 Plan is a non-dilutive option plan, implying that no new shares are issued upon the exercise of the stock options. Upon the exercise of stock options, the Company is able to require certain shareholders of the Company (namely Benaruca S.A., which is controlled by Rudi Pauwels, Ferdinand Verdonck and Philippe Renaud) to deliver the shares underlying the exercised stock options directly to the staff members who exercised the respective stock options and do so in exchange for the exercise price to be paid by the respective staff members.

The key features of the stock options granted under the 2008 Plan are as follows: (i) each option can be exercised for one share, (ii) the stock options are granted for free, i.e. no consideration is due upon the grant of the stock options, (iii) the stock options have a term of seven years, (iv) the exercise price of one stock option is equal to CHF 4.14 (rounded), and (v) the stock options vest in 48 monthly instalments.

On 31 December 2018, a total number of 19,101 stock options are still outstanding under the 2008 Plan, entitling the holders to acquire 19,101 shares of the Company. All stock options are vested.

### 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 stock options (each stock option having the form of a warrant) 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 warrants. The key features of the warrants under the 2013 Plan are as follows: (i) each warrant can be exercised for one share, (ii) the warrants are granted for free, i.e. no consideration is due upon the grant of the warrants unless the grant stipulates otherwise, (iii) the warrants have a term of ten years when they were created but this term is contractually reduced to seven years upon grant of the warrants, (iv) the exercise price of the warrants is determined at the time of the grant of the warrants, and (v) in principle the warrants vest in 48 monthly instalments, subject to acceleration in case of a change of control event. The vesting of 50% of the warrants granted to Benoit Devogelaere is time-based (15,625 warrants will vest on each of the first and second anniversary dates of the date of grant and 31,250 warrants 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 warrants have been granted under the 2013 Plan, having an exercise price of EUR 8.1308. The exercise price of the warrants that have been granted since the IPO of the Company is determined on the basis of the stock exchange price of the underlying shares at the time of the grant or an average price calculated over a previous period.

On 31 December 2018, a total of 987,840 warrants have been granted and 516,755 warrants are outstanding (i.e. warrants under the 2013 Plan which have been created under the plan and which have not yet been exercised or became null and void for any reason). A total number of 12,160 warrants can still be granted under the 2013 Plan.

## 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, 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 warrants. The key features of the warrants under the 2015 Plan are as follows: (i) each warrant can be exercised for one share, (ii) the warrants are granted for free, i.e. no consideration is due upon the grant of the warrants, (iii) the warrants 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 warrant is determined at the time of the grant of the warrants, and (v) in principle the warrants vest in 48 monthly instalments, subject to acceleration in case of a change of control event. The exercise price of the warrants is determined on the basis of the stock exchange price of the underlying shares 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 2018, a total of 262,500 warrants have been granted and 250,422 warrants are outstanding (i.e. warrants under the 2015 Plan which have been created under the plan and which have not yet been exercised or became null and void for any reason). A total number of 434 warrants can still be granted under the 2015 Plan.

## 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. The key features of the warrants under the 2017 Plan are as follows: (i) each warrant can be exercised for one share, (ii) the warrants are granted for free, i.e. no consideration is due upon the grant of the warrants, (iii) the warrants have a term of five years as from 11 September 2017, (iv) the exercise price of the warrants is determined at the time of the grant of the warrants (i.e., EUR 9.92), and (v) 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 exercise windows of the 2017 Plan are 16-31 March, 16-30 September and 1-15 December.

On 31 December 2018, a total of 1,340,000 warrants have been granted, all of which were outstanding at such date (i.e. none of the warrants under the 2017 Plan which have been granted to and accepted by Herman Verrelst have been exercised, nor have they become null and void for any reason). All warrants issued under the 2017 Plan have been granted, and no warrants can still be issued under the 2017 Plan.

## 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.

The 2018 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective warrants. The key features of the warrants under the 2018 Plan are as follows: (i) each warrant can be exercised for one share, (ii) the warrants are granted for free, i.e. no consideration is due upon the grant of the warrants, (iii) the warrants 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 warrant is determined at the time of the grant of the warrants. In principle and subject to acceleration in case of a change of control event, the warrants 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 warrants vest on March 30 of the year following the year in which the date of grant occurs, and 6.25% of the warrants vest at the end of each subsequent calendar quarter; or (b) for directors

of the Company as follows: the warrants 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. The exercise price of the warrants is determined on the basis of the stock exchange price of the underlying shares 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 2018, a total of 273,900 warrants have been granted and 1,334,426 warrants are outstanding (i.e. warrants under the 2018 Plan which have been created under the plan and which have not yet been exercised or became null and void for any reason). A total number of 1,061,526 warrants can still be granted under the 2018 Plan.

# 4.6/ SHARE CAPITAL AND SHARES

## ISSUE OF SHARES BY THE COMPANY IN 2018

On 1 January 2018, the share capital of the Company amounted to EUR 511,022,72, represented by 51,102,272 shares. In the course of 2018, there were three capital increases resulting from the exercise of warrants under the 2013 and 2015 warrant plans, resulting in the issuance of 258,816 new shares and an increase of the share capital of EUR 2.588,16. Consequently, on 31 December 2018, the total share capital of the Company amounted to EUR 513,610.88, represented by 51,361,088 shares. An overview of the major shareholders of the Company on 31 December 2018 based on the transparency notifications received until that date can be found in the section 'Major shareholders' on the Biocartis website under 'investors'. The Company is not aware of any shareholders' agreements with respect to the Company.

## NUMBER AND FORM OF SHARES OF THE COMPANY

Of the 51,361,088 shares of the Company outstanding at 31 December 2018, 6,189,223 were registered shares and 45,171,865 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 warrants 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 the Belgian Companies Code 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, pursuant to Article 545 of the Belgian Companies Code, 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 (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 Article 592 and following of the Belgian Companies Code). 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 warrant plan 2018.

As a result, the board of directors still had the authority on 31 December 2018 under the authorized capital to increase the Company's share capital with an aggregate amount of EUR 273,496.70.

## 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

In accordance with the Belgian Companies Code, the Company may purchase, subject to the provisions of the Belgian Companies Code, its own shares and dispose thereof if authorized by a prior decision of an extraordinary shareholders' meeting approved by a majority of 80% 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 board of directors is currently not authorized by an extraordinary shareholders' meeting to purchase or sell its own shares. On 31 December 2018, 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 warrants and convertible bonds, if any) 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 15.0m subordinated loan agreement dated 19 July 2016 entered into between PMV NV (formerly PMV-Tina Comm.VA, liquidated), FPIM Federale Participatie- en Investeringsmaatschappij NV, the Company and Biocartis NV, of which the change of control clause was approved by the annual shareholders' meeting of 2017 and whereby the lenders will, for a period of 30 days after becoming aware that a change of control will take place or has taken place, have the right to require an early repayment of the outstanding principal amount of the loan (including the cash interest and capitalized interest accrued on the loan until the early repayment date).

The EUR 17.5m credit contract dated 10 October 2017 entered into between KBC Bank NV, the Company and Biocartis NV, of which the change of control clause was submitted for approval 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, of which the change of control clause was submitted for approval 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 EUR 24m finance contract dated 28 February 2018 entered into between the European Investment Bank, the Company and Biocartis NV, of which the change of control clause was submitted for approval by the annual shareholders' meeting held in 2018 and whereby the European Investment Bank is entitled, after a thirty day consultation period, to cancel the undisbursed portion of the credit and/or demand prepayment of the loan, together with accrued interest and all other amounts accrued or outstanding under the finance contract upon any person or group of persons acting in concert gaining control of the Company resulting in the Company being controlled by (i) a non-EU party or (ii) a party that does not comply with the bank's KYC requirements.

In addition, the Company's warrant plans (2013 Plan, 2015 Plan, 2017 Plan and 2018 Plan, all as defined below) provide for an accelerated vesting of the warrants in case of a change of control event. These plans are described in more detail in the Remuneration Report (see 'Characteristics of the stock option and warrant plans').

# 4.7/ EXTERNAL AND INTERNAL CONTROL

## EXTERNAL CONTROL

The Company's statutory auditor is Deloitte Bedrijfsrevisoren BV ovve CVBA, represented by Gert Vanhees, auditor.
The statutory auditor performs the external audit of the consolidated and statutory accounts of the Company and of its Belgian subsidiary (Biocartis NV). 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 2018, a total amount of EUR 136,800 was paid to the statutory auditor. This amount includes the following elements: EUR 120,000 for audit fees, and EUR 16,800 for work performed in relation to legal mission work of 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 team 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 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 2018 AND 2017

## 5.1.1/ CONSOLIDATED INCOME STATEMENT

| In EUR 000 | Notes | Years ended 31 December, 2018 | 2017 |
|---|---|---|---|
| **Revenue** | | | |
| Collaboration revenue | 5.2.4 | 8,329 | 7,739 |
| Product sales revenue | 5.2.4 | 18,843 | 12,936 |
| Service revenue | 5.2.4 | 639 | 282 |
| | | 27,811 | 20,957 |
| **Other operating income** | | | |
| Grants and other income | 5.2.5 | 840 | 2,153 |
| **Total operating income** | | **28,651** | **23,110** |
| **Operating expenses** | | | |
| Cost of sales | 5.2.6 | -15,349 | -8,673 |
| Research and development expenses | 5.2.7 | -36,842 | -39,594 |
| Sales and marketing expenses | 5.2.8 | -15,349 | -11,600 |
| General and administrative expenses | 5.2.9 | -7,971 | -6,832 |
| | | **-75,511** | **-66,699** |
| **Operating loss for the year** | | **-46,860** | **-43,589** |
| Financial expense | 5.2.11 | -1,565 | -1,714 |
| Other financial results | 5.2.11 | 163 | -22 |
| **Financial result, net** | | **-1,402** | **-1,736** |
| **Loss for the year before taxes** | | **-48,262** | **-45,325** |
| Income taxes | 5.2.28 | 109 | 3,365 |
| **Loss for the year after taxes** | | **-48,153** | **-41,960** |
| Attributable to owners of the Company | | -48,153 | -41,960 |
| Attributable to non-controlling interest | | | |
| **Earnings per share** | | | |
| Basic and diluted loss per share | 5.2.12 | -0.94 | -0.93 |

## 5.1.2/ CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

| In EUR 000 | Notes | Years ended 31 December, 2018 | 2017 |
|---|---|---|---|
| **Loss for the year** | | **-48,153** | **-41,960** |
| **Other comprehensive income (loss), not to be reclassified to profit or loss:** | | | |
| Re-measurement gains and losses on defined benefit plan | 5.2.23 | -23 | 45 |
| Income taxes on items of other comprehensive income | | 8 | -15 |
| **Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss:** | | | |
| Exchange differences on translation of foreign operations | | 123 | 0 |
| **Total comprehensive loss for the year** | | **-48,045** | **-41,930** |
| Attributable to owners of the Company | | -48,045 | -41,930 |
| Attributable to non-controlling interest | | 0 | 0 |

5.1.3/

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

| In EUR 000 | Notes | As of 31 December, 2018 | 2017 |
|---|---|---|---|
| **Assets** | | | |
| **Non-current assets** | | | |
| Intangible assets | 5.2.13 | 6,579 | 10,267 |
| Property plant and equipment | 5.2.14 | 30,391 | 26,199 |
| Financial assets | 5.2.15 | 5,052 | 5,052 |
| Other non-current receivables | | 11 | 11 |
| Deferred tax assets | 5.2.16 | 6,569 | 6,572 |
| | | 48,602 | 48,102 |
| **Current assets** | | | |
| Inventories | 5.2.17 | 11,919 | 9,060 |
| Trade receivables | 5.2.18 | 9,744 | 6,892 |
| Other receivables | 5.2.18 | 3,751 | 2,856 |
| Other current assets | 5.2.19 | 1,830 | 1,517 |
| Cash and cash equivalents* | 5.2.20 | 63,539 | 112,765 |
| | | 90,783 | 133,090 |
| **Total assets** | | **139,385** | **181,191** |
| **Equity and liabilities** | | | |
| **Capital and reserves** | | | |
| Share capital | 5.2.21 | -220,718 | -220,721 |
| Share premium | 5.2.21 | 632,769 | 630,670 |
| Share based payment reserve | 5.2.22 | 3,445 | 2,381 |
| Accumulated deficit | 5.2.21 | -328,145 | -280,091 |
| **Total equity attributable to owners of the Company** | | 87,351 | 132,239 |
| **Non-current liabilities** | | | |
| Provisions | 5.2.23 | 28 | 16 |
| Financial liabilities | 5.2.24 | 30,221 | 31,359 |
| Deferred income | 5.2.26 | 6 | 10 |
| Accrued charges | 5.2.27 | 1,501 | 1,767 |
| | | 31,756 | 33,152 |
| **Current liabilities** | | | |
| Financial liabilities | 5.2.24 | 5,114 | 4,029 |
| Trade payables | 5.2.25 | 7,973 | 5,555 |
| Deferred income | 5.2.26 | 3,010 | 2,777 |
| Other current liabilities | 5.2.25 | 4,181 | 3,439 |
| | | 20,278 | 15,800 |
| **Total equity and liabilities** | | **139,385** | **181,191** |

*Cash and cash equivalents for 31 December 2018 include EUR 1.2 million restricted cash related to KBC Lease financing

## 5.1.4/ CONSOLIDATED CASH FLOW STATEMENT

| In EUR 000 | Notes | Years ended 31 December, 2018 | 2017 |
|---|---|---|---|
| **Operating activities** | | | |
| Loss for the year | | -48,153 | -41,960 |
| **Adjustments for** | | | |
| Depreciation and amortization | 5.2.13/5.2.14 | 4,273 | 5,096 |
| Impairment losses | 5.2.7 | 3,456 | 0 |
| Income taxes in profit and loss | 5.2.28 | 109 | -3,365 |
| Financial result, net | 5.2.11 | 1,402 | 1,736 |
| Net movement in defined benefit obligation | 5.2.23 | -15 | -31 |
| Share based payment expense | 5.2.22 | 1,065 | 665 |
| Other | | -19 | -38 |
| **Changes in working capital** | | | |
| Net movement in inventories | 5.2.17 | -2,859 | 769 |
| Net movement in trade and other receivables and other current assets | 5.2.18/5.2.16 | -4,060 | -4,197 |
| Net movement in trade payables & other current liabilities | 5.2.25 | 2,893 | -95 |
| Net movement in deferred income | 5.2.26 | 229 | 682 |
| | | **-41,679** | **-40,738** |
| Interests paid | | -215 | -562 |
| Taxes paid | 5.2.28 | -99 | -105 |
| **Cash flow used in operating activities** | | **-41,993** | **-41,405** |
| **Investing activities** | | | |
| Interests received | | 8 | -2 |
| Acquisition of property, plant & equipment | 5.2.14 | -5,571 | -3,157 |
| Acquisition of intangible assets | 5.2.14 | -257 | -1,161 |
| **Cash flow used in investing activities** | | **-5,820** | **-4,320** |
| **Financing activities** | | | |
| Net proceeds from the issue of ordinary shares, net of transaction costs | 5.2.21 | 2,102 | 76,669 |
| Repayment of borrowings | 5.2.24 | -3,580 | -1,375 |
| Bank charges | | -29 | -38 |
| **Cash flow from financing activities** | | **-1,507** | **75,256** |
| **Net increase / (decrease) in cash and cash equivalents** | | **-49,320** | **29,531** |
| Cash and cash equivalents at the beginning of the year | | 112,765 | 83,246 |
| Effects of exchange rate changes on the balance of cash held in foreign currencies | | 94 | -12 |
| **Cash and cash equivalents at the end of the year*** | | **63,539** | **112,765** |

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

## 5.1.5/

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| | | Attributable to owners of the Company | | | | | | |
|---|---|---|---|---|---|---|---|---|
| In EUR 000 | Notes | Share capital | Share premium | Share based payment reserve | Gains and losses on defined benefit plans | Accumulated deficit | Total equity attributable to the owners of the Company | Total equity |
| **Balance as at 1 January 2017** | | **-220,786** | **554,065** | **1,716** | **-19** | **-238,088** | **96,889** | **96,889** |
| Loss for the period | | | | | | -41,960 | -41,960 | -41,960 |
| Other comprehensive loss | 5.2.21 | | | | -26 | 0 | -25 | -25 |
| **Total comprehensive loss** | 5.2.21 | | | | **-26** | **-41,960** | **-41,985** | **-41,985** |
| Share-based payment expense | 5.2.22 | | | 665 | | | 665 | 665 |
| Share issue - exercise of stock options on 5 October 2017 | 5.2.21 | 0 | 176 | | | | 176 | 176 |
| Share issue - private placement 28 November 2017 | 5.2.21 | 64 | 79,936 | | | | 80,000 | 80,000 |
| Costs related to private placement | 5.2.21 | | -3,771 | | | | -3,771 | -3,771 |
| Share issue - exercise of stock options on 21 December 2017 | 5.2.21 | 0 | 264 | | | | 264 | 264 |
| Consolidation translation difference | 5.2.21 | | | | | 2 | 2 | 2 |
| **Balance as at 31 December 2017** | | **-220,722** | **630,670** | **2,381** | **-45** | **-280,046** | **132,240** | **132,240** |
| **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 | 5.2.21 | | | | -23 | | -23 | -23 |
| Consolidation translation difference | 5.2.21 | | | | | 123 | 123 | 123 |
| **Total comprehensive loss** | 5.2.21 | | | | **-23** | **-48,030** | **-48,053** | **-48,053** |
| Share-based payment expense | 5.2.22 | | | 1,064 | | | 1,064 | 1,064 |
| Share issue - exercise of stock options on 5 April 2018 | 5.2.21 | 2 | 1,807 | | | | 1,809 | 1,809 |
| Share issue - exercise of stock options on 4 October 2018 | 5.2.21 | 1 | 239 | | | | 240 | 240 |
| Share issue - exercise of stock options on 20 December 2018 | 5.2.21 | 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** |

# 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), Lausanne (Switzerland) and New Jersey (US).

The consolidated financial statements have been authorized for issue on 21 February 2019 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 2018 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 2018:

- IFRS 9 Financial Instruments and subsequent amendments (applicable for annual periods beginning on or after 1 January 2018)
- IFRS 15 Revenue from Contracts with Customers (applicable for annual periods beginning on or after 1 January 2018)
- Improvements to IFRS (2014-2016) (applicable for annual periods beginning on or after 1 January 2017 or 2018)
- Amendments to IFRS 2 Classification and Measurement of Share-based Payment Transactions (applicable for annual periods beginning on or after 1 January 2018)
- Amendments to IFRS 4 Insurance Contracts – Applying IFRS 9 Financial Instruments with IFRS 4 (applicable for annual periods beginning on or after 1 January 2018)
- Amendments to IAS 40 Transfers of Investment Property (applicable for annual periods beginning on or after 1 January 2018)
- IFRIC 22 Foreign Currency Transactions and Advance Consideration (applicable for annual periods beginning on or after 1 January 2018)

## 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

As of January 2018, IFRS 15 replaces IAS 11 Construction Contracts, IAS 18 Revenue, IFRIC 13 Customer Loyalty Programmes, IFRIC 15 Agreements for the Construction of Real Estate, IFRIC 18 Transfers of Assets from Customers and SIC 31 Revenue Barter Transactions involving Advertising Services.

In accordance with the transitional provisions of IFRS 15, the Group adopted the new policies using the modified retrospective approach as of 1 January 2018. The initial application of IFRS 15 did not have a significant impact on the opening balance of the equity of the Group as per 1 January 2018.

The Group has established and is continuing to improve internal working procedures and ERP processes for adequately administering customer trade agreements with its appropriate fair market price allocations, and the control thereof.

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.
For the purpose of the IFRS 15 analysis, the Group has considered the following revenue streams:

## Reagent rental contracts

Under its reagent rental 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 lease under IAS 17 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. The majority of the Group's reagent rental contracts have minimum purchase requirements, which however may not be contractually enforceable and are cancellable with a notice period, therefore the lease component present in these contracts generally qualify as an operating lease and the lease payments are generally to be considered as contingent payments. As explained in 6.2.2.15 Revenue Recognition, the total Idylla™ cartridge price 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.

## Regular sales contracts

Under its regular sales contracts, The Group does not bundle multiple elements together. Revenue is recognized at a point in time, i.e. when the goods are delivered, as control is passed. The same applies to the regular rental contracts, except that the service cost is included in the rental price and is individualized from the rental fee based on a fair market price allocation similar to the above.

As a conclusion, both in terms of amounts and timing of the revenue recognized in the Group's product related income, the application of IFRS 15 has no significant impact on the Group's financial reporting since the fair market allocation principles have already being applied since 2014.

## Collaboration contracts

Under its research and development collaboration contracts, the Group regularly provides a license and further development services. The consideration in these contracts mainly consist of a non-refundable upfront fee, milestone payments, compensation for research and development services and royalties. 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 milestones payments are development milestones.

The recognition of development milestones might be different from what was previously applied under IAS 18. If one would conclude 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. If the license is considered to be a distinct performance obligation under the agreement, the recognition of a development milestone depends on the nature of the license. If the license is a right to use, the portion of the milestone

allocated to the license will be recognized at the moment of reaching the development milestone criteria; if the license is a right to access, the portion of the milestone allocated to the license will be recognized at the moment of reaching the development milestone criteria over the license period. After analysis the Group concluded that the initial application of IFRS 15 had no impact on the previous revenue that has been recognized under collaboration agreements.

The Group concluded after thorough analysis that the revenue recognition under IFRS 15 did not have an impact on the previous revenues recognized under IAS 18.

### IFRS 9

IFRS 9 Financial instruments replaces IAS 39 Financial Instruments: Recognition and Measurement and brings together the following aspects of accounting for financial instruments: classification and measurement, impairment, and hedge accounting. IFRS 9 changes the classification and measurement of financial assets and includes a new model for assessing the impairment of the financial assets based on expected credit losses. Most of the basics of hedge accounting do not change as a result of IFRS 9. However, hedge accounting can be applied to a larger number of risk exposures than before and hedge accounting principles have been harmonized with those used in risk management. IFRS 9 was applied without restating comparative information in accordance with the transition provisions of the standard. The adoption of IFRS 9 from 1 January 2018 resulted in changes in accounting policies but did not result in adjustments to the amounts recognized in the financial statements as per 31 December 2017. The new accounting policies are set out below. As there was no impact on the amounts recognized in the financial statements as per 31 December 2017, the opening equity as per 1 January 2018 was not impacted by the adoption of IFRS 9. Main change to the accounting policies is the methodology to determine and recognize impairment losses on financial assets. As such, IFRS 9 requires to assess financial assets for impairment losses based on an expected loss model instead of an incurred loss model as prescribed by IAS 39. For trade receivables, the Company 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.

Biocartis applies a credit loss policy for accounts receivable that resulted in a provision for doubtful debt. For amounts overdue between 61 and 90 days, a provision of 10% is booked and for amount overdue longer than 90 days a provision of 50% is booked.

The other new standards did not have a significant impact on the financial position and the results of the Group. Standards and interpretations published, but not yet applicable for the annual period beginning on 1 January 2018, 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 its subsidiaries as at 31 December 2018.

The Company has 100% of the shares in its subsidiaries at the end of the reporting date.

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/ 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:

| Item | 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.

## 5.2.2.6/ 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.

| Item | 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.

## 5.2.2.7/ 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.

## 5.2.2.8/ 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.

## 5.2.2.9/ 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 only has financial liabilities classified as financial liabilities measured at amortized cost. The Group does not have financial liabilities at fair value through profit or loss or derivatives. The Group's financial liabilities include trade and other payables and loans and borrowings.

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.

## 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.

## 5.2.2.10/ 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.

## 5.2.2.11/ 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'.

## 5.2.2.12/ 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.

## 5.2.2.13/ 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.

## 5.2.2.14/ 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.

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.

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 income from R&D 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 Company 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.

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, 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.

**Operational lease reagent rental agreements:**
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.

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

### 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.

## 5.2.2.15/ 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.

## 5.2.2.16/ LEASES

Leases are classified as financial leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. All other leases are classified as operating leases.

### The Group as lessee

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.

## 5.2.2.17/ BORROWING COSTS

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

# 5.2.3/ CRITICAL ACCOUNTING ESTIMATES, ASSUMPTIONS AND JUDGMENTS

## 5.2.3.1/ CRITICAL ACCOUNTING ESTIMATES, ASSUMPTIONS AND JUDGMENTS

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

### CRITICAL JUDGMENTS

#### Going concern

The financial statements have been established on a going-concern basis.

Based on management's judgment and taking into account available cash and cash equivalents per 31 December 2018, and as of the date of these financial statements, as well as current cash flow projections, going concern is assured for at least 12 months from the date of these financial statements. Also on 23 January 2019, the Group successfully raised equity for an amount of EUR 55.5m.

The board of directors supports management's efforts in securing additional financial means inter alia by signing non-dilutive cash-generating deals (including for example non-refundable upfront payments on licensing deals and grants).

The board of directors is confident that the Group's financial future will be safeguarded at least until the annual general meeting to be held in 2020.

#### 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

### Estimates of post-employment benefit obligations

The Belgian defined contribution plans classify as defined benefit plans due to the guaranteed minimum rates of return. Before the law changed on 18 December 2015, under the previous legal framework, the application of the Projected Unit Credit (PUC) method was considered problematic, and there was uncertainty with respect to the future evolution of the minimum guaranteed rates of return. Therefore, the Company did not apply the PUC method for the Belgian Defined Contribution Plans.

The related liabilities recognized in the consolidated balance sheet represent the present value of the defined benefit obligations calculated annually by independent actuaries. These actuarial valuations include assumptions such as discount rates and mortality rates. These actuarial assumptions vary according to the local prevailing economic and social conditions. Details of the assumptions used are provided in note 5.2.23.

### Share-based payments

The Group has several equity-settled shared based payment plans in place, valued using the Black-Scholes Merton option valuation model. Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which is dependent on the terms and conditions of the option plan. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them.

The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in note 5.2.23.

### Revenue recognition

For revenue recognition, the significant estimates relate to the allocation of the transaction price to the separate performance obligations in multiple-element arrangements. With respect to the allocation of the transaction price to the separate performance obligations, the Company is using the stand-alone selling prices or management's best estimates of selling prices to estimate the fair value of the elements and account for them separately. Management estimates the stand-alone selling price at contract inception based on observable prices of the type of services likely to be provided and the services rendered in similar circumstances to similar customers/partners. Revenue is allocated to each deliverable based on the fair value of each individual element and is recognized when the revenue recognition criteria described above are met.

Management estimates this period at the start of the collaboration and validates the remaining estimated collaboration term at each reporting date.

The Company assesses for each performance obligation the transaction price, which may include fixed amounts and variable amounts. Management applies judgement in assessing the probability of meeting the conditions for recognition of the variable consideration. As such, 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.

### Variable considerations relating to the purchase of intangible assets

Any variable consideration payable as part of the purchase of an intangible asset and when certain milestones are achieved, is not recognized until the achievement of the related milestone(s). The variable consideration liability, when recognized, is then recorded with a corresponding increase of the related intangible asset.

### 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 5.2.2.6.

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, all non-current assets of the Group are located in the country of domicile (Belgium) per 31 December 2018.

## 5.2.4/ REVENUE

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

| In EUR 000 | Years ended 31 December, | | | |
|---|---|---|---|---|
| | 2018 | | 2018 | 2017 |
| | At a point in time | Over time | | |
| **Collaboration revenue** | | | | |
| R&D services | 0 | 4,338 | 4,338 | 670 |
| License fees | 3,075 | 83 | 3,158 | 4,569 |
| Milestones | 833 | 0 | 833 | 2,500 |
| | **3,908** | **4,422** | **8,329** | **7,739** |
| **Product related revenue** | | | | |
| Idylla™ System Sales revenue | 2,404 | 0 | 2,404 | 3,390 |
| Idylla™ System Rental revenue | 1,781 | 0 | 1,781 | 1,230 |
| Cartridge revenue | 14,658 | 0 | 14,658 | 8,316 |
| | **18,843** | **0** | **18,843** | **12,936** |
| **Service revenue** | | | | |
| Idylla™ System Service revenue | 636 | 3 | 639 | 282 |
| | **636** | **3** | **639** | **282** |
| **Total** | **23,386** | **4,425** | **27,811** | **20,957** |

The Group has recognized the following revenue-related accrued and deferred income:

| In EUR 000 | As at 31 December, | |
|---|---|---|
| | 2018 | 2017 |
| **Accrued income** | | |
| Collaboration arrangements | 30 | 50 |
| Product sales | 0 | 0 |
| Service arrangements | 0 | 0 |
| | **30** | **50** |
| **Deferred income** | | |
| Collaboration arrangements | -2,029 | -1,486 |
| Product sales | 0 | 0 |
| Service arrangements | 0 | 0 |
| | **-2,029** | **-1,486** |
| **Net accrued/deferred income** | **-1,999** | **-1,436** |

The above table corresponds to the revenue expected to be recognized in the future relating to (partially) unsatisfied performance obligations:

| In EUR 000 | Deferred income |
|---|---|
| 2019 | 1,999 |
| 2020 | 0 |
| 2021 | 0 |
| 2022 | 0 |
| 2023 | 0 |
| After 2023 | 0 |

The aggregate amount of the transaction price allocated to collaboration arrangements that are partially or fully unsatisfied as at 31 December 2018 is EUR 2.0m.

## 5.2.4.1/ 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 section 5.2.2.14:

### Amgen

In 2016, Biocartis NV, a subsidiary of the Company, and Amgen entered into a collaboration agreement to evaluate Idylla™ RAS testing as a tool for rapid decentralized testing in several geographies. This collaboration was expanded in December 2016 with a new agreement that includes up to 10 European countries and that will enable several dozen additional selected hospitals 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.

On 4 December 2017, Biocartis entered into a companion diagnostic (CDx) 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 this CDx agreement 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).

## Genomic Health

On 13 September 2017, Biocartis and Genomic Health, Inc. entered into an exclusive agreement to develop an IVD version of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform that can be performed locally by laboratory partners and in hospitals around the world. The strategic collaboration will provide Genomic Health 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. On November 30, 2018, Genomic Health exercised its urology field option right and took an initial first right for six months to add a Genomic Health Pre-Biopsy Prostate Assay to the pipeline. Additional payments to Biocartis will be made as certain developmental and commercial milestones will be achieved in the future. Upon commercialization, Genomic Health 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.

## 5.2.4.2/ REVENUES BY MAJOR COUNTRIES AND CUSTOMERS

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | 2018 | 2017 |
| **Country of domicile** | **765** | **2,565** |
| Belgium | 765 | 2,565 |
| **Total all foreign countries, of which** | **27,046** | **18,392** |
| United States of America | 11,974 | 6,802 |
| Spain | 2,461 | 1,985 |
| Rest of the world | 12,611 | 9,604 |
| **Total** | **27,811** | **20,957** |

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

The Group has recognized revenues from two customers representing at least 10% of the total revenues. These customers account for EUR 7.3m of the revenues in 2018 (2017: three customer for EUR 8.4m). Customer A represents 16% and customer B represents 10% of the total revenue.

## 5.2.5/ OTHER OPERATING INCOME

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | 2018 | 2017 |
| R&D project support (IWT grants) | 576 | 1,844 |
| Other project grants | 0 | 62 |
| Other income | 264 | 247 |
| **Total** | **840** | **2,153** |

Other operating income mainly consists out of grants that were awarded to support R&D activities. By the end of 2017 some grant programs ended and were fully recognized, for these grant programs no revenue was recognized in 2018.

## 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 | 2018 | 2017 |
| Employee benefit expenses | -4,573 | -1,952 |
| Material, lab consumables & small equipment | -7,302 | -4,407 |
| Depreciation and amortization | -1,302 | -1,435 |
| Royalty expense | -1,088 | -785 |
| Other | -1,084 | -93 |
| **Total** | **-15,349** | **-8,673** |

For the explanation on the increase of the cost of sales we refer to chapter 2, '2018 highlights and business review'.

## 5.2.7/ RESEARCH & DEVELOPMENT EXPENSES

| In EUR 000 | Years ended 31 December, 2018 | 2017 |
|---|---|---|
| Employee benefit expenses | -19,671 | -19,027 |
| R&D Consultancy | -2,855 | -1,873 |
| R&D subcontracting | -1,685 | -2,922 |
| Laboratory and cartridge costs | -1,731 | -6,344 |
| Quality, regulatory and intellectual property | -636 | -710 |
| Facilities, office & other | -2,922 | -3,567 |
| ICT | -1,232 | -1,299 |
| Travel, training & conferences | -535 | -575 |
| Depreciation and amortization | -2,333 | -3,276 |
| Impairment of assets | -3,242 | 0 |
| **Total** | **-36,842** | **-39,594** |

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 decrease of the research and development expenses we refer to chapter 2, '2018 highlights and business review'. For the impairment of assets we refer to note 5.2.13.

## 5.2.8/ SALES & MARKETING EXPENSES

| In EUR 000 | Years ended 31 December, 2018 | 2017 |
|---|---|---|
| Employee benefit expenses | -9,237 | -6,833 |
| Subcontracting | -329 | -243 |
| Sales and promotional expenses | -420 | -652 |
| Business development | -697 | -506 |
| Consultancy | -306 | -112 |
| Facilities, office & other | -1,165 | -846 |
| Travel, training & conferences | -2,234 | -1,978 |
| Depreciation and amortization | -902 | -430 |
| Impairment of receivables | -59 | 0 |
| **Total** | **-15,349** | **-11,600** |

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 2, '2018 highlights and business review'.

## 5.2.9/ GENERAL & ADMINISTRATIVE EXPENSES

| In EUR 000 | Years ended 31 December, 2018 | 2017 |
|---|---|---|
| Employee benefit expenses | -4,757 | -4,003 |
| External advice | -1,155 | -985 |
| Facilities, office & other | -816 | -923 |
| Human resources | -940 | -689 |
| Travel, training & conferences | -314 | -243 |
| Depreciation and amortization | 11 | 11 |
| **Total** | **-7,971** | **-6,832** |

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.

## 5.2.10/ EMPLOYEE BENEFIT EXPENSES

| In EUR 000 | Years ended 31 December, 2018 | 2017 |
|---|---|---|
| Short term employee benefits | -36,469 | -30,383 |
| Post-employment benefit expenses | -547 | -611 |
| Termination benefits | -157 | -157 |
| Share-based payments | -1,065 | -665 |
| **Total** | **-38,238** | **-31,816** |

Employee benefit expenses amounted to EUR 38.2m in 2018 compared to EUR 31.8m in 2017, a year-over-year increase of 20%. 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 2018 | 2017 |
|---|---|---|
| Operations staff | 119 | 123 |
| Research and development staff | 154 | 134 |
| Marketing and sales staff | 84 | 50 |
| General and administrative staff | 53 | 24 |
| Total headcount | **410** | **331** |
| Average full time equivalents | 394 | 316 |

## 5.2.11/ FINANCIAL INCOME AND EXPENSE

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| Interest expense | -1,358 | -1,250 |
| Other financial expense | -207 | -463 |
| **Total** | **-1,565** | **-1,714** |
| Other financial result | 163 | -22 |
| **Total** | **163** | **-22** |
| **Financial result, net** | **-1,402** | **-1,736** |

## 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, | |
|---|---|---|
| | **2018** | **2017** |
| Profit/loss for the period attributable to the owners of the Company (in EUR 000) | -48,153 | -41,960 |
| Weighted average number of ordinary shares for basic loss per share (in number of shares) | 51,170,552 | 45,149,567 |
| **Basic loss per share (EUR)** | **-0.94** | **-0.93** |

## 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 2017** | | | |
| Opening carrying amount | 9,717 | 204 | 9,922 |
| Additions | 1,000 | 161 | 1,161 |
| Disposals | 0 | 0 | 0 |
| Disposal amortizations | 0 | 0 | 0 |
| Amortization expense | -699 | -116 | -815 |
| **Closing carrying amounts** | **10,018** | **249** | **10,267** |
| **As at 31 December 2017** | | | |
| Cost | 15,034 | 1,572 | 16,606 |
| Accumulated amortizations | -5,016 | -1,323 | -6,338 |
| **Carrying amount** | **10,018** | **249** | **10,267** |
| **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 amount** | **6,418** | **161** | **6,579** |
| **As at 31 December 2017** | | | |
| Cost | 11,992 | 1,629 | 13,621 |
| Accumulated amortizations | -5,574 | -1,468 | -7,042 |
| **Carrying amount** | **6,419** | **161** | **6,579** |

Patents and licenses primarily include a number of technology licenses acquired by the Group from Philips in 2010 for EUR 10.0m relating to the Group's flagship diagnostic platform Idylla™. The carrying amount per 31 December 2018 is EUR 5.5m (2017: EUR 6m). The remaining useful life is 10 years.

In 2011, the Group acquired a license from the same partner for to get access to an ancillary platform for selective enrichment of pathogen DNA for use with bloodstream infection tests for EUR 0.5m. Simultaneously with this agreement, Philips and the Group have entered into asset transfer agreements, for the purpose of transferring the assets to the Group relating to the 'Idylla™' technology and the selective enrichment technology mentioned above. Up to 2018, the group recognized variable considerations, based on contractual obligation with a corresponding increase of the licenses from Philips related to the selective enrichment technology for EUR 2,8m. During H2 2018, a review of infectious disease oriented collaborations and license agreements was conducted, which resulted in the termination of certain collaborations that were no longer of strategic importance to Biocartis. As part of this review, the agreement with Koninklijke Philips N.V., under which Biocartis had gained access to certain patent rights and know-how, in relation to the above mentioned selective enrichment technology was ended. The net book value of the related intangible assets was EUR 3.2m, which has been impaired and the cost is shown in the income statement under research and development expenses.

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, assets held under lease and Idylla™ systems for rent.

The most significant addition to 'Property, plant and equipment' concerns the category 'Equipment under construction' and is related to the Idylla™ cartridge production expansion.

The transfer from equipment under construction to assets held under lease are related to cartridge production equipment that became fully operational in 2018 and which was funded for through lease financing.

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 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Opening carrying amount** | **639** | **783** | **1,313** | **2,396** | **426** | **1,121** | **230** | **13,698** | **1,342** | **1,140** | **23,089** |
| Additions | 53 | 111 | 252 | 1,136 | 53 | 193 | 0 | 3,824 | 512 | 1,835 | **7,969** |
| Disposals | 0 | 0 | 0 | -69 | 0 | 0 | 0 | -423 | 0 | -85 | **-577** |
| Disposal depreciation | 0 | 0 | 0 | 30 | 0 | 2 | 0 | 0 | 0 | 16 | **48** |
| Depreciation charge of the period | -194 | -276 | -711 | -807 | -72 | -337 | -5 | 0 | -1,588 | -339 | **-4,329** |
| Transfers gross carrying amount | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | **0** |
| Transfers depreciations | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | **0** |
| **Closing carrying amount** | **499** | **618** | **854** | **2,687** | **407** | **979** | **225** | **17,099** | **265** | **2,566** | **26,199** |
| **As at 31 December 2017** | | | | | | | | | | | |
| Cost | 1,645 | 2,013 | 6,881 | 4,827 | 733 | 2,629 | 243 | 17,099 | 7,648 | 2,973 | **46,691** |
| Accumulated depreciation | -1,147 | -1,395 | -6,026 | -2,141 | -325 | -1,650 | -18 | 0 | -7,383 | -407 | **-20,492** |
| **Carrying amount** | **499** | **618** | **854** | **2,687** | **407** | **979** | **225** | **17,099** | **265** | **2,566** | **26,199** |
| **Opening carrying amount** | **499** | **618** | **854** | **2,687** | **407** | **979** | **225** | **17,099** | **265** | **2,566** | **26,199** |
| Additions | 309 | 556 | 470 | 1,226 | 23 | 38 | 0 | 3,929 | 0 | 2,613 | **9,164** |
| Disposals | -142 | 0 | -55 | -130 | -22 | 0 | -214 | -638 | 0 | -221 | **-1,422** |
| Disposal depreciation | 142 | 0 | 56 | 27 | 22 | 0 | 0 | 0 | 0 | 50 | **297** |
| Depreciation charge of the period | -237 | -369 | -542 | -1,217 | -71 | -392 | -5 | 0 | -283 | -753 | **-3,869** |
| Transfers gross carrying amount | 0 | 0 | 0 | 0 | 0 | 0 | 0 | -3,354 | 3,354 | 0 | **0** |
| Transfers depreciations | 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 | **25** |
| Currency translation depreciations | 0 | 0 | 0 | -3 | 0 | 0 | 0 | 0 | 0 | 0 | **-3** |
| **Closing carrying amount** | **571** | **810** | **783** | **2,610** | **359** | **625** | **6** | **17,036** | **3,336** | **4,255** | **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 | **54,458** |
| Accumulated depreciation | -1,242 | -1,764 | -6,512 | -3,334 | -374 | -2,042 | -23 | 0 | -7,666 | -1,110 | **-24,067** |
| **Carrying amount** | **571** | **810** | **783** | **2,609** | **359** | **625** | **6** | **17,036** | **3,336** | **4,255** | **30,391** |

## 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 5.1 million by Debiopharm Diagnostics SA. The participation is not accounted for under the equity method as the Group has no significant influence over MyCartis NV.

The stake in MyCartis NV has decreased to 7.10% per 31 December 2018 because the Group did not participate in the additional capital increases as from 2016 in MyCartis NV. No impairment has been made per 31 December 2018.

## 5.2.16/ DEFERRED TAX ASSETS

Deferred taxes relate to the investment tax credit on research and development and amount to EUR 6.6m per 31 December 2018 (2017: 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. Therefore EUR 0.2 of the tax credit on research and development has become a short term receivable, see section 5.2.18.

| | As of 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| Tax credit research and development | 6,559 | 6,567 |
| Other | 10 | 5 |
| **Total** | **6,569** | **6,572** |

## 5.2.17/ INVENTORIES

The inventory can be analyzed as follows:

| | As of 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| **Inventory** | | |
| Raw materials | 4,609 | 4,184 |
| Semi-finished products | 760 | 611 |
| Finished products | 6,550 | 4,265 |
| **Total** | **11,919** | **9,060** |
| Amount recognized as an expense | **-15,349** | **-8,673** |

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 2018, EUR 1.0 m of the total inventory value was older than 12 months (2017: EUR 0.4m) for which EUR 0.3m impairment was recognized (2017: EUR 0.1m). It is the expectation that a significant part of the current inventory will be sold within the next 12 months.

## 5.2.18/ TRADE AND OTHER RECEIVABLES

Trade and other receivables can be analyzed as follows:

| | As of 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| Trade receivables | 9,803 | 7,275 |
| Allowance for doubtful receivables | -59 | -383 |
| **Total** | **9,744** | **6,892** |

| | As of 31 December, | |
|---|---|---|
| | **2018** | **2017** |
| VAT receivables | 2,084 | 1,662 |
| Tax credit research and development | 223 | |
| Other receivables | 1,444 | 1,195 |
| **Total** | **3,751** | **2,856** |

Trade receivables have increased from EUR 7.3 million per 31 December 2017 to EUR 9.8 million per 31 December 2018. Approximately half of the total trade receivable balance is related to a limited number of parties. The credit concentration risk is limited in view of the creditworthiness of these partners. The other half consists of many small outstanding balances.

At the reporting date, the Group has approximately EUR 2.8 million (2017: EUR 1.1m) trade and other receivables that were past due but were not impaired. In 2018 an allowance for doubtful receivables was recorded for EUR 0.06m (2017: EUR 0.4m) 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 2018 or 1 January 2018 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 on research and development has been recognized since this tax credit 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.

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.

## 5.2.19/ OTHER CURRENT ASSETS

Other current assets can be analyzed as follows:

| In EUR 000 | As of 31 December, 2018 | 2017 |
|---|---|---|
| Accrued grant income | 331 | 639 |
| Other accrued income | 35 | 0 |
| Deferred charges | 1,464 | 878 |
| **Total** | **1,830** | **1,517** |

Other current assets include accrued income mainly related to Flemish government grants for EUR 0.2 m (2017: EUR 0.6m). 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.

## 5.2.20/ CASH AND CASH EQUIVALENTS

The cash and cash equivalents can be analyzed as follows:

| In EUR 000 | As of 31 December, 2018 | 2017 |
|---|---|---|
| **Cash and cash equivalents** | | |
| Cash at bank and on hand | 62,339 | 111,565 |
| **Total cash and cash equivalents** | **62,339** | **111,565** |
| Total restricted cash | 1,200 | 1,200 |
| **Total cash and cash equivalents for cash flow purposes** | **63,539** | **112,765** |

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.

# 5.2.21/ 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 2017 and 31 December 2018. 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 2016** | **44,648,105** | **446** | **-221,232** | **-220,786** |
| Share issue - exercise of stock options on 5 October 2017 | 21,667 | 0 | | 0 |
| Capital increase - private placement 28 November 2017 | 6,400,000 | 64 | | 64 |
| Share issue - exercise of stock options on 21 December 2017 | 32,500 | 0 | | 0 |
| **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 | | 2 |
| Share issue - exercise of stock options on 4 October 2018 | 29,500 | 1 | | 1 |
| 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** |

The following capital transactions took place at the Company from 1 January 2018 until 31 December 2018:

On 5 April 2018, the Company raised EUR 1.8m following the exercise of 222,816 stock options. The amount is fully paid by an increase in share capital of EUR 0.002m and an increase in share premium of EUR 1.8m.

On 4 October 2018, the Company raised EUR 0.2m following the exercise of 29,500 stock options. The amount is fully paid by an increase in share capital of EUR 0.001m and an increase in share premium of EUR 0.2m.

On 20 December 2018, the Company raised EUR 0.05m following the exercise of 6,500 stock options. The amount is fully paid by an increase in share capital of EUR 0.00007m and an increase in share premium of EUR 0.05m.

## 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.

## 5.2.22/ SHARE BASED PAYMENTS

The table below provides an overview of the movement in stock options since 1 January 2018:

| | | 2008 Plan | 2013 Plan | 2015 Plan | 2017 Plan | 2018 Plan | Total |
|---|---|---|---|---|---|---|---|
| **Total outstanding at 31 December 2016** | | **42,101** | **589,291** | **232,500** | **0** | **0** | **863,892** |
| Options granted | + | 0 | 237,500 | 15,000 | 1,340,000 | | 1,592,500 |
| Options exercised | - | -2,000 | -54,167 | 0 | 0 | | -56,167 |
| Options forfeited | - | 0 | -10,029 | -7,088 | 0 | | -17,117 |
| Options cancelled | - | 0 | 0 | 0 | 0 | | 0 |
| **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** | **249,988** | **1,340,000** | **274,900** | **2,388,584** |

## 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 total 21,000 options were exercised in 2018 at CHF 4.14 exercise price (rounded) and a weighted average share price of EUR 13.01 at the moment of the exercise of the options. A total of 19,101 options are still outstanding per 31 December 2018. The weighted average remaining contractual life is 0.6 years.

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 2018.

In total 255,904 options were exercised in 2018 at an exercise price of EUR 8.1309 with a weighted average share price of EUR 12.31 at the moment of the exercise of the options. In 2018 2,096 options were forfeited.

A total of 504,595 options are still outstanding per 31 December 2018 of which:

- 218,435 options have an exercise price of EUR 8.1309
- 24,160 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 3.8 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:
  - (i) as of 16 March until 31 March,
  - (ii) as of 16 September until 30 September,
  - (iii) 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 31/12/2018 | 15,021 | 3,549 | 8,352 | 8,992 | 32,303 | 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 total 15,000 options were granted in 2018 at weighted average exercise price of EUR 12.37. In total 2,912 options were exercised in 2018 at an exercise price of EUR 12.73 with a weighted average share price of EUR 12.38 at the moment of the exercise of the options. In 2018 2,512 options were forfeited. A total of 249,988 options are still outstanding per 31 December 2018 and the weighted average remaining contractual life is 4.4 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 31/12/2018 | 12,932 | 1,888 | 19,534 | 0 | 7,088 | 29,950 | 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 |
| 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 31/12/2018 | 1,172,500 |
| Exercise price | EUR 9.92 |
| Expected dividend yield | 0 |
| Expected stock price volatility | 32% |
| Risk-free interest rate | -0.3% |
| Expected duration | 2.5 years |
| Forfeiture rate | 0% |
| Fair value | EUR 2.14 |

## 2018 PLAN

On 10 September 2018, a warrant plan was established by the board of directors pursuant to which 1,335,426 warrants were issued, enabling the Company to grant a maximum of 1,335,426 warrants to selected staff members (consisting of employees, consultants and members of the management) and directors.

In 2018, 273,900 warrants were granted. No warrants were exercised and 1,000 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** |
|---|---|
| Number of warrants granted | 273,900 |
| Number of warrants not vested at 31/12/2018 | 273,900 |
| Exercise price | EUR 11.95 |
| Expected dividend yield | 0 |
| Expected stock price volatility | 34% |
| Risk-free interest rate | -0.3% |
| Expected duration | 4 years |
| Forfeiture rate | 0% |
| Fair value | EUR 3.11 |

## 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 | **2018** | **2017** |
| Share based compensation | 1,064 | 665 |
| **Total** | **1,064** | **665** |

## 5.2.23/ 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 | **2018** | **2017** |
| Provisions for pensions and similar obligations | 28 | 16 |
| **Total** | **28** | **16** |

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 2017** | **16** |
| Service cost | 547 |
| Pension expense/income | -19 |
| Company contributions | -550 |
| Benefits paid/ Transfer | -1 |
| Actuarial gains/losses | 35 |
| **As per 31 December 2018** | **28** |

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

| | **2018** |
|---|---|
| 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:

| | **2018** |
|---|---|
| Discount rate + 0.5% | 17 |
| 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.

## 5.2.24/ FINANCIAL LIABILITIES

The financial liabilities can be analyzed as follows:

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| PMV & FPIM loans | 16,272 | 16,331 |
| Lease liabilities | 13,767 | 14,723 |
| Bank borrowings | 182 | 305 |
| **Total non-current** | **30,221** | **31,359** |
| PMV & FPIM loans | 1,202 | 0 |
| Lease liabilities | 3,790 | 3,909 |
| Bank borrowings | 122 | 120 |
| **Total current** | **5,114** | **4,029** |
| **Total financial liabilities** | **35,335** | **35,388** |

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. The lease had an initial term of 5 years at a 3.35% interest rate and included a purchase option of EUR 0.2m. In 2015, the term was extended until 1 June 2021 to align with the new 2015 lease as described below. The purchase option was also reduced to EUR 0.1m. As a security, a debt service reserve account is to be maintained, starting at EUR 2.5m, decreasing over time according to the following milestones: fundraising 2013, CE approval, FDA approval. The current debt service reserve account amounts to EUR 1.2m.

In 2015, Biocartis NV obtained two new financing facilities for the modifications to the current cartridge production line in Mechelen. The first new facility entails an investment credit for an amount of EUR 0.6m, provided by a bank. This facility has a payment term of 5 years and an interest rate of 1.93%. The second one entails a leasing facility for EUR 4.4m, provided by a lease company. The interest applicable for this leasing facility amounts to 1.77% and the leasing includes a purchase option of 1% of the financed amount. The duration of the lease agreement is 54 months.

In 2016, Biocartis NV obtained a lease financing facility for the development of a second cartridge production line in Mechelen, for EUR 15m, provided by a lease company. In 2018 Biocartis obtained an increase in the lease financing facility of EUR 2.3m and the amount is fully withdrawn per 31 December 2018. The interest applicable for this lease facility equals. 1.865% and the lease includes a purchase option of 1% of the financed amount.

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). Both PMV and FPIM granted a loan of EUR 7.5m each, bearing an interest rate of 7% and with a maturity date at 30 September 2021 (except in case of extension of the loan upon the Company's request or voluntary or mandatory early repayment). The interest on the loans is capitalized during the first three years of the agreement and accrued in the consolidated balance sheet at the reporting date. The agreement contains a set of business covenants, which require obtaining the lenders' approval for certain major transactions outside the ordinary course of business.

In 2017, Biocartis reached agreement with KBC and BNP Paribas Fortis to replace the Company's EUR 25m committed multiple purpose credit facility (partially guaranteed by the Flemish Government) with a new committed multiple purpose credit facility of EUR 27.5m (not covered by a government guarantee). The new committed multiple purpose credit facility consists of a EUR 18.5m rollover credit line and a EUR 9m working capital credit line, and has lower overall financing costs compared to the previous facility. No amount has been withdrawn on this credit facility per 31 December 2018.

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%. No amount has been withdrawn on this credit facility per 31 December 2018.

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 2018, 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 2018.

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

| Loan | Year | Nominal amount (In EUR 000) | Secured(s) Non secured (ns) | Interest rate | Maturity 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 |
| PMV | 2016 | 7,500 | S | 7.00% | 30/09/2021 |
| FPIM | 2016 | 7,500 | S | 7.00% | 30/09/2021 |
| Bank | 2018 | 1,000 | S | 2.53% | 31/12/2023 |

The reconciliation between the total of future minimum lease payments of the finance leases at the end of the reporting period and their present value is described in the table below:

| | As of 31 December, | | | |
|---|---|---|---|---|
| In EUR 000 | 2018 | | 2017 | |
| | Minimum lease payments | Present value of minimum lease payments | Minimum lease payments | Present value of minimum lease payments |
| **Financial lease** | | | | |
| < 1 year | 4,126 | 3,790 | 4,212 | 3,909 |
| >1 and < 5 years | 14,228 | 13,767 | 15,260 | 14,723 |
| > 5 years | 0 | 0 | 0 | 0 |
| **Total** | **18,354** | **17,557** | **19,472** | **18,632** |
| less interests | -750 | | -840 | |
| Present value | **17,604** | **17,557** | **18,632** | **18,632** |

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

| In EUR 000 | PMV & FPIM | Lease company | Bank |
|---|---|---|---|
| **As per 31 December 2017** | **16,331** | **18,632** | **425** |
| Changes from financial cash flows | 0 | -3,460 | -120 |
| Changes arising from obtaining or losing control of subsidiaries or other business | 0 | 0 | 0 |
| Changes due to the effect of changes in FX rates | 0 | 0 | 0 |
| Changes in fair value | 0 | 0 | 0 |
| Capitalized interest | 1.143 | 0 | 0 |
| Lease additions | 0 | 2,384 | 0 |
| **As per 31 December 2018** | **17,474** | **17,556** | **305** |

## 5.2.25/ TRADE PAYABLES AND OTHER CURRENT LIABILITIES

| | As of 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| Trade payables | 7,973 | 5,555 |
| **Total trade payables** | **7,973** | **5,555** |

| | As of 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| Provision vacation pay and end-of-year premium & other social debt | 4,139 | 3,404 |
| VAT payables | 42 | 35 |
| **Other current liabilities** | **4,181** | **3,439** |

## 5.2.26/ DEFERRED INCOME

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| Grants | 987 | 1,213 |
| Collaboration income | 2,029 | 1,575 |
| **Total** | **3,016** | **2,862** |
| Current | 3,010 | 2,777 |
| Non-current | 6 | 10 |

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.

| | Deferred partner income |
|---|---|
| **As per 31 December 2016** | **1,837** |
| Invoiced | 1394 |
| Recognized in profit or loss | -1,656 |
| **As per 31 December 2017** | **1,574** |
| Invoiced | 2,454 |
| Recognized in profit or loss | -1,999 |
| **As per 31 December 2018** | **2,029** |

## 5.2.27/ ACCRUED EXPENSES

Accrued expenses primarily include accruals for rental charges.

## 5.2.28/ INCOME TAXES

### 5.2.28.1/ COMPOSITION OF TAX EXPENSE

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| Current tax | -112 | 118 |
| Deferred tax | 3 | -3,483 |
| **Income tax expense (profit) recognized in loss for the period** | **-109** | **-3,365** |

In 2017, the recognized research and development tax credit in Belgium increased with EUR 3.4m as a consequence of an adjusted fiscal treatment for certain historical IP investments.

The recognition of the tax credits is accounted for in the income statement under the line 'Income taxes'.

## 5.2.28.2/ TAX RECONCILIATION

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

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| **Loss before taxes** | **-48,262** | **-45,325** |
| Income tax credit calculated at 29,58%/33.99% | -14,244 | -14,262 |
| Effect of different tax rates | -76 | 3 |
| Effect of income that is exempt from taxation | -3,200 | -5,339 |
| Effect of expenses that are non-deductible in determining tax profit | 566 | 494 |
| Effect of unused tax losses and tax offsets not recognized as deferred tax assets | 16,969 | 19,105 |
| Effect of previously unrecognized and unused tax losses | 0 | 0 |
| Effect of tax credit for research and development | -216 | -3,493 |
| Effect of capital tax in Biocartis SA | 103 | 105 |
| Other | -8 | 24 |
| | **-106** | **-3,364** |
| Adjustments recognized in the current year in relation to the current tax of prior years | -3 | 0 |
| **Income tax expense (profit) recognized in loss for the period** | **-109** | **-3,365** |

The effect of the tax credit for research and development decreased significantly, since in 2017 the tax credit increased with EUR 3.4m as a consequence of an adjusted fiscal treatment for certain historical IP investments.

## 5.2.28.3/ UNRECOGNIZED DEFERRED TAX ASSETS

Due to the uncertainty surrounding the Group's ability to realize taxable profits in the near future, the Group has not recognized any deferred tax assets on tax loss carry forwards and temporary differences.

The Group has tax losses available for carry forward of EUR 309.0m (2017: EUR 250.8m). The tax losses related to Biocartis SA amount to EUR 37,1m in 2018 (2017: EUR 36.9m) with the following expiration years. Each annual tax loss expires seven years after the fiscal period it has been realized.

In EUR 000

| Tax losses | Expiry year |
|---|---|
| 6,883 | 2020 |
| 29,427 | 2021 |
| 724 | 2023 |
| 100 | 2024 |
| **37,134** | |

The tax losses of Biocartis NV for EUR 254.1m per 31 December 2018 (2017: EUR 199.0m) in Belgium will not expire as they can be carried forward indefinitely.

## 5.2.28.4/ RECOGNIZED DEFERRED TAX ASSETS

The Group has R&D tax credit carry-forwards in Belgium for a total amount of EUR 6.8m (2017: EUR 6.6m) for which a deferred tax asset of EUR 6.8m (2017: EUR 6.6m) has been recognized as the recognition criteria have been met as from 2014.

# 5.2.29/ FINANCIAL RISK MANAGEMENT

## 5.2.29.1/ CAPITAL RISK MANAGEMENT

Capital comprises equity attributable to shareholders, borrowings and cash and cash equivalents. The Group's policy is to maintain a strong capital base in order to maintain investor and creditor confidence and to sustain the future development of the business. The Group's objectives when managing capital are to maintain sufficient liquidity to meet its working capital requirements, fund capital investment and purchases and to safeguard its ability to continue operating as a going concern.

The Group monitors capital regularly to ensure that the statutory capital requirements are met and may propose capital increases to the shareholders' meeting to ensure the necessary capital remains intact.

## 5.2.29.2/ FINANCIAL RISK FACTORS

The Group's activities expose it to a variety of financial risks such as market risk, credit risk, and liquidity risk. The Group's finance department identifies and evaluates the financial risks in close co-operation with the operating units.

## 5.2.29.3/ MARKET RISK

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The Group's activities expose it primarily to changes in foreign currency exchange rates and interest rates.

### FOREIGN EXCHANGE RISK

The Group is exposed to foreign currency risks primarily through its operating activities. Certain purchase transactions and certain sales transactions of the Group are undertaken in Swiss Franc ("CHF"), 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 CHF, 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 2018 and 2017.

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 | **2018** | **2017** |
| **Liabilities** | | |
| CHF – Switzerland | 0 | 0 |
| USD - United States | 119 | 43 |
| GBP - Great Britain | 29 | 3 |
| | | |
| **Assets** | | |
| CHF – Switzerland | 4 | 11 |
| USD - United States | 3,565 | 2,908 |
| GBP - Great Britain | 98 | 200 |

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.

The following shows the trade and other receivables towards customers representing more than 10% of total trade and other receivable balances as per 31 December 2018:

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | 2018 | 2017 |
| **Carrying value** | | |
| Amgen | 1,099 | 2,295 |
| Genomic Health | 2,629 | 179 |
| Capital grant | 1,428 | 1,195 |
| Other trade and other receivables | 6,255 | 4,418 |
| | **11,411** | **8,087** |

None of the above receivables are impaired. None of the financial assets reported 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 5.2.24.

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 2018, 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 2018.

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, | | | | | |
|---|---|---|---|---|---|---|
| | 2018 | | | 2017 | | |
| In EUR 000 | Trade payables | Financial debt | Other current liabilities and accrued expense | Trade payables | Financial debt | Other current liabilities and accrued expense |
| Less than 1 month | 7,973 | 323 | 4,181 | 5,555 | 540 | 3,439 |
| 1-3 months | | 648 | | | 630 | |
| 3 months to 1 year | | 4,143 | | | 2,859 | |
| 1-5 years | | 30,221 | 746 | | 31,359 | 663 |
| 5+ years | | 0 | 754 | | 0 | 1,105 |
| **Total** | **7,973** | **35,335** | **5,681** | **5,555** | **35,388** | **5,206** |

# 5.2.30/ FAIR VALUE

The fair value of the financial assets has been determined on the basis of the following methods and assumptions:

- The carrying amount of the cash and cash equivalents and the current receivables approximate their value due to their short term character;
- Other current financial assets such as current other receivables are being evaluated on the basis of their credit risk and interest rate. Their fair value is not significantly different than its carrying amount on 31 December 2018 and 2017.
- The fair value of the participation in MyCartis is not significantly different than its carrying amount on 31 December 2018 and is based upon the valuation used in the latest capital increase in MyCartis in March 2016. The fair value measurement is classified as level 2.

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 no financial instruments carried at fair value in the consolidated balance sheet on 31 December 2018 and 2017.

Except for the borrowings (financial liabilities, see note 5.2.24), the carrying amount of the financial assets and liabilities approximate their fair values. The borrowings with a carrying amount of EUR 35.3m (2017: EUR 35.4m) have a fair value of EUR 35.1m (2017: EUR 34.7m).

# 5.2.31/ CONTINGENCIES

## Legal claims

The Group is currently not facing any outstanding litigation that might have a significant adverse impact on the Group's financial position.

## Potential claw back of government grants received

The Group recognizes grant income from Flemish, Dutch and European grant bodies when all contractual conditions are met. The government institutions may however perform an audit afterwards which may result in a (partial) claw back of the grant. The Group deems that the claw back risk is remote in view of the continuous monitoring of the contractual conditions. Currently the Group has fulfilled all the existing conditions relating to the recognition of its grant income. Contracts with these grant bodies also typically include clauses that define the need for future validation of the project results after completion of the initial grant term during which the subsidized expenses or investments have been incurred and for which the grant was earned. Should this validation not occur or be deemed inadequate, the grant bodies have the right to reclaim funds previously granted.

## Royalties

With respect to the Group's licensing agreements, the Group could in the future experience instances where royalty claims on sales of licensed products under these agreements exceed royalties reported by the Group.

# 5.2.32/ COMMITMENTS

## 5.2.32.1/ CAPITAL COMMITMENTS

Capital commitments relate mainly to the upgrade of the current cartridge production lines located in Mechelen (Belgium) for which the Group is engaged in several contractual arrangements with specified suppliers (2018: EUR 0.6m; 2017: EUR 2.2m). The group is also adding some office space for investments (lease hold improvements) will be made for EUR 0.6m. The Group had no other material commitments to capital expenditures on 31 December 2018.

## 5.2.32.2/ OPERATING COMMITMENTS

The Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 7.3m (2017: EUR 6.0m). It is expected that the majority of the commitments will be fulfilled in 2019.

## 5.2.32.3/ PRINCIPAL OPERATING LEASES AND CONTRACTS

The Group has entered into a number of operating leases in relation with its office and research and development and manufacturing facilities in Mechelen (Belgium), as well as in relation to company cars for which the average lease term is 48 months.

The breakdown of the Group's committed future payments as per 31 December 2018 under its lease contracts per nature and maturity is summarized in the table below.

| In EUR 000 | As of 31 December, | | | |
|---|---|---|---|---|
| | 2018 | | 2017 | |
| | Rent/Lease facilities | Car Lease | Rent/Lease facilities | Car Lease |
| Not later than 1 year | 1,875 | 1,052 | 1,677 | 821 |
| More than 1 year and less than 5 years | 4,274 | 1,506 | 4,516 | 880 |
| More than 5 years | 5,286 | 76 | 3,009 | 0 |
| **Total** | **11,435** | **2,634** | **9,202** | **1,700** |

| In EUR 000 | As of 31 December, | |
|---|---|---|
| | 2018 | 2017 |
| **Payments recognized as an expense** | | |
| minimum lease payments | 1,794 | 2,084 |
| **Total** | **1,794** | **2,084** |

## 5.2.32.4/ 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 and a list of the subsidiaries are disclosed below. There were no other transactions with related parties.

## 5.2.32.5/ REMUNERATION OF DIRECTORS AND MEMBERS OF THE EXECUTIVE MANAGEMENT

| In EUR 000 | Years ended 31 December, | |
|---|---|---|
| | 2018 | 2017 |
| Short-term employee benefits (salaries, social security bonuses and fringe benefits) | 1,775 | 2,509 |
| Post-employment benefits (Group insurance) | 17 | 65 |
| Share-based payment | 762 | 539 |
| **Total** | **2,544** | **3,113** |

The post-employment benefits for the key management are part of the retirement benefit scheme to which all qualifying personnel are entitled. The contributions are paid as a percentage of the gross annual salary for the defined contribution schemes and provisionally calculated based on regulations following the defined benefit schemes in place. No loans, quasi-loans or other guarantees have been given to a member of the executive management.

Share-based payments are related to the stock options over the vesting period 2018 and 2017 under the ESOP 2013, 2015, 2017 and 2018 plan, the roll forward of the options granted to key management is included in the remuneration report.

## 5.2.32.6/ SUBSIDIARIES

Details of the Company's subsidiaries at 31 December 2018 are as follows:

| Name of subsidiary | Principal activity | Place of incorporation and operation | Proportion of ownership interest and voting power held by the Group | |
|---|---|---|---|---|
| | | | 2018 | 2017 |
| Biocartis SA | Intermediate holding company | Scientific Parc EPFL, PSE-C<br>1015 Lausanne<br>Switzerland | 100% | 100% |
| Biocartis NV | Develop and market diagnostic platforms | Generaal de Wittelaan 11<br>B - 2800 Mechelen, Belgium | 99.99%* | 99.99%* |
| Biocartis BV | Develop and market diagnostic platforms | High Tech Campus 9<br>PO Box 775<br>NL - 5600 AT Eindhoven<br>The Netherlands | Liquidated in 2018 | 100%** |
| Biocartis US Inc | Develop and market diagnostic platforms | 2500 Plaza, 25th Floor, Suite 2547<br>Jersey City, NJ 07311<br>USA | 100% | 100% |

* All shares held by Biocartis SA, except for one share held by Biocartis BV.
** All shares of Biocartis BV are held by Biocartis SA, a wholly owned subsidiary of Biocartis Group NV.

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

## 5.2.33/ EVENTS AFTER THE BALANCE SHEET DATE

Three important events were announced after the reporting date.

**Equity raise –** On 23 January 2019, Biocartis successfully raised an amount of EUR 55.5m in gross proceeds by means of a private placement via an accelerated bookbuild offering of 5,000,000 new shares (being approximately 9.73% of the Company's outstanding shares). Consequently, Biocartis' cash position per end January 2019 amounted to over EUR 110m (unaudited figure). In addition, the Company has EUR 27.5m of multiple purpose credit lines at its disposal on which no drawdowns were made as per end of January 2019.

**New investment credit facility -** In 2019 a new investment credit facility from a bank was concluded for EUR 0.6m. This credit facility will be used for leasehold improvements and has an initial term of two years with an interest rate of 2.75%.

**China joint venture closing -** The closing of the joint venture for commercialization of the Idylla™ platform in China took place in January 2019 and triggered an initial capital contribution by both parties.

There were no further important events between 31 December 2018 and the approval date of this annual report.

## 5.2.34/ RELEVANT STANDARDS AND INTERPRETATIONS PUBLISHED, BUT NOT YET APPLICABLE FOR THE ANNUAL PERIOD BEGINNING ON 1 JANUARY 2018

IFRS 16 Leases (applicable for annual periods beginning on or after 1 January 2019)

Improvements to IFRS (2015-2017) (applicable for annual periods beginning on or after 1 January 2019, but not yet endorsed in EU)

Amendments to References to the Conceptual Framework in IFRS Standards (applicable for annual periods beginning on or after 1 January 2020, but not yet endorsed in EU)

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

Amendments to IFRS 9 Prepayment Features with Negative Compensation (applicable for annual periods beginning on or after 1 January 2019, but not yet endorsed in the EU)

Amendments to IAS 19 Plan Amendment, Curtailment or Settlement (applicable for annual periods beginning on or after 1 January 2019, but not yet endorsed in EU)

IFRIC 23 Uncertainty over Income Tax Treatments (applicable for annual periods beginning on or after 1 January 2019, but not yet endorsed in the EU)

Amendments to IAS 1 and IAS 8 Definition of Material (applicable for annual periods beginning on or after 1 January 2020, but not yet endorsed in the EU)

## IFRS 16 LEASES

IFRS 16 supersedes IAS 17 Leases and related interpretations. For lessees, IFRS 16 requires most leases to be recognized on-balance (under a single model), eliminating the distinction between operating and finance leases. In accordance with the new standard, the lessee will recognize assets and liabilities for the rights and obligations created by leases. The new standard will increase interest-bearing liabilities and property, plant and equipment in the consolidated financial statements. In addition, the rental expenses recognized in profit or loss will decrease and depreciation and amortization as well as interest expenses will increase.

Lessor accounting under IFRS 16 is substantially unchanged from today's accounting under IAS 17 and will not have an impact on the Groups accounting of its reagent rental agreements.

IFRS 16 is effective for the reporting periods beginning on 1 January 2019. The Group will apply the modified retrospective approach upon transition to IFRS 16 which means that comparatives will not be restated. For the transition the Group will use the following optional exemptions:

- 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;
- Use hindsight to determine the lease term at initial application; and
- Apply single discount rate to a portfolio of leases with reasonably similar characteristics on transition.

The Group expects main impacts for leases currently classified as operating leases and for which the Group acts as a lessee. As at December 31, 2018, the Group had non-cancellable (undiscounted) operating lease commitments of EUR 11,6m. The leases for which the low value and short term exemption has been used have a value of EUR 0,03m.

The other issued standards, amendments to standards and interpretations which are applicable for reporting periods beginning on or after 1 January 2019 are expected not to have a significant impact on the Groups consolidated financial statements.

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 in oncology and infectious diseases.

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

## INCOME STATEMENT

| | Years ended 31 December, | |
|---|---|---|
| In EUR 000 | **2018** | **2017** |
| Revenues | 4,436 | 4,457 |
| Other operating income | 50 | 1,257 |
| **Total operating income** | **4,486** | **5,714** |
| Services and other goods | -1,426 | -1,776 |
| Salaries, social security contributions and pensions | -2,909 | -3,809 |
| Other operating expenses | -800 | -7 |
| **Operating expenses** | **-5,135** | **-5,592** |
| Financial income | 2,158 | 1,498 |
| Financial expenses | -1,218 | -4,921 |
| **Result from continuing operations** | **291** | **-3,301** |
| Income taxes | 0 | 17 |
| **Net result** | **291** | **-3,284** |

## BALANCE SHEET

| In EUR 000 | As of 31 December, 2018 | 2017 |
|---|---|---|
| Financial fixed assets | 235,933 | 228,822 |
| **Non-current assets** | **235,933** | **228,822** |
| Trade receivables | 0 | 63 |
| Other receivables | 200,032 | 161,492 |
| Cash and cash equivalents | 49,495 | 91,895 |
| Transitory accounts | 17 | 29 |
| **Current assets** | **249,545** | **253,479** |
| **Total assets** | **485,478** | **482,302** |
| | | |
| Share capital | 514 | 511 |
| Share premium | 479,680 | 477,581 |
| Accumulated deficit | -13,057 | -13,348 |
| **Total equity** | **467,137** | **464,782** |
| Financial debt | 16,272 | 16,331 |
| **Non-current liabilities** | **16,272** | **16,331** |
| Financial debt | 1,202 | - |
| Trade payables | 499 | 687 |
| Provision taxes | 16 | 131 |
| Salaries, social security contributions and pensions | 352 | 408 |
| **Current liabilities** | **2,069** | **1,188** |
| **Total equity and liabilities** | **485,478** | **482,302** |

# 6.4/ DISCUSSION OF STATUTORY ACCOUNTS

## INCOME STATEMENT

Total operating income in 2018 amounted to EUR 4.5m (2017: EUR 5.7m) and consists mainly of expense recharges to the Biocartis Group NV subsidiaries. Operating expenses recorded in the period under review amounted to EUR 5.1m (2017 EUR 5.6m) and consist of salaries, social security contributions and pensions expenses for EUR 2.9m (2017: EUR 3.8m) and of expenses for services and other goods of EUR 1.4m (2017: EUR 1.7m). Services and other goods mainly consist of recurring general and administrative expenses.

Financial income amounted to EUR 2.2m (2017: EUR 1.5m) 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 1.2m (2017: EUR 4.9m) and relate to the interest charges on the PMV loan In 2017 the financial expenses also related to the non-recurring expenses made in relation of the capital increases of Biocartis NV in November 2017 for EUR 3.8m.

The net result after taxes for the period ended 31 December 2018 amounts to EUR 0.3m (2017: EUR -3.3m).

# BALANCE SHEET

## ASSETS

The financial fixed assets consist of shares in the Biocartis Group NV subsidiaries for EUR 230.9m and a financial participation in a third party company MyCartis NV for EUR 5.1m.

Other receivables amounted to EUR 200.0m (2017: EUR 161.5m) and mainly relate to receivables on the Biocartis Group NV subsidiaries, mainly related to financial advances. Cash and equivalents amounted to EUR 49.5m per 31 December 2018 (2017: EUR 91.9m). Deferred charges relate to prepaid expenses.

## EQUITY

Total equity per 31 December 2018 amounted to EUR 467.1m (2017: EUR 464.8m) and the legal share capital and share premium amount to respectively EUR 0.5m (2017: EUR 0.5m) and EUR 479.7m (2017: EUR 477.6m).

Following movements in equity were recorded during the reporting period:

- Capital increase following the execution of stock options of 5 April 2018 for an amount of EUR 0.002m. The share premium account was increased with EUR 1.8m.
- Capital increase following the execution of stock options of 4 October 2018 for an amount of EUR 0.001m. The share premium account was increased with EUR 0.2m.
- Capital increase following the execution of stock options of 20 December 2018 for an amount of EUR 0.00007m. The share premium account was increased with EUR 0.05m.

## FINANCIAL DEBT

In 2016, Biocartis Group NV obtained a new 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% and with a maturity date at 30 September 2021. The interest on the loans is capitalized during the first three years of the agreement and accrued in the consolidated balance sheet at the year-end.

## OTHER LIABILITIES

As per 31 December 2018, trade payables amounted to EUR 0.5m (2017: EUR 0.6m), provision for taxes to EUR 0.02m (2017: EUR 0.1m) and payables for salaries, social security contributions and pensions to EUR 0.4m (2017: EUR 0.4m).

## TOTAL ASSETS AND LIABILITIES

Total assets and on the other hand total liabilities amounted per 31 December 2018 to EUR 486.3m (2017: EUR 482.3m).

## 6.5/ APPROPRIATION OF RESULTS

The statutory accounts of the Company reported a net profit of EUR 0.3m for the year 2018. The Board of Directors proposes to carry forward the statutory net profit of EUR 0.3m of 2018 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 96 6° of the Code of Companies 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 on top of that the company raised EUR 2.0m through the exercising of warrants in 2018., Taken into account the strong cash position of the Company at the end of 2018 as well as the expectations for 2019, 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 2020, 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 2018 - Consolidated financial statements

The original text of this report is in Dutch

## STATUTORY AUDITOR'S REPORT TO THE SHAREHOLDERS' MEETING OF BIOCARTIS GROUP NV FOR THE YEAR ENDED 31 DECEMBER 2018 - CONSOLIDATED FINANCIAL STATEMENTS

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 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 four 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 2018, the consolidated income statement, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated cash flow statement for the year then ended, as well as the summary of significant accounting policies and other explanatory notes. The consolidated statement of financial position shows total assets of 139.385 (000) EUR and the consolidated income statement shows a loss for the year then ended of 48.153 (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 2018 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

## Revenue recognition

Revenue for the year 2018 amounts to 27.811 KEUR and mainly consists of:

- Product related revenues (18.843 KEUR) including various combinations of instruments and cartridges in multiple element sales agreements, operational reagent rental agreements and rental agreements; and
- Collaboration revenues (8.329 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 Company adopted the new revenue recognition standard (IFRS 15) beginning January 1, 2018, which required that management perform a detailed assessment of the revenue accounting treatment for both new and existing agreements. 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 5.2.2.14 Revenue recognition and 5.2.4 Revenue of the consolidated financial statements.

How our audit addressed the key audit matters:

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 (revenue) 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.

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 management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our statutory auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our statutory auditor's report. However, future events or conditions may cause the group to cease to continue as a going concern;

**evaluate** the overall presentation, structure and content of the consolidated financial statements, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

**obtain** sufficient appropriate audit evidence regarding the financial information of the entities and business activities within the group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

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

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

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

## OTHER LEGAL AND REGULATORY REQUIREMENTS

### Responsibilities of the board of directors

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

### Responsibilities of the statutory auditor

As part of our mandate and in accordance with the Belgian standard complementary (revised in 2018) 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 and other matters disclosed in the annual report on the consolidated financial statements, as well as to report on these matters.

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

In our opinion, after performing the specific procedures on the directors' report on the consolidated financial statements, this report is consistent with the consolidated financial statements for that same year and has been established in accordance with the requirements of article 119 of the Companies Code.

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

### Statements regarding independence

- Our audit firm and our network have not performed any prohibited services and our audit firm has remained independent from the group during the performance of our mandate.

- The fees for the additional non-audit services compatible with the statutory audit, as defined in article 134 of the Companies Code, have been properly disclosed and disaggregated in the notes to the consolidated financial statements.

### Other statements

- This report is consistent with our additional report to the audit committee referred to in article 11 of Regulation (EU) No 537/2014.

**Zaventem, 28 March 2019**
**The statutory auditor**
**Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises CVBA/SCRL**

*Represented by Gert Vanhees*

CHAPTER 8

# GLOSSARY

| | |
|---|---|
| **Assay** | In the field of diagnostics, an assay is a process or method aimed at determining the presence or amount (quantitative assay) of a certain substance in a sample. |
| **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'). |
| **ctDNA** | This is circulating tumor DNA. |
| **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/). |
| **Deoxyribonucleic acid (DNA)** | DNA is a nucleic acid molecule that contains the genetic instructions used in the development and functioning of living organisms. |
| **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 authorisation 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 analyse 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. |
| **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). |
| **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 |
| **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." |
| **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. |
| **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. |
| **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. |
| **Sepsis** | Severe overall inflammatory response of the body to an infection. |

# BIBLIOGRAPHY


**1:** Number of permanent positions, including positions filled by employees, temporary workers or consultants.
**2:** RUO = Research Use Only, not for use in diagnostic procedures.
**3:** 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.
**4:** RUO = Research Use Only, not for use in diagnostic procedures.
**5:** FFPE = Formalin fixed, parrafin embedded.
**6:** Sources: Maertens G. et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42; De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268; De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639)>.
**7:** Including urothelial, prostate, pancreas, adreno-cortical, small bowel, sarcoma, mesothelioma, melanoma, gastric, and germ cell tumors (Latham et al. (2018) J Clin Oncol 36, 1-9. 10.1200/JCO. 18.00283.) Recently MSI has been associated with overall mutational and indel load of the tumor, neoantigen load, and lymphocyte infiltration of the tumor, and has been shown to be predictive for response to immunotherapies such as anti-PD-1 in a pan-cancer setting (Le et al. (2017) Science 10.1126/science. aan6733.)
**8:** All study abstracts can be found in the AMP Abstract Book available on https://amp18.amp.org/abstracts-posters/.
**9:** The performance review study was performed by Dr. Arnaud Uguen (MD, PhD, Department of Pathology of the Brest University Hospital, Brest, France) and Dr. Giancarlo Troncone (MD, PhD, Professor of Anatomic Pathology, University of Naples Federico II, Naples, Italy) and was published in the Journal of Clinical Pathology on 14 June 2018.
**10:** All study abstracts can be found in the AMP Abstract Book available on https://amp18.amp.org/abstracts-posters/.
**11:** Source: DataMintelligence, "Global Molecular Diagnostics Market 2018-2025".
**12:** Formalin-fixed, parrafin embedded.
**13:** Maertens G. et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42; De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268; De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639)>.
**14:** Formalin fixed, paraffin embedded.
**15:** The Oncotype DX GPS test is the only commercially available tissue biopsy-based, multi-gene test that has been clinically validated to assess the aggressiveness of prostate cancer in men with clinically low-risk or favorable intermediate-risk cancer at the time of diagnosis, helping to make better informed and more personalized treatment decisions. The vast majority of men currently diagnosed with low-risk prostate cancer undergo surgery or radiation treatment, although there is only a three percent chance that their disease will become life-threatening. In response to this issue, Genomic Health's tissue biopsy-based, multi-gene test has been clinically validated to predict aggressive cancer at the time of diagnosis, helping to identify those men who need immediate surgery or radiation therapy versus those who can confidently choose active surveillance. The result is a more precise and accurate assessment of risk, which helps more men avoid the lifelong complications associated with treatments they do not need, while directing aggressive therapy to those men who require immediate treatment. Source: website Genomic Health, last consulted on 28 November 2018.
**16:** Source: https://c212.net/c/link/?t=0&l=en&o=2365856-1&h=4238720714&u=https%3A%2F%2Fwww.goldjournal.net%2Farticle%2FS0090-4295(19)30001-9%2Ffulltext&a=Urology, last consulted on 5 February 2019.
**17:** All study abstracts can be found in the AMP Abstract Book available on https://amp18.amp.org/abstracts-posters/.
**18:** The MSI Biomarkers were identified by Prof. Diether Lambrechts' laboratory and exclusively licensed to Biocartis from the Flemish Institute for Biotechnology (VIB) in 2013.
**19:** On 17 May 2018, Biocartis announced that two studies conducted in cooperation with VIB regarding the performance of its exclusively licensed novel set of biomarkers for microsatellite instability (MSI) that are included in the Idylla™ MSI Assay (the 'MSI Biomarkers'), have been selected for publication at the ASCO. B. De Craene et al., "Detection of microsatellite instability (MSI) in colorectal cancer samples with a novel set of highly sensitive markers by means of the Idylla™ MSI Assay prototype", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, US; H. Zhao et al., "A novel set of 7 homopolymer indels for detection of MSI is associated with tumor mutation burden and total indel load in endometrial and colorectal cancers", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, US. The methodology used for detection of the seven biomarkers, TMB (tumor mutation burden,) and indel load, was whole-exome sequencing.
**20:** It concerns two studies, one treatment outcome study on the Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests (CE-IVD) and one on the performance of the prototype Idylla™ MSI test. Montagut et al., "Clinical impact of circulating tumor RAS and BRAF mutation dynamics in metastatic colorectal cancer patients treated with first-line chemotherapy plus anti-EGFR therapy: Combined analysis of two prospective clinical trials", presented at ESMO, 19-23 October 2018, Münich, Germany, and published in the ESMO 2018 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology; Decraene et al., "Detection of microsatellite instability (MSI) with a novel set of 7 Idylla™ biomarkers on colorectal cancer samples in a multi-center study", presented at ESMO, 19-23 October 2018, Münich, Germany, and published in the ESMO 2018 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology.
**21:** The Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests (CE-IVD).
**22:** The performance review study was performed by Dr. Arnaud Uguen (MD, PhD, Department of Pathology of the Brest University Hospital, Brest, France) and Dr. Giancarlo Troncone (MD, PhD, Professor of Anatomic Pathology, University of Naples Federico II, Naples, Italy) and was published in the Journal of Clinical Pathology on 14 June 2018.
**23:** B Jacobs, B Claes, P Laurent-Puig, JP Bachet, S Tejpar, G Maertens, E Sablon, "Analytical and clinical validation of the Idylla™ ctKRAS and ctNRAS-BRAF Liquid biopsy tests", first presented at the 2018 AACR Annual Meeting in Chicago, US, 14-18 April 2018.
**24:** De Luca et al, University of Naples Federico II, "The Idylla™ Assay and Next Generation Sequencing: an integrated EGFR mutational testing algorithm", Journal of Clinical Pathology, to consult online on http://jcp.bmj.com/content/jclinpath/early/2018/05/24/jclinpath-2018-205197.full.pdf?ijkey=V8eBoaMDpKZ7t9N&keytype=ref, 24 May 2018.
**25:** The Idylla™ KRAS and NRAS-BRAF-EGFR492 Mutation Assays (RUO, not for use in diagnostic procedures). M. Rabie Al-Turkmani et al., "Rapid Somatic Mutation Testing in Colorectal Cancer Using a Fully Automated System and Single-Use Cartridge: A Comparison with Next-Generation Sequencing", first presented at 70th AACC Annual Scientific Meeting in Chicago, IL (US).
**26:** CRBA Management BVBA, represented by Christian Reinaudo (chairman of the board), Ann-Christine Sundell, Harry Glorikian, CLSCO BVBA, represented by Leo Steenbergen, and Luc Gijsens BVBA, represented by Luc Gijsens.
**27:** Peter Piot (independent director), Hilde Windels BVBA, represented by Hilde Windels (non-executive director) and Roald Borré (non-executive director).
**28:** Bratzman SV et al. Expert Rev Mol Diagn. 2015; 15(6): 715—719, Siravegna G and Bardelli A. Genome Biol. 2014; 15(8): 449.
**29:** 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.
**30:** 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
**31:** Accès aux tests moléculaires EGFR, RAS et BRAF /Résultats d'une enquête dans 5 régions françaises, appui à la décision, INCa, janvier 2016
**32:** CAGR = Compound Annual Growth Rate.

**33:** Grand View Research, Cancer Diagnostics Market, March 2017, https://www.grandviewresearch.com/press-release/global-cancer-diagnostics-market.
**34:** Research and Markets: Global In-Vitro Diagnostics/IVD Market 2018-2023: Increasing Adoption of Fully Automated Instruments and Automation in Laboratories, April 2018, http://www.researchandmarkets.com
**35:** Grand View Research, Cancer Diagnostics Market, March 2017, https://www.grandviewresearch.com/press-release/global-cancer-diagnostics-market.
**36:** Molecular Diagnostics Market Size, Share & Trend Analysis Report By Technology (PCR, ISH, INNAT, Chips & Microarrays, Mass spectrometry, Sequencing, TMA), And Segment Forecasts, 2018 – 2024, ReportLinker, August 2018, http://www.reportlinker.com
**37:** Allied Market Research, Liquid Biopsy Market - Global Opportunity Analysis and Industry Forecast, 2017-2023
**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:** Source: https://www.globalreporting.org/standards/
**40:** US FDA, https://en.wikipedia.org/wiki/Food_and_Drug_Administration.
**41:** 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.
**42:** Source: MedTech Europe, https://www.medtecheurope.org/news-and-events/default/funding-and-reimbursement/
**43:** Source: NILA USA, https://www.nila-usa.org/nila/PAMA.asp.
**44:** Source: Pacific Bridge Medical, https://www.pacificbridgemedical.com/publication/ivd-registration-reimbursement-china/
**45:** REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and is a European Union regulation dated 18 December 2006.
**46:** World Cancer Research Fund International, http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/colorectal-cancer-statistics, last consulted on 26 January 2017
**47:** 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
**48:** 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
**49:** ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016.
**50:** NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016
**51:** Allegra C.J. et al. Extended RAS gene mutation testing in metastatic Colorectal Carcinoma to predict response to antiepidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. Journal of Clinical Oncology 2016; 34(2):179-85
**52:** http://www.amp.org/committees/clinical_practice/CRCOpenComment.cfm
**53:** 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)
**54:** ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016
**55:** 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
**56:** ESMO @ ECC 2015: Response to EGFR Agents in Combination With Chemotherapy Demonstrated in Patients with Metastatic Colorectal Cancer of Rare KRAS Molecular Subtype. http://www.esmo.org/Conferences/Past-Conferences/European-Cancer-Congress-2015/News/Response-to-EGFR-Agents-in-Combination-With-Chemotherapy-Demonstrated-in-Patients-with-Metastatic-Colorectal-Cancer-of-Rare-KRAS-Molecular-Subtype. Sept 2015.; P A Janne et al. BJC 2015. Impact of KRAS codon subtypes from a randomised phase II trial of selumetinib plus docetaxel in KRAS mutant advanced non-small-cell lung cancer; Alona Zer et al. J Thor Onco 2015. Pooled Analysis of the Prognostic and Predictive Value of KRAS Mutation Status and Mutation Subtype in Patients with NSCLC Treated with EGFR TKI's.
**57:** NCCN Clinical Practice Guidelines in Oncology – NSCLC – Version 6.2017
**58:** Allegra et al, Extended RAS Gene Mutation Testing in Metastatic Colorectal Carcinoma to Predict Response to Anti–Epidermal Growth Factor Receptor Monoclonal Antibody Therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015, J Clin Oncol 2016, 34:179-185, http://ascopubs.org/doi/pdf/10.1200/jco.2015.63.9674. See also http://gicasym.org/asco-updates-guideline-include-testing-new-ras-mutations.
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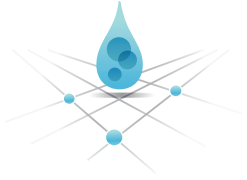
**60:** Aaltonen, L. A. et al. (1993) Clues to the pathogenesis of familial colorectal cancer. Science 260, 812–816.
**61:** Dudley JC et al. (2016) Microsatellite instability as a biomarker for PD-1 blockade. Clin Cancer Res. 22(4):813–820.
**62:** Cortes-Ciriano I et al (2017) A molecular portrait of microsatellite instability across multiple cancers. Nat Commun. 8:15180.
**63:** Sigurdis Haraldsdottir (2017) Microsatellite instability testing using next-generation sequencing data and therapy implications. JCO Precision Oncology 1, 1-4.
**64:** 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 July 25, 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 July 25, 2018. To view the most recent and complete version of the guidelines, go online to NCCN.org.(30) NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Uterine Neoplasms V.2.2018. Accessed July 25, 2018. To view the most recent and complete version of the guidelines, go online to NCCN.org.
**65:** Le DT et al. (2015) PD-1 blockade in tumors with mismatch-repair deficiency. N Engl J Med. 372:2509-2520; Le DT et al. (2017) Mismatch repair deficiency predicts response of solid tumors to PD-1 blockade. Science 357:409-413.
**66:** World Cancer Research Fund International, http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/colorectal-cancer-statistics, last consulted on 26 January 2017
**67:** 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
**68:** Mutations of the BRAF gene in human cancer. Helen Davies et al; Nature 2002, 417, 949-954
**69:** Clinical Practice Guidelines - Cutaneous melanoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 26 (Supplement 5): v126–v132, 2015.
**70:** ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016
**71:** Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey
**72:** This test was developed by Janssen Diagnostics (a division of Janssen Pharmaceutica NV) and intended for the detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV). It was launched as a CE-marked IVD test. In September 2017 it received 510(k) clearance by the US FDA as the first US FDA cleared test on the Idylla™ platform.
**73:** This test was co-developed by Biocartis NV, Janssen Diagnostics and the Belgian Institute of Tropical Medicine. In June 2016, Biocartis received Emergency Use Authorization (EUA) by the US FDA for the Idylla™ Ebola Virus Triage Test for detection of the Ebola Zaire virus.
**74:** The collaboration does not include the US, China and Japan
**75:** In November 2016, Biocartis announced a distribution agreement with Fisher Healthcare.
**76:** And some European countries.
**77:** MarketsandMarkets, Molecular Diagnostics Market - Forecast to 2020, February 2017
**78:** JMD, May 2017
**79:** The transparency notification of Debiopharm Innovation Fund S.A was dated 20 December 2017, referring to the transaction date of 28 November 2017



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