2016

Annual report

High Precision Diagnostics for Personalized Medicine

BIOCARTIS


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Seeing is believing
Accurate* and fast Molecular Diagnostics at your convenience
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Biocartis at a glance

BIOCARTIS

Innovative molecular diagnostics company committed to revolutionize molecular 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.

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

Biocartis' solutions focus on addressing unmet needs in oncology and infectious diseases.

CHAPTER 1

Overview

1.1.

2016 highlights

Installed base of **389** Idylla™ instruments and **4** new test launches

Test menu of **7** oncology assays and **2** infectious disease assays

Over 25,000 assays sold, **7.5** times the total commercial volume for 2015

Active in **60** countries worldwide

New commercial collaboration agreements with renowned pharmaceutical companies **Merck KGaA** and **Amgen**

Thermo Fisher Scientific selected as US commercialization partner

EUR 6.8m product revenues, an increase of **88%** compared to 2015

Successful equity placement of **EUR 32.7m** and **EUR 55m** of non-dilutive financing secured

EUR 83.2m year-end cash position

Strong progress made in building a
second cartridge manufacturing line

Management team **strengthened** with Hilde Eylenbosch as chief commercial officer and Reginald Vangenechten as new head of manufacturing & supply chain, and Ulrik Cordes taking up the role of EVP pharma collaborations & companion diagnostics

308 employees, **25** nationalities, balanced gender diversity: **50%** men / **50%** women

1.2.

Chairman and CEO reflections and outlook

Biocartis Chairman Rudi Mariën and CEO* and Founder Rudi Pauwels look back on 2016 and reflect on the challenges and opportunities that lie ahead

* Rudi Pauwels is Founder and was CEO of Biocartis until 2 March 2017. See also under 'Events after the reporting date'.

"We are pleased to present our annual report for 2016, in which we want to share with you the strong progress we made in 2016, together with our employees, partners, customers and shareholders."

How would you characterize 2016 for Biocartis?

Rudi Mariën: "2016 was a year in which we clearly showed strong commercial traction which was reflected in a significant growth of our product sales. This was driven by amongst others the continued menu expansion: three new core assays for oncology have been launched together with second infectious disease test. Another key element was the further expansion of our global commercial footprint, also driven the new collaborations we signed with Amgen and Merck[1]. I am proud to state that we had close to 390 Idylla™ instruments in the field end of 2016. This is a great starting point to further increase our commercial cartridge volumes in 2017."

How did your customer base develop in 2016?

Rudi Pauwels: "Our client base grew significantly in 2016. Being present at key oncology conferences worldwide played an important role in connecting with new clients. Where we initially focused on large reference labs with a high volume of molecular diagnostic oncology tests, we saw in 2016 a growing number of new customers from smaller pathology laboratories and hospitals, some of them did not yet run molecular diagnostic testing in oncology. They can now do so, thanks to Idylla™. This is a fantastic evolution, as this really shows the true potential of Idylla™ as a decentralized and flexible 'minilab', not requiring specialized personnel or infrastructure, enabling rapid and highly accurate diagnostic information, closer to where patients and healthcare workers are interacting."

Let's talk partners. You announced two new collaborations with large health care companies in 2016, expanding one of them already in the same year. You also announced a US partnership with Thermo Fisher Scientific. What is this telling us?

Rudi Mariën: "Our efforts to build solid partnerships with large pharmaceutical companies bore fruit. Both Merck and Amgen, two large players in the pharmaceutical industry, identified our diagnostics solutions as a tool to significantly shorten turnaround time of testing for patients, enabling faster treatment selection. This is one of the key elements behind Idylla™ and we are proud to have them as partners. It was great to see that we could already, within a short timeframe, expand our collaboration with Amgen in Europe, another confirmation to me that we can clearly make the difference with our solutions."

Rudi Pauwels: "Regarding the US, this market is expected to account for the largest share of the global molecular diagnostics testing market in oncology and infectious diseases. Being successful in this market is consequently of great importance to Biocartis. That is why the partnership we announced in November 2016 with Thermo Fisher Scientific is indeed an important milestone for Biocartis. Its commercial power, combined with its knowledge of the US oncology market, will help us to kick-start commercialization in the US in 2017. Another important element was the US FDA 510(k) submission of the Idylla™ platform, and the parallel submission of the Idylla™ Respiratory (IFV-RSV) Panel Test by our partner Janssen Diagnostics. This was an impressive joint effort between the teams of Janssen Diagnostics and Biocartis, demonstrating the true strength of our partnership."

[1] Merck KGaA.

In oncology, we see a lot of players intensifying their activities in molecular diagnostics (MDx). How are these impacting Biocartis?

Rudi Pauwels: "The global population growth to an expected 10bn people by 2050 and factors such as the rapidly ageing population puts increasing cost pressure on the healthcare system. For example, 30% or more of the population will at some point in their life be confronted with cancer and they will likely seek and need treatment and care close to where they live. As a result of a global effort to better understand the molecular basis of diseases and develop better, more precise treatments, molecular diagnostics will increasingly be pivotal in selecting and monitoring these best treatments. As a consequence, new molecular diagnostic technologies are needed that bring more value to the patient, payers and healthcare professionals, closer to the point where they can make an impact. Within this context, Biocartis' position in oncology is characterized by the unique features of our Idylla™ technology and products towards easy, fast and highly accurate high precision diagnostics closer to the point of care. The quality of the Idylla™ platform and first assays was further demonstrated in a series of external studies and resulted in 12 publications by the end of 2016. An important such study, first presented by global biopharmaceutical company AstraZeneca in October 2016, compared the performance of 12 different MDx platforms with a series of standardized blinded samples each containing a particular cancer driving mutation. It confirmed best-in-class status of the Idylla™ KRAS mutation detection technology. The conclusions from all of these studies, combined with our unique FFPE sample preparation ability, put us in a great position to grow share in the global oncology MDx market."

Rudi Mariën: "Obviously continuous innovation is key in maintaining our competitive position. That is why technological innovations such as our NGS (Next-Generation Sequencing) Prep Panel tests, our first step within the field of NGS, but also innovations on test level such as our microsatellite instability (MSI) test are so important. I expect a lot from the market that we are in, as we see an increasing number of targeted oncology treatments and immune-oncology treatments that will become available as well as a growing need for patient monitoring."

What do you expect for 2017?

Rudi Mariën: "I foresee that the acceleration in cartridge volume that you saw in 2016 will continue in 2017. This is driven by our current installed base, the further menu expansion in the course of 2017 but also because of more commercial activity in our distribution markets. Add to that our first sales coming from the US and the commercial traction from our collaborations with pharmaceutical partner companies."

Rudi Pauwels: "On top of that, we are aiming to start building a business in Companion Diagnostics (CDx), where a diagnostic test is used as a companion to a therapeutic drug to determine its applicability to a specific patient. We already have one CDx program in place and aim to expand that in 2017. Due to the growing cartridge volumes, we will put a lot of efforts in 2017 into completion of the construction of our second cartridge manufacturing line, as well as further strengthening of our supply chain. All in all, 2017 will bring us one step closer to realizing our ambition of becoming a global leading player in molecular diagnostics."

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 2016 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 takes precedence. An electronic version of the annual report 2016 is available on the website of Biocartis at www.biocartis.com. 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 2016 and 31 December 2016.

Forward-looking statement

Certain statements, beliefs and opinions in this report are forward-looking, which reflect the Company or, as appropriate, the Company's directors 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 update or revisions to any forward-looking statements in this report as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. 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 bus 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 trademark and logo are trademarks belonging to Biocartis and are used and registered in Europe. Idylla™ is a registered trademark in the United States and other countries. Idylla™ trademark and logo are used trademarks belonging to Biocartis. The Idylla™ platform, Idylla™ BRAF Mutation Test, Idylla™ KRAS Mutation Test, Idylla™ Respiratory (IFV-RSV) Panel Test and Idylla™ NRAS-BRAF Mutation Test are CE-marked. The Idylla™ EGFR Mutation Assay, ctBRAF Mutation Assay, Idylla™ ctKRAS Mutation Assay, Idylla™ NRAS-BRAF-EGFRS492R Mutation Assay and the Idylla™ ctNRAS-BRAF-EGFRS492R Mutation Assay are for Research Use Only and not for use in diagnostic procedures. Due to regulatory restrictions, not all of the products may be available in all countries. Not for sale in the US. The Idylla™ NRAS Mutation Test, Idylla™ ctEGFR Mutation Test, MSI, NGS Prep Panel, GeneFusion Panel, Respiratory MP and Sepsis assays are in development.

1.4.

Business review 2016

1.4.1.

Commercial highlights

INSTALLED BASE

A total of 224 Idylla™ instruments were added to the installed base in 2016, resulting in a total installed base of close to 390 instruments per year end 2016. This compared to an installed base of 165 instruments at the beginning of 2016 and the latest 2016 guidance of adding at least 175 instruments. The three key drivers behind the installed base growth in 2016 were menu expansion, an increased awareness by end customers on the excellent performance of the Idylla™ technology (as demonstrated in recent published comparative studies[2]) and the growing interest from pharmaceutical companies. The growth in installed base end of 2016 was also driven by the regulatory upgrade, i.e. the CE-marking of the Idylla™ NRAS-BRAF Mutation Test.

CARTRIDGE CONSUMPTION

In line with the installed base growth and menu expansion, commercial Idylla™ cartridge consumption in 2016 was over 25,000 cartridges, which is approx. 7.5 times the total commercial cartridge volume of 2015.

AMGEN COLLABORATION

AMGEN

On 3 February 2016, Biocartis announced a collaboration with Amgen to evaluate Idylla™ RAS testing as a tool for rapid decentralized testing in a range of countries[3]. This collaboration was expanded in December 2016 to include up to 10 new European countries and will enable several dozen additional selected hospitals to accelerate patient access to RAS biomarker information using Biocartis' Idylla™ platform and RAS tests.

COMMERCIAL FOOTPRINT

ThermoFisher SCIENTIFIC

During 2016, Biocartis further executed the expansion of its global commercial footprint by obtaining new market authorizations for 8 additional geographies and signing 9 new distribution agreements. More specifically, on 17 November 2016, Biocartis announced its partnership with Thermo Fisher Scientific Inc. to distribute in the US its Idylla™ platform and accompanying assays, with a first focus on oncology products. Both parties expect to start commercial roll-out in the US as of H2 2017. Biocartis has retained the option to sell both its Idylla™ platform and assays via direct sales channels into the US market.

[2] See further under 'Performance studies'. An overview of the publications can be found on www.biocartis.com.

[3] The collaboration announced on 3 February 2016 focused on selected reference hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey.

1.4.2.

Idylla™ test menu highlights

Colorectal cancer menu - During 2016, Biocartis significantly expanded and strengthened its colorectal cancer menu by:

- Completing its offering of metastatic colorectal cancer (mCRC) tests for clinical use on the Idylla™ platform with the CE-marking of its solid biopsy Idylla™ NRAS-BRAF Mutation Test on 15 December 2016. Biocartis' mCRC offering follows the most recent clinical guidelines and opens routes towards faster treatment selection.
- Entering into a collaboration with Merck KGaA (Merck) for the development and commercialization of a new liquid biopsy RAS biomarker test for patients with mCRC that was announced on 7 January 2016. This comprises two Idylla™ assays of which the first one, the Idylla™ ctKRAS Mutation Assay was launched in December 2016 under a Research Use Only (RUO) label and is Biocartis' second liquid biopsy test. The second assay under the agreement, the Idylla™ ctNRAS-BRAF-EGFR492 Mutation Assay (RUO) was launched on 2 March 2017. Biocartis and Merck plan to implement the Idylla™ liquid biopsy RAS test in numerous medical centers across the world[4] following CE-marking of both tests, expected in H2 2017.
- Signing an exclusive licensing of a recently detected set of ectodomain mutations in the Epidermal Growth Factor Receptor (EGFR)[5] that convey resistance to certain anti-EGFR therapies in colorectal cancer from Dr. Montagut (Hospital del Mar, Barcelona, Spain), Dr. Bardelli and Dr. Arena (University of Torino, Italy), entered into on March 2016. The aim is to integrate these novel biomarkers (which complement the EGFR S492R marker licensed by Biocartis in 2013) into molecular diagnostic tests for the Idylla™ platform, to enable physicians to monitor therapy resistance in patients and thereby allowing for optimizations of treatment regimes.

Lung cancer menu - On 21 June 2016, Biocartis launched the first test of its lung cancer menu with the Idylla™ EGFR Mutation Assay (RUO). This advanced, fully automated molecular test is designed to detect over 50 EGFR mutations which commonly occur in lung cancer on the basis of only a single slice of tumor[6] tissue. Its extreme ease-of-use allows for testing irrespective of location or laboratory expertise level and, as such, this assay has the potential to enable more wide-spread testing of lung cancer specimens.

[4] The collaboration does not include the US, China and Japan.

[5] It concerns a new set of mutations in the EGFR ectodomain. While the commonly known EGFR mutations reside in the kinase domain of the EGFR receptor, which is located inside the cell, the EGFR ectodomain is the portion of the receptor located outside the cell, and represents the true receptor function where EGF binds, and where anti-EGFR antibodies for the treatment of colorectal cancer such as cetuximab and panitumumab engage the EGFR receptor and prevent EGF binding.

[6] The analysis is done based on a slice of FFPE (formalin fixed paraffin embedded) tumor.

[7] Janku et al. BRAF Mutation Testing in Cell-Free DNA from the Plasma of Patients with Advanced Cancers Using a Rapid, Automated Molecular Diagnostics System. Mol Cancer Ther (2016) 15(6): 1–8; Schreuer et al. Quantitative assessment of BRAF V600 mutant cell-free tumor DNA from plasma as a diagnostic and therapeutic biomarker in patients with BRAF V600 mutant melanoma. ASCO 2015; De Biase et al. 'Fully Automated PCR detection of KRAS Mutations on Pancreatic Endoscopic Ultrasound Fine Needle Aspirates'. J Clin Pathol 2016; Reijans et al. ESMO 2016, published on 6 October 2016; De Luca et al., J Clin Pathol 2016; J.L. Sherwood et al., KRAS – ESMO Abstract 91 P: "Implications of key differences across 12 KRAS mutation detection technologies and their relevance in clinical practice", publically available on https://cslide.ctimeetingtech.com/library/esmo/browse/itinerary/5286/2016-10-10#2z95w; Ellen Vercauteren et al., NRAS – ESMO Abstract 1175P: "Ultra-rapid, sensitive, and fully automated extended RAS testing for metastatic colorectal cancer – evaluation of an NRAS/BRAF/EGFR492 module", publically available on https://cslide.ctimeetingtech.com/library/esmo/browse/itinerary/5286/2016-10-10#2z95w; Preliminary Performance Study based on Research data. Martin Reijans et al., EGFR – ESMO Abstract 1173P: "Fully automated and sensitive detection of EGFR exon 18, 19, 20 and 21 mutational status in less than 2.5 hours from a single FFPE slice", publically available on https://cslide.ctimeetingtech.com/library/esmo/browse/itinerary/5286/2016-10-10#2z95w; Jérôme Solassol et al., "Multi-Center Evaluation of the Fully Automated PCR-Based Idylla™ KRAS Mutation Assay for Rapid KRAS Mutation Status Determination on Formalin-Fixed Paraffin-Embedded Tissue of Human Colorectal Cancer", available for download: http://journals.plos.org/plosone/article/asset?id=10.1371/journal.pone.0163444.PDF

Performance studies - During 2016, a total of eight different promising publications[7] were issued on the performance of Idylla™ oncology tests, four of them were presented at the renowned international oncology conferences ASCO and ESMO. This included a comparative study[8] organized by AstraZeneca, a global biopharmaceutical company, where 12 different KRAS mutation detecting technologies, including Next-Generation Sequencing (NGS) and quantitative Polymerase Chain Reaction (PCR), were compared for the detection of KRAS mutations, using blinded samples. This study confirmed the best-in-class status of the Idylla™ KRAS technology.

US FDA achievements - Two important achievements were realized with the US Food and Drug Administration (FDA) in 2016:

- On 1 June 2016, Biocartis received Emergency Use Authorization by the US FDA for the Idylla™ Ebola Virus Triage Test (Idylla™ EBOV Test) that runs on the Idylla™ platform. This test was co-developed by Biocartis, Janssen Diagnostics (a division of Janssen Pharmaceutica NV) and the Belgian Institute of Tropical Medicine.
- On 22 December 2016, Biocartis completed the 510(k) submission[9] to the US FDA of its Idylla™ platform, comprising of the Idylla™ Instrument and the Idylla™ Console. This submission was done in parallel with the 510(k) submission by Biocartis' strategic partner Janssen Diagnostics of the Janssen Idylla™ Respiratory (IFV-RSV) Panel Test.

1.4.3.

Operational highlights

Strengthening management team - Hilde Eylenbosch, who joined Biocartis' Board of Directors in May 2016, took over the position of Chief Commercial Officer as of 17 November 2016. Ulrik Cordes (the Company's previous Chief Commercial Officer since September 2013) transitioned on that date into the function of EVP Pharma Collaborations and Companion Diagnostics, aimed at building a strong complementary and companion diagnostic business. Furthermore, during Q1 2016, Biocartis strengthened its manufacturing expertise with the appointment of Reginald Van Genechten as Head of Manufacturing and Supply Chain.

Cartridge manufacturing - During 2016, Biocartis together with its partners continued the works on a second cartridge manufacturing line. The aim is to have this line operational by the end of 2017. It should provide for an additional annual cartridge capacity of over 1 million Idylla™ cartridges.

[8] James L. Sherwood, "Implications of Key Differences Across 12 KRAS Mutation Detection Technologies and Their Relevance in Clinical Practice", first presented at ESMO in October 2016.

[9] Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k).

1.4.4.

Financial highlights

Product sales revenues - Total product sales revenues in 2016 increased with approx. 88% to EUR 6.8m from EUR 3.6m in 2015. This increase was predominantly driven by cartridge sales that amounted to EUR 4.0m in 2016, representing over 3 times the 2015 cartridge sales of EUR 1.3m. System sales increased with approx. 20% from EUR 2.3m in 2015 to EUR 2.8m in 2016.

Equity raise - On 17 November 2016, Biocartis successfully raised EUR 32.7m of gross proceeds by means of a private placement via an accelerated bookbuild offering of 4,058,917 new shares (being approximately 10% of the Company's outstanding shares) at an issue price of EUR 8.05 per share.

Debt financing - On 20 July 2016, Biocartis announced it had attracted EUR 55m of non-dilutive financing consisting of a EUR 40m bank and lease financing facility as well as a new subordinated loan of EUR 15m. The bank and lease financing facility consists of EUR 15m lease financing and EUR 25m multiple purpose credit lines (the credit lines are partially guaranteed by the Flemish Government). Biocartis' total debt outstanding amounted to EUR 31.4m as per 31 December 2016, compared to EUR 10.8m as per 31 December 2015.

Cash flow - Biocartis' cash flow from operational and investment activities amounted to EUR -62.7m in 2016, compared to EUR -32.8m in 2015, mainly driven by increased operational expenses and higher investments for cartridge manufacturing expansion. Given a cash flow from financing activities in 2016 of EUR 41.8m, the total net cash flow of 2016 amounted to EUR -20.9m.

Cash position - Biocartis' cash position as per 31 December 2016 amounted to EUR 83.2m compared to EUR 104.1m as per 31 December 2015.

Rudi Pauwels, Chief Executive Officer* of Biocartis: "Our 2016 performance and the continued feedback from our customers and their patients confirms our belief that with Idylla™ we can disrupt the global market of molecular diagnostics. We continue to see an increased interest by large pharmaceutical companies for easy and rapid molecular diagnostics testing needed for their high precision treatments, and to keep the healthcare model sustainable. We already saw this translated into valuable new long-term partnerships for Biocartis. Continued innovation around cancer treatments, such as liquid biopsy based monitoring, also indicates that the market for our current and future products is larger than initially thought. Still a lot of work is needed to materialize our ambitions. Starting commercialization in the US in 2017 is an important next step here. This not only because of the size of this market, but also due to the US' current centralized nature of MDx testing which will allow our clients to optimally benefit from the USPs Idylla™ has to offer. 2017 is definitely going to be another exciting year for Biocartis!"

* Rudi Pauwels is Founder and was CEO of Biocartis until 2 March 2017. See also under 'Events after the reporting date'.

1.4.5.

Update test menu strategy

Biocartis continuously monitors market, technological and scientific developments that have an impact on the competitive positioning of its current and future menu of Idylla™ tests. These reviews have resulted in a menu optimization as summarized below:

Biocartis is observing a stronger than expected traction of the Idylla™ platform in oncology. This traction is primarily fueled by Biocartis' unique position in providing FFPE[10]-based sample-to-result solutions, strong performance data of Idylla™ tests, and Biocartis' potential to benefit from the promises of liquid biopsy testing, immuno-oncology therapies and Next-Generation Sequencing (NGS). This has led to increased interest from customers and pharmaceutical companies. Therefore, the Company has decided to increase its focus on oncology and to turn this positive momentum into solid market share and revenue growth which:

- From a **menu perspective**, hould result in a faster and broader expansion of the Company's oncology offering into comprehensive menus for colorectal, lung, breast, urology and related tumors from a biomarker point of view, as well as expansion into immunotherapy and DNA repair fields[11]. This is facilitated by capturing the potential of oncology test development with collaboration partners, including CDx partnerships; and
- From a **commercialization perspective**, entails entering into additional commercial and regulatory collaborations with pharmaceutical and biotech companies to further accelerate worldwide market adoption of Idylla™.

Idylla™ is designed to be extremely versatile and therefore the Company remains committed to valorize the potential of the platform in other areas. This especially holds true for infectious diseases given the unique position Idylla™ has within the field of syndromic panels and bloodstream infections (including sepsis). Over the coming months, the Company plans to update its infectious disease strategy which could include more partnership elements.

For an updated menu overview, see 'Outlook 2017' below or consult the corporate presention on www.biocartis.com.

[10] FFPE = formalin fixed paraffin embedded.

[11] Disruptions in DNA repair pathways predispose cells to accumulating DNA damage. A growing body of evidence indicates that tumors accumulate progressively more mutations in DNA repair proteins as cancers progress. DNA repair mechanisms greatly affect the response to cytotoxic treatments, so understanding those mechanisms and finding ways to turn dysregulated repair processes against themselves to induce tumor death is the goal of all DNA repair inhibition efforts. Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4125008/, last updated on 14 February 2017.

1.4.6.

Financial review 2016

The tables below show an overview of the key figures and a breakdown of operating income for 2016. A consolidated income statement, balance sheet, cash flow statement and statement of changes in equity of Biocartis Group NV can be found in chapter 7 under 'Consolidated annual accounts'.

Key figures (EUR 1,000)	2016	2015	% Change
Total operating income	13,772	14,951	-8%
Cost of goods sold	-5,701	-2,642	116%
Research and development expenses	-42,091	-36,554	15%
Marketing and distribution expenses	-10,324	-8,747	18%
General and administrative expenses	-5,827	-6,662	-13%
Operating expenses	-63,943	-54,606	17%
Operational result	-50,171	-39,655	27%
Net financial result	-586	-790	-26%
Income tax	980	648	51%
Net result	-49,777	-39,797	25%
Cash flow from operating activities	-53,312	-27,335	95%
Cash flow from investing activities	-9,342	-5,436	72%
Cash flow from financing activities	41,804	125,934	-67%
Net cash flow	-20,850	93,172	-122%
Cash and cash equivalents[1]	83,247	104,087	-20%
Financial debt	31,407	10,815	190%

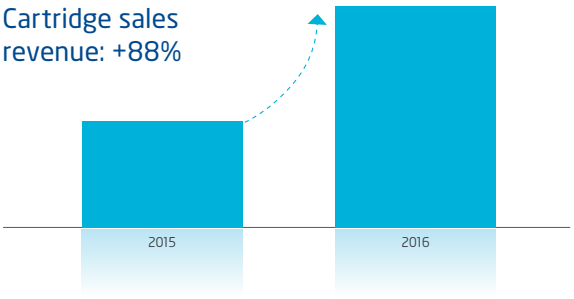
[1] Including EUR 1.2m of restricted cash (as a guarantee for KBC lease financing)

Breakdown operating income (EUR 1,000)	2016	2015	% Change
Collaboration revenue	5,278	9,686	-46%
Product sales revenue	6,767	3,593	88%
Idylla™ system sales	2,752	2,299	20%
Cartridge sales revenue	4,015	1,294	210%
Service revenue	53	54	-1%
Total revenue	12,098	13,334	-9%
Grants and other income	1,674	1,617	3%
Total operating income	13,772	14,951	-8%

Income statement

Operating income

In 2016, collaboration revenues, predominantly consisting of recognized upfront license revenues and milestone revenues from strategic partners, amounted to EUR 5.3m compared to EUR 9.7m in 2015, a decrease of approx. 46%. This was mainly driven by the fact that EUR 4.0m of one-off milestone payments were collected in 2015 versus EUR 332k of milestone payments that were received in 2016 (a decrease of approx. 92%). Recognized upfront license revenues amounted to EUR 4.7m, representing a decrease of approx. 7%. Product sales revenues on the other hand increased with approx. 88% in 2016 to EUR 6.8m from EUR 3.6m in 2015, predominantly driven by higher cartridge sales for commercial purposes.



Recognized grants and other income in 2016 amounted to EUR 1.7m being a 3.5% increase compared to 2015. During 2016, Biocartis obtained two new grants for a total amount of EUR 3.9m, consisting of a EUR 2.5m strategic grant from the Flemish Agency for Innovation & Entrep r its Strat tion Support o support expansion capacity (18 October 2016) and a EUR 1.4m grant from VLAIO, the Flanders organization for Innovation & Entrepreneurship, to support development of its rapid NGS Prep Panels (31 October 2016). Of these grants, EUR 0.4m was recognized in 2016.

Total operating income in 2016 consequently amounted to EUR 13.8m compared to EUR 15.0m in 2015.

Operating expenses

Total operating expenses in 2016 amounted to EUR 63.9m compared to EUR 54.6m in 2015, an increase of 17%. This included EUR 5.7m of cost of sales compared to EUR 2.6m in 2015, driven by the increase in product sales revenues in 2016. Excluding cost of sales, operating expenses increased in 2016 from EUR 52.0m in 2015 to EUR 58.2m, an increase of 12.1% driven by higher expenses in R&D and Marketing & Distribution and lower expenses for General & Administrative (G&A).

R&D expenses increased from EUR 36.6m in 2015 with 15.1% in 2016 to EUR 42.1m. This as the consequence of increased staffing (and related costs) as well as increased R&D activities for test and platform development which were partially offset by lower expenses for subcontracting. The increase in staffing and related costs was driven by the 38 headcount increase of the R&D team in 2015 (majority was only recruited towards the end of 2015, staffing costs for these employees consequently only had a full year impact as of 2016) as well as a headcount increase of the R&D team with 5 employees in 2016.

Marketing and Distribution expenses increased from EUR 8.7m in 2015 to EUR 10.3m in 2016 (18.0% increase) as a result of an expansion of the Marketing & Distribution team and increased sales and promotional expenses. During 2016, the Marketing & Distribution team was expanded with 16 employees of which several were already externally sourced from Janssen Pharmaceutica NV since 2015. That has also been the main reason for the decreased subcontracting costs in 2016.

G&A expenses decreased in 2016 with 12.5% to EUR 5.8m (EUR 6.7m in 2015) due to lower expenses for external advice (2015 was exceptionally impacted by the Company's IPO in April 2015), facilities & office and human resources that were partially offset by increased staff costs.

Operating result

The operational result in 2016 amounted to a loss of EUR 50.2m compared to a loss of EUR 39.7m in 2015.

Net financial result

The net financial result improved from EUR -0.8m in 2015 to EUR –0.6m in 2016, driven by decreased interest expenses partially compensated by higher other financial expenses, the latter being commitment fees, guarantee provisions and intercalary interests.

Income taxes

Driven by its operational loss in 2016, Biocartis had no taxable income and therefore incurred no income taxes. Due to research and development tax credits that Biocartis received in Belgium, the Company realized a positive tax result of EUR 1.0m compared to EUR 0.6m in 2015.

Net result

As a result of the foregoing, the loss for the year after taxes increased from EUR 39.8m in 2015 to EUR 49.7m in 2016.

Balance sheet

Non-current assets

The Company's intangible assets predominantly consist of patents and licenses on third party intellectual property and amounted to EUR 9.9m in 2016 compared to EUR 9.0m in 2015. This increase was driven by additions of EUR 1.9m and amortization expenses of EUR 1.0m.

Property plant & equipment predominantly consist, amongst others, of manufacturing equipment (including equipment owned by Biocartis, equipment held under lease and equipment that is under construction for the expansion of its current cartridge manufacturing line and for the building of its second cartridge manufacturing line), Idylla™ systems placed at clients (under operational lease contracts or rental contracts) or held for internal use as well as laboratory & ICT equipment. In 2016, property, plant & equipment increased with EUR 8.8m from EUR 14.2m in 2015 to EUR 23.1m as the results of investments (net, after disposals) of EUR 12.6m and depreciation of EUR 3.8m. Investments predominantly consisted of manufacturing equipment and Idylla™ systems for internal use and systems placed at clients under operational lease contracts or rental contracts.

Per 31 December 2016, a financial participation of EUR 5.1m was included on the balance, as the result of the acquisition of a participation in MyCartis NV on 15 January 2015, following the exercise by Debiopharm Diagnostics SA of a put option in December 2014. Biocartis currently holds an 8.40% participation in MyCartis NV.

Deferred tax assets per 31 December 2016 amounted to EUR 3.1m and relate to tax credits for research and development in Belgium.

Current assets

Inventory increased from EUR 5.8m in 2015 to EUR 9.8m end of 2016 mainly driven by higher levels of raw materials and semi-finished products in view of the increased commercial cartridge volumes. Finished products included cartridges and systems held for expected commercialization, including systems placed at customers under the Company's early adopter program.

Trade receivables decreased in 2016 with EUR 2.9m from EUR 5.9m in 2015 to EUR 2.9m mainly driven by collection of milestone and upfront payments from strategic partners. Other receivables related to VAT receivables and capital grants and amounted EUR 2.2m as per end of 2016. Other current assets included accrued grant income and deferred charges and increased in 2016 to EUR 1.9m compared to EUR 1.3m in 2015.

The Company's cash and cash equivalents end of 2016 amounted to EUR 83.2m compared to EUR 104.1m end of 2015.

Equity

Biocartis' total equity end of 2016 amounted to EUR 96.9m compared to EUR 114.9m end of 2015. This decrease was driven by the loss for the period which was partially offset by the proceeds from shares issued in the private placement of 17 November 2016.

Financial debt

Total financial debt amounted to EUR 31.4m as per end of 2016, representing an increase of EUR 20.6m compared to the EUR 10.8m of total financial debt outstanding end of 2015. The increase is for EUR 12.6m related to obtained lease financing for the funding of investments for Biocartis' current and second cartridge manufacturing line. Furthermore, EUR 8.1m is related to the new subordinated loan of EUR 15.0m that the Company attracted in July 2016 to refinance an existing subordinated loan (nominal amount of EUR 5m, excluding accrued interest charges) that was due end of 2016. The current portion of financial debt as per 31 December 2016 amounted to EUR 3.7m and the non-current portion to EUR 27.7m.

Other liabilities

Trade payables end of 2016 amounted to EUR 6.3m, representing a decrease of EUR -7.6m compared to the EUR 13.9m that was outstanding end of 2015. This decrease was predominantly driven by invoices received in 2015 for manufacturing expansion that were paid for in 2016. Deferred income decreased in 2016 to EUR 2.1m (EUR 5.2m end of 2015), mainly because of recognized upfront payments from Janssen Pharmaceutica in relation to the strategic licensing, development and commercialization collaborations.

Accrued charges as of 31 December 2016 remained flat compared to 2015 and predominantly consisted of accruals for rental charges. Other current liabilities increased to EUR 2.9m as per end of 2016 (EUR 2.0m end of 2015) and consist predominantly of provisions for vacation pay and other social debt.

Cash flow statement

Cash flow from operating activities

The cash flow from operating activities amounted to EUR -53.4m in 2016 compared to EUR -27.3m in 2015 driven by an increased loss for the period (predominantly due to higher operational expenses) in combination with investments in working capital in 2016 compared to significant positive moments in working capital for 2015.

Cash flow from investing activities

The cash flow from investing activities in 2016 amounted to EUR -9.3m compared to EUR -5.4m in 2015 principally driven by increased investments for the cartridge manufacturing expansion and higher investments in intangible assets, mainly consisting of software and IP licenses.

Cash flow from financing activities

The cash flow from financing activities in 2016 amounted to EUR 41.8m driven by the net proceeds from the private placement in November 2016 and proceeds from new borrowings, as well as the proceeds received from the Company's lease financing provider related to manufacturing equipment that was initially paid for by Biocartis and afterwards re-financed with lease financing. The cash flow from financing activities in 2015 amounted to EUR 125.9m, which was exceptionally impacted by the net proceeds from the Company's IPO in April 2015.

Total net cash flow

Driven by the aforementioned, the total net cash flow in 2016 amounted to EUR -20.9m compared to EUR 93.2m in 2015.

Representation cash flow statement 2015

Please note that the representation of the cash flow statement, compared to what is included in the annual report of 2015, has been adjusted to better reflect the actual cash flows behind investments in manufacturing equipment which are funded through lease financing. A detailed explanation is provided in the Notes to the Consolidated Financial Statements.

1.4.7.

Important events and announcements after the reporting date

Four important events were announced after the reporting date.

- **Companion diagnostics (CDx)** – In January 2017, Biocartis signed a first companion diagnostics partnership with an undisclosed pharmaceutical company (ranked amongst the global top 10 pharmaceutical companies by sales) for the joint development of an Idylla™ CDx test for an undisclosed phase II oncology compound.
- **Launch of the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Test** – On 2 March 2017, Biocartis launched the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (RUO[12]), an important milestone in the partnership with Merck[13] as well as the Company's third liquid biopsy test for oncology.
- **Change CEO position** – On 2 March 2017, Biocartis announced a change in the CEO position of the Company.
- **Grant for the development of MSI Test** – On 15 March 2017, Biocartis announced to have received an approximately EUR 750k grant from VLAIO, the Flanders organization for Innovation & Entrepreneurship, for the development of a fully automated MSI test on the Idylla™ platform.

There were no further important events between 31 December 2016 and the approval date of this annual report.

[12] Research Use Only.

[13] Merck KGaA, Darmstadt, Germany.

1.4.8.

Outlook 2017

Target of growing the total installed base to **640** Idylla™ instruments by adding **250-275** new instrument placements, driven by the ongoing menu and geographical expansion.

Annual commercial cartridge consumption in 2017 is targeted to grow over at least **3 times** the 2016 volume.

Menu expansion is aimed at further completing Biocartis' core oncology menu in the course of 2017:

- CE-marking Idylla™ **EGFR** Mutation Test (Q2 2017);
- CE-marking of Idylla™ **NRAS** Mutation Test (Q2/Q3 2017): this test will give more flexibility to customers and will allow for price differentiation with the Idylla™ NRAS-BRAF Mutation Test in geographies where BRAF testing for mCRC patients is not reimbursed;
- CE-marking Idylla™ **ctKRAS** Mutation Test and Idylla™ **ctNRAS-BRAF** Mutation Test as part of the partnership with Merck (H2 2017); and
- Launch of a **liquid biopsy version** of the Idylla™ EGFR Mutation Assay (RUO, H2 2017). Note: this product will be initially launched on the basis of a manual DNA extraction protocol anticipating a fully automated ctEGFR Mutation Assay that is also under development.

510(k) approval from the **US FDA** is expected for the Idylla™ Instrument, the Idylla™ Console and the Idylla™ Respiratory (IFV-RSV) Panel Test.

Biocartis targets a cash position by the end of 2017 of around EUR **40**m.

1.5.

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 rapidly and continuously changing technology, 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. 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. 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 in September 2014. Since that date, Biocartis and/or its partners have launched eight additional tests, of which three are CE-marked, and so far they have 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 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 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 all products.

Operational risks

Delays in the development of tests may occur resulting in a slower development of a broad and clinically relevant menu of tests.

To date, the Idylla™ platform has only 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 (including in the United States). Biocartis may experience unexpected delays or difficulties in the remaining stages of development and commercialization of its menu of tests, which may jeopardize and/or delay market acceptance of the Idylla™ platform. Such delays may occur due to a variety of factors.

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, Biocartis is placing its diagnostic platform with clients under, amongst others, operational lease contracts. These clients 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 instruments and consoles.

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 in the course of 2015 to a contract manufacturing partner (CMO). The manufacturing or assembly of the cartridge to date is performed in-house at Biocartis' facilities in Mechelen (Belgium). Management believes that Biocartis' current in-house production line for Idylla™ cartridges will provide it with sufficient capacity to meet volume projections to early 2018 driven by continuous efficiency improvement programs, by adding work stations and operating additional work shifts. In order to meet expected demand thereafter, Biocartis has started construction of a more automated and higher volume production line for Idylla™ cartridges in partnership. There can be no assurance that the second cartridge manufacturing line will be operational on time and be able to manufacture Biocartis' products in sufficient quantities, to the same standards and at an economically attractive cost compared to Biocartis' competitors, or at all. This could affect Biocartis' ability to continue supply to its customers which could result in potential financial and reputational damages. However, in preparing for this second cartridge manufacturing line, Biocartis and the CMO that it has partnered with for this line have followed a thorough process (backed by external experts). Furthermore, Biocartis has set up internal project teams to monitor all outsourced production activities on a regular basis.

In parallel, Biocartis is also preparing the execution of its longer term strategic plan by working on the design of a high volume, fully automated production line for Idylla™ cartridges. Such design work is also prepared in collaboration with a CMO.

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 the 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. Where possible, Biocartis tries to identify whether secondary sources are available for certain components. However, as this is not always possible, Biocartis tries to establish close relationships with its key suppliers and to perform regular quality checks to quickly identify potential quality issues.

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 amongst 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. Currently, the patent portfolio of Biocartis consists of 38 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 overlap in certain cases. 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. In order to mitigate these risks, Biocartis' IP team tries to get a good understanding of the IP landscape and to take action where required.

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. Therefore, Biocartis has set up an HR team that is not only focused on attracting the right employees but also on overall employee satisfaction.

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. In order to try to mitigate this risk, Biocartis' IT system uses a universal threat management system (UTM) that combines different levels of protection measures from firewalls to intrusion detection and data analysis (deep package inspection) for suspicious packets of data. This UTM works closely together with protection measures at the client side (e.g. anti-virus and spam detection programs). Furthermore, Biocartis has implemented rules governing access and use of the systems aimed at further reducing the risk of cyber-attacks.

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. In order to minimize this risk, all of the data on the Idylla™ platform is designed to be de-identified as much as possible and patient-identifiable details should only be available at the point of test. Furthermore, Biocartis tries to accurately anticipate the application or interpretation of the above mentioned laws when developing its products.

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. The Regulatory and Marketing teams within Biocartis work closely together to ensure all marketing materials accurately reflect the product claims as approved or cleared within the respective markets and only products meeting the local requirements are permitted to enter the respective 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 has set up a quality department that controls different quality related procedures throughout the Group. The most important procedures are further described in this report under 'Corporate Governance'.

Biocartis' business could be significantly and negatively affected by substantial changes in government regulations, particularly in 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. 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. The Regulatory team in Biocartis monitors the regulatory environment in the current and proposed markets to anticipate and plan for any projected changes.

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

From time to time, legislation is enacted that could significantly change the statutory provisions governing the clearance or approval, manufacture, marketing or taxation of Biocartis' products. In addition, regulations and guidance are often revised or reinterpreted in ways that may significantly affect Biocartis' products (e.g. healthcare systems related legislation). It is impossible to predict whether legislative changes will be enacted or regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Biocartis monitors these evolutions through different channels (including outside counsel, industry journals, attendance of relevant industry conferences, etc.).

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 its growth. Existing sources of financing and any funds generated from operations may not provide Biocartis with sufficient capital. Biocartis may require additional equity or debt funding from time to time to 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 sale 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.

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 its 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. Following a capital increase of MyCartis in December 2015 Biocartis holds approximately 9,53% of the share capital in MyCartis NV. 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.

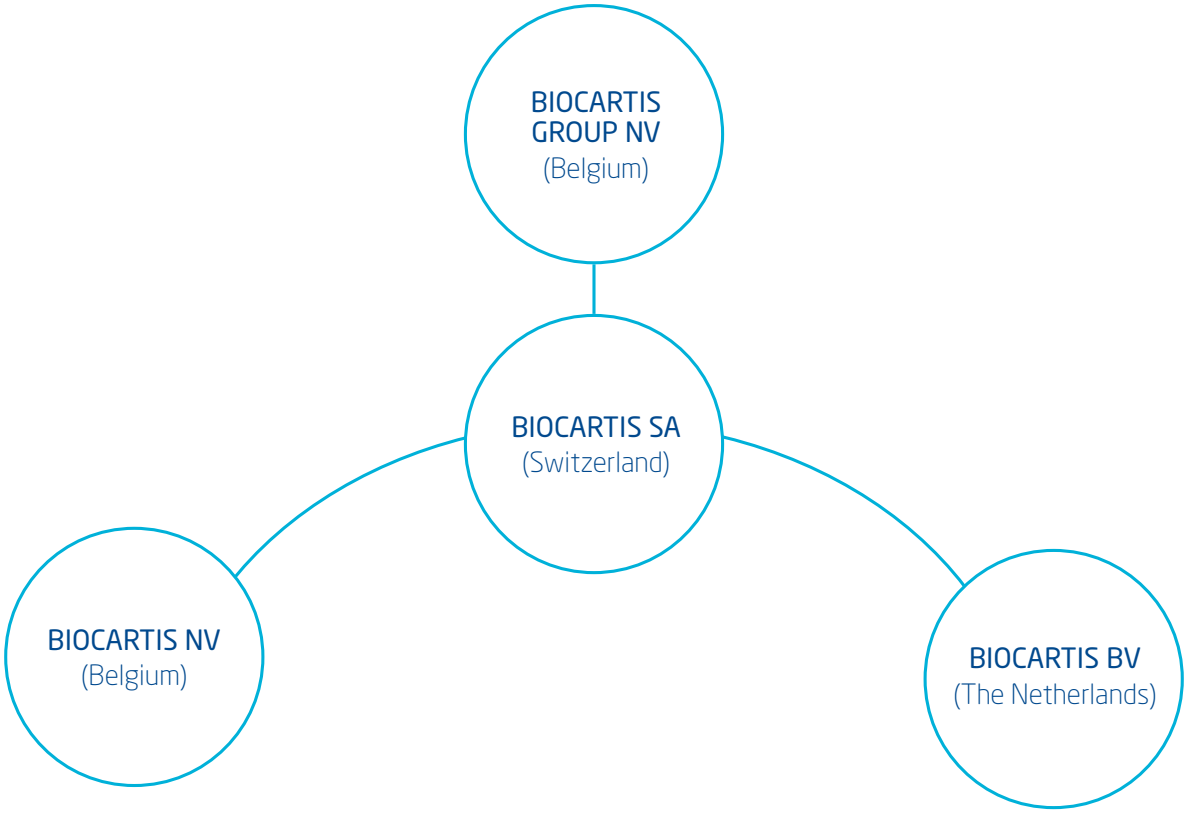
Biocartis has not declared or paid dividends on its shares. In the future, Biocartis' dividend policy will be determined and may change from time to time by proposal of the Biocartis' board of directors. Any declaration of dividends will be based upon Biocartis' earnings, financial condition, capital 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 2

About Biocartis Group

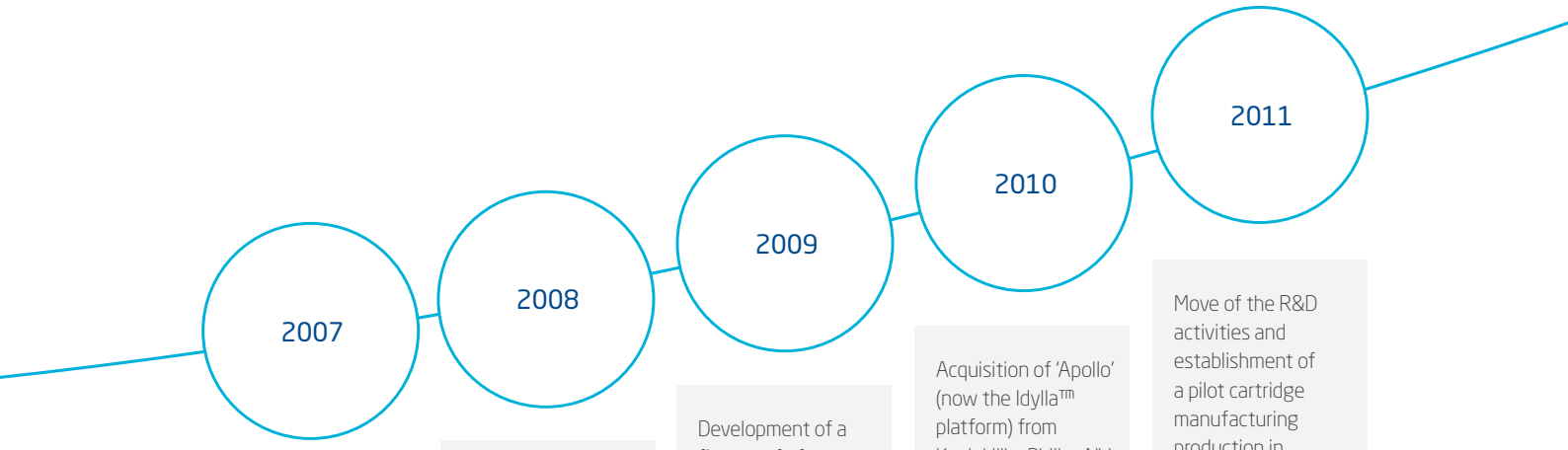
The Biocartis group consists of the holding company, Biocartis Group NV, and three wholly owned subsidiaries. The following chart represents the structure of Biocartis as of 31 December 2016:



Biocartis' headquarters are located in Mechelen, Belgium, incorporated on 24 November 2014 and registered in Belgium under enterprise number 0505.640.808 (register of legal entities Antwerp, division Mechelen). Since end 2015, the manufacturing of the Idylla™ Instrument and the Idylla™ Console is outsourced to an external Contract Manufacturing Organization (CMO). All other functions, including R&D, cartridge manufacturing and engineering and all support services are currently centralized in Mechelen, Belgium on several premises with a total size of approx. 5,500 sq m (premises leased from Intervest).

2.1.

Biocartis History



2007

Biocartis was founded in Switzerland

Biocartis acquired patent rights from the University of Ghent (Belgium) and Tibotec-Virco (a Johnson & Johnson company) for the development of a multiplex detection platform called Evalution™.

2008

Development of a first proof of concept for multiplexed immunoassays using our proprietary digitally encoded micro particle technology.

2009

Development of a first proof of concept for multiplexed molecular detection of DNA and RNA-based biomarkers.

A Biocartis subsidiary was established at high tech campus in Eindhoven (The Netherlands).

2010

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

Strategic partnership with bioMérieux to co-develop and co-distribute tests.

Strategic licensing, development and commercialization agreement with Johnson & Johnson to co-develop tests.

2011

Move of the R&D activities and establishment of a pilot cartridge manufacturing production in Mechelen (Belgium).

Biocartis received the 2012 Technology Pioneer Award by the World Economic Forum. co-develop tests.

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 was named Idylla™

New collaborations and license agreements with Hospital del Mar and the Flemish Institute for Biotechnology (VIB), in connection with its aim to develop tests for several cancers using new biomarkers.

2014

Strategic collaboration with Abbott Molecular to develop and commercialize companion diagnostics tests.

Spin out of the multiplex detection platform Evalution™ into a separate company MyCartis NV

Launch of the Idylla™ platform and its first oncology test, the Idylla™ BRAF Mutation Test as CE-IVD.

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 (the Idylla™ KRAS Mutation Test (CE-IVD), the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay (RUO) and the Idylla™ ctBRAF Mutation Assay (RUO), and the Idylla™ Respiratory (IFV-RSV) Panel Test, developed by Janssen Diagnostics.

Signing of five new collaborations for test development and/or commercialization, with Microbiome, Fast-track diagnostics, A*STAR, Merck KGaA and Amgen.

Outsourcing of the Idylla™ Instrument and Idylla™ Console to a renowned Contract Manufacturing Organization (CMO) to enable scaling of production.

2.2.

The molecular diagnostics market

Since the unravelling of the human genome in the 2000's, the study of human health and diseases has led to the discovery of macro-molecules, 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 is the primary tool used to identify such biomarkers, paving the way for high-precision personalized medicine.

The following trends are expected to further expand the molecular diagnostics market over the next years:

Increased personalized medicine and growth of companion diagnostics: society is increasingly shifting from the 'one drug fits all' paradigm to a more personalized medicine, driven by a better understanding of diseases, health economic studies, access to advanced technologies and better informed patients. This increasingly emphasizes the future importance of diagnostics, traditionally helped to confirm or screen the presence of a disease, towards predicting for example the course of a disease or the response to a specific treatment (companion diagnostics).

Enhanced biomarker identification and molecular techniques: certain key developments over the last decade, particularly the rise of NGS, have significantly accelerated the discovery of new biomarkers in clinical research, the elaboration of the tumor genome atlas, the growing availability of big data solutions, the discovery of the relevance of circulating tumor DNA, and growing insights in targeted and immunotherapies. These are expected to further boost the development of innovative diagnostic tests that are able to analyze a multitude of biomarkers in a single sample.

Decentralized molecular testing: accurate diagnostic information needs to be made available in a timely manner, near the patient. This is expected to require the diagnostic solutions that can be used in non-expert settings by healthcare workers with no special laboratory training. Such solutions should also allow for molecular testing in less developed areas of the world. Currently, only a tiny fraction of the global population has access to MDx tests.

Growing prevalence and management of chronic illness: chronic illnesses increase the importance of monitoring disease, for which diagnostic testing is crucial.

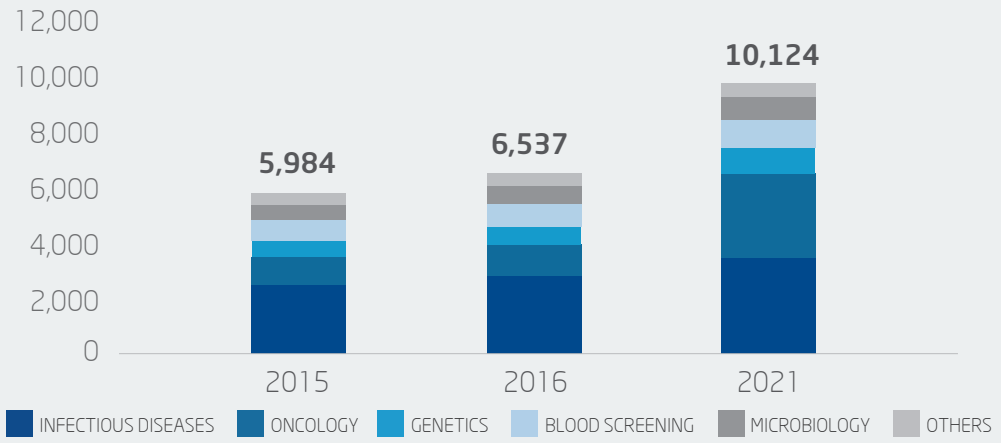
Expected shift of healthcare spending from treatment to more pro-active diagnosis: rising healthcare costs and budget constraints push towards a more intelligent approach where MDx provides clinicians with more and better information, leading to better treatment outcomes. Healthcare policy makers, governments, insurers and other payers are implementing price control systems that favor early diagnosis, better screening and monitoring and cost-effective therapies. As such, diagnostic testing is increasingly being accepted as a critical tool to reduce healthcare costs.

The rising global population towards 10bn people in 2050 and increasing threat of emerging infectious diseases, also related to a rapidly growing awareness on AMR (Antimicrobial resistance), show that our world needs improved infectious diseases detection solutions.

Technological advancements are transforming the entire healthcare industry: driven to improve healthcare outcome for the patient, new technologies such as wearable tracking devices to monitor physical activity or sleep patterns will make their way into the healthcare space. More and more, in return of improved healthcare outcome, the patient will be in the lead when it comes to proactively sharing data with healthcare providers and clinicians to help them make the right health outcome decisions.

The global in vitro diagnostics (IVD) market was valued at USD 60.22 billion in 2016. This market is expected to grow at a CAGR of 5.5% during the forecast period (2016–2021) to reach USD 78.74 billion by 2021[14].

The molecular diagnostics market size, by application, 2014–2021 (USD MILLION)[15]



By application, the largest MDx segment in 2016 was infectious disease, representing 43% of the MDx market, followed by oncology (19%), blood screening (13%), genetics (10%), microbiology (9%) and others[16] (7%). Biocartis currently focuses on the two largest segments: **oncology** (primary focus) and **infectious diseases**.

Biocartis' primary focus is on oncology, the fastest growing segment of the MDx market[17]. Oncology diagnostics are being driven by increasing incidences of certain cancers and the growing acceptance of companion diagnostics (CDx) to improve treatment efficiencies, while controlling healthcare costs as cancer remains a major direct and indirect burden on society.

What is cancer?[18]

Cancer is a group of diseases characterized by the uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. Cancer is caused by external factors, such as tobacco, infectious organisms, and an unhealthy diet, and internal factors, such as inherited genetic mutations, hormones, and immune conditions. These factors may act together or in sequence to cause cancer. Ten or more years often pass between exposure to external factors and detectable cancer. Treatments include surgery, radiation, chemotherapy, hormone therapy, immune therapy, and targeted therapy (drugs that interfere with cancer cell growth by targeting specific molecules). Worldwide, one in seven deaths is due to cancer; cancer causes more deaths than AIDS, tuberculosis, and malaria combined. When countries are grouped according to income, cancer is the second leading cause of death in high-income countries (following cardiovascular diseases) and the third leading cause of death in low- and middle-income countries (following cardiovascular diseases and infectious and parasitic diseases).

[14] MarketsandMarkets: In Vitro Diagnostics (IVD) Market by Product Technology (Immunoassay, Clinical Chemistry, Molecular Diagnostics, Hematology) by Application (Diabetes, Cancer, Cardiology, Autoimmune Diseases) - Forecast to 2021. See http://www.marketsandmarkets.com/Market-Reports/ivd-in-vitro-diagnostics-market-703.html

[15] MarketsandMarkets—Molecular Diagnostics Market, Global Forecast to 2021 (December 2016) (MarketsandMarkets).

[16] MarketsandMarkets—Molecular Diagnostics Market, Global Forecast to 2021 (December 2016) (MarketsandMarkets).

[17] MarketsandMarkets—Molecular Diagnostics Market, Global Forecast to 2018 (August 2014) (MarketsandMarkets).

[18] American Cancer Society. Global Cancer Facts & Figures 3rd Edition. Atlanta: American Cancer Society; 2015.

There were an estimated **14.1** million cancer cases around the world in 2012, of these 7.4 million cases were in men and 6.7 million in women. This number is expected to increase to **24** million by 2035.
Lung cancer was the most common cancer worldwide contributing **13%** of the total number of new cases diagnosed in 2012. **Colorectal cancer** was the third most common cancer with nearly **1.4 million new cases** in 2012[19].

The cost of cancer[20]

In addition to the human toll of cancer, the financial cost is substantial. Direct costs include expenditures for treatment, as well as the cost of care and rehabilitation related to the illness. Indirect costs include the loss of economic output due to missed work (morbidity costs) and premature death (mortality costs). There are also hidden costs of cancer, such as health insurance premiums and nonmedical expenses (transportation, lost productivity, child or elder care, housekeeping assistance, wigs, etc[21]).
The exact global cost of cancer is unknown, but it is thought to be in the hundreds of billions of dollars per year. In the US alone, the estimated direct medical cost for cancer in 2011 was **$88.7 billion**[22]. The estimated cost of lost productivity due to premature cancer mortality in Europe in 2008 was **EUR 75 billion**[23].
The global cost of cancer is expected to increase due to increases in the number of new cancer cases, as well as the increasing cost of cancer therapies[24].

The pace of **FDA approvals of oncology drug indications** has picked up dramatically in recent years. Between 1949 and mid-2015, the FDA approved nearly **300** unique indications for oncology drugs. This means that four times as many indications for cancer drugs have been granted in the past 25 years than in the four decades prior to 1990. As such, this works out to an average of 4.4 indications per year[25].
As a result of the foregoing, oncology, the second largest MDx segment in 2016, is expected to account for the highest growth rate, resulting in a CAGR of 17% in the period 2016-2021[26].

[19] World Cancer Research Fund International, http://www.wcrf.org/int/cancer-facts-figures/worldwide-data, last accessed on 31 January 2017.

[20] American Cancer Society. Global Cancer Facts & Figures 3rd Edition. Atlanta: American Cancer Society; 2015.

[21] Mackay J, Jemal A, Lee NC, Parkin DM. The Cancer Atlas, First Edition. Atlanta: American Cancer Society; 2006.

[22] Agency for Healthcare Research and Quality. Total Expenses and Percent Distribution for Selected Conditions by Type of Service: United States, 2011. Medical Expenditure Panel Survey Household Component Data. Generated interactively. (October 02, 2014)

[23] Hanly P, Soerjomataram I, Sharp L. Measuring the societal burden of cancer: The cost of lost productivity due to premature cancer-related mortality in Europe. Int J Cancer. 2014:doi 10.

[24] Elkin EB, Bach PB. Cancer's next frontier: addressing high and increasing costs. JAMA. 2010;303(11):1086-1087.

[25] https://www.managedcaremag.com/archives/2015/10/fda-approval-oncology-drug-indications-1949-2015, last updated on 9 February 2017.

[26] MarketsandMarkets—Molecular Diagnostics Market, Global Forecast to 2021 (December 2016) (MarketsandMarkets).

2.3.

Misson,vision and strategy

2.3.1.

Mission and vision

High Precision Diagnostics for Personalized Medicine

Biocartis is an innovative commercial-stage molecular diagnostics (MDx) company, aiming to establish a new gold standard in diagnostic testing by providing high precision diagnostic solutions which improve clinical practice for the benefit of patients, clinicians, payers and industry.

Personalized medicine is about every person's unique genetic profile. Understanding and leveraging the molecular mechanisms underlying diseases empowers doctors to shift away from the one-drug-fits-all paradigm and tailor a treatment to the genetic profile of the patient. Specific molecular diagnostics tests can help make treatments more effective, with better outcomes and as such, reduce healthcare costs. For instance, detailed molecular diagnostics information helps a doctor determine what drug is the preferred treatment for a melanoma patient whose tumor carries a specific genetic mutation.

However, for a truly sustainable long term healthcare system, molecular information needs to be accurate, gathered quickly and easily, accessible to all, and available at the point of need. Today, this is not the case. Many hospitals do not perform molecular tests in-house, but send the test samples out to specialized labs, sometimes even to other countries. Furthermore, it is common that samples are processed in batches using a workflow that requires usage of multiple complex instruments that are to be operated by highly trained personnel. This is a time-consuming and labor-intensive process, and it normally takes several days or even weeks before results are available, thereby delaying treatment decisions, which are often crucial to save patients' lives.

Biocartis' flagship product, its proprietary MDx Idylla™ platform, has been designed specifically to offer fully automated, real time accurate and highly-reliable molecular information, from virtually any biological sample, in virtually any setting to overcome the drawbacks of today's testing as outlined above . Idylla™ addresses the growing demand for personalized medicine by allowing fast and effective treatment selection and treatment monitoring.

2.3.2.

Strategy: become a global leading player in rapid, easy and high precision diagnostics

Biocartis aims to become a global leading player in the molecular diagnostics market with an initial focus on oncology, followed by infectious diseases, aiming to offer diagnostics solutions for treatment selection, treatment monitoring and early disease detection.

Oncology

Biocartis' strategy is driven, one the one hand, by an increasing number of new targeted therapies and immunotherapies launched by large pharmaceutical companies, which require the identification of specific biomarkers that can drive cancer growth. On the other hand, Biocartis' strategy is driven by the increasing needs of oncologists and pathologists for more rapid, easy and highly accurate diagnostic tests which guide treatment decisions for the majority of their cancer patients.

With Idylla™, Biocartis believes it can meet specific needs in the oncology segment, thanks to its capability to develop highly sensitive, multiplexed assays, which can process a wide variety of samples including solid FFPE tissue and liquid samples such as blood plasma. This instead of batch based, on an on-demand basis which is in contrast to most MDx systems used in oncology as these are mainly tailored to higher throughputs. Biocartis is striving to first achieve a critical mass in its test menu availability for each of these core customer groups:

It is Biocartis' intention to first develop both solid (operating directly on a slice of FFPE tissue) and liquid biopsy assays (operating directly on liquid biopsy samples such as blood plasma) of its core oncology menu for melanoma, colorectal and lung cancer, as well as for breast and urological cancers, for which guidelines recommend molecular diagnostic testing for selection of on-market targeted treatments. In most cases, reimbursement for these tests is in place.

Liquid biopsy

With an expected growth rate to reach **USD 1.66 Billion** by 2021 from USD 0.58 Billion in 2016, growing at a CAGR of **23.4%** between 2016 and 2021[27], Biocartis believes that liquid biopsy assays are well positioned to transform current clinical practice. With liquid biopsy testing, sample taking is non-invasive, does not require prior information of the location of the tumor and is suitable for repeat sampling.

[27] MarketsandMarkets, "Liquid Biopsy Market Cancer Type (Lung, Breast, Colorectal, Prostate, Liver), Circulating Biomarkers (Circulating Tumor Cells, Circulating Tumor DNA), Product (Instruments, Software), End User (Reference Laboratory, Research Centers) - Forecast to 2021", http://www.marketsandmarkets.com/PressReleases/liquid-biopsy.asp

Secondly, Biocartis focusses on tests for novel cancer biomarkers linked to new targeted oncology treatments that are in development, as well as tests that would suit the emerging field of immuno-oncology therapies. In both cases, Biocartis aims to accelerate or expand menu development and related regulatory approvals through partnerships with pharmaceutical or biotech companies.

In order to address the needs of customers/patients with rare cancer driving mutations and/or cancer driving mutations that are not yet clinically validated, Biocartis will develop gateways to molecular diagnostic detection technologies that are more suitable for that market segment by the development of unique technological extensions on the Idylla™ platform. This will include the development of a rapid Idylla™ NGS Prep Panel Test which will enable more rapid and easy NGS testing by using the Idylla™ technology's unique best-in-class sample preparation technologies to generate DNA libraries that contain information relevant for oncology diagnostics, which can then be analyzed in the sequencing process.

Infectious diseases

As the Idylla™ platform is extremely versatile and hence a broad range of disease applications can be developed on Idylla™, Biocartis also targets the infectious disease market, more specifically the development of new, advanced syndromic panel tests which are expected to continue to drive growth and the adoption of MDx in decentralized settings.

Biocartis' infectious diseases (ID) tests are aimed at rapid response and microbiology laboratories. Our unique position in this segment is driven by the combination of Idylla™'s high sensitivity, its speed and its multiplexing capability. This enables syndromic panel tests that simultaneously detect a multitude of pathogens, with short turnaround time.

Further building on these unique features and aiming at improving the very high mortality rate in sepsis, Idylla™ Enrich is a product line extension under development, which will function as a dedicated pre-enrichment platform for bloodstream infections, intended to be used with an accompanying sepsis assay for the Idylla™ platform. With this solution, Biocartis intends to significantly reduce the current sample-to-result time for bloodstream infections from the currently more than 24 hours to approx. two hours, and reduce the rate of erroneous results.

CHAPTER 3

Our products

3.1.

The Idylla™ platform

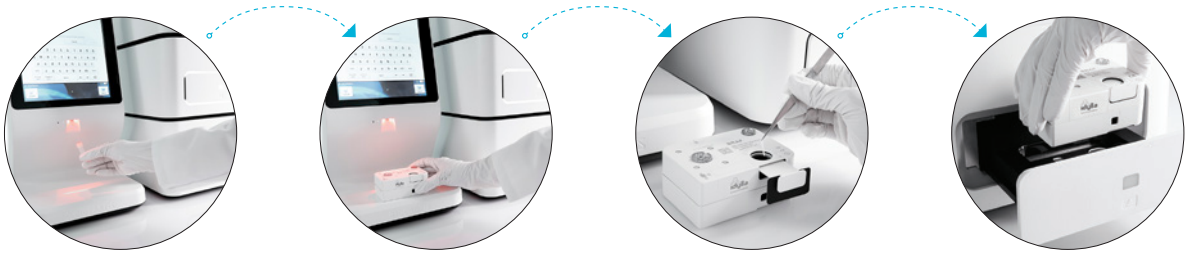
Idylla™ platform, launched in September 2014 as a CE-marked product, is a fully-automated, real-time PCR-based compact laboratory that integrates all the sample processing and analytical procedures required to provide high quality MDx results at the point-of-impact. The Idylla™ platform works on-demand in virtually any setting, allowing even decentralized laboratories to rapidly report results. The entire process from sample-to-result is covered in a timeframe between 35 minutes (for less complex tests) and 150 minutes (for highly complex tests). The Idylla™ platform is composed of a console, an instrument and a disposable cartridge.

The console: a touch-screen operated computer, with integrated barcode scanning and communication capabilities. Here, clinical sample information is entered, tests are initiated, results are displayed and, when required, test results are communicated to the Idylla™ Connect central data center and/or the user's laboratory information system.

The instrument: a stackable, independent unit that executes the entire test procedure within the cartridge. Multiple instruments can be connected to an Idylla™ console to match a range of throughput needs. A single instrument measures only around 30 x 50 x 20 cm and weighs approximately 20 kg.

The cartridge: a single use, disposable, self-contained 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 provides unsurpassed ease of use, making the system suitable for use by non-expert personnel in a non-specialized laboratory environment, close to the patient[28]. 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:



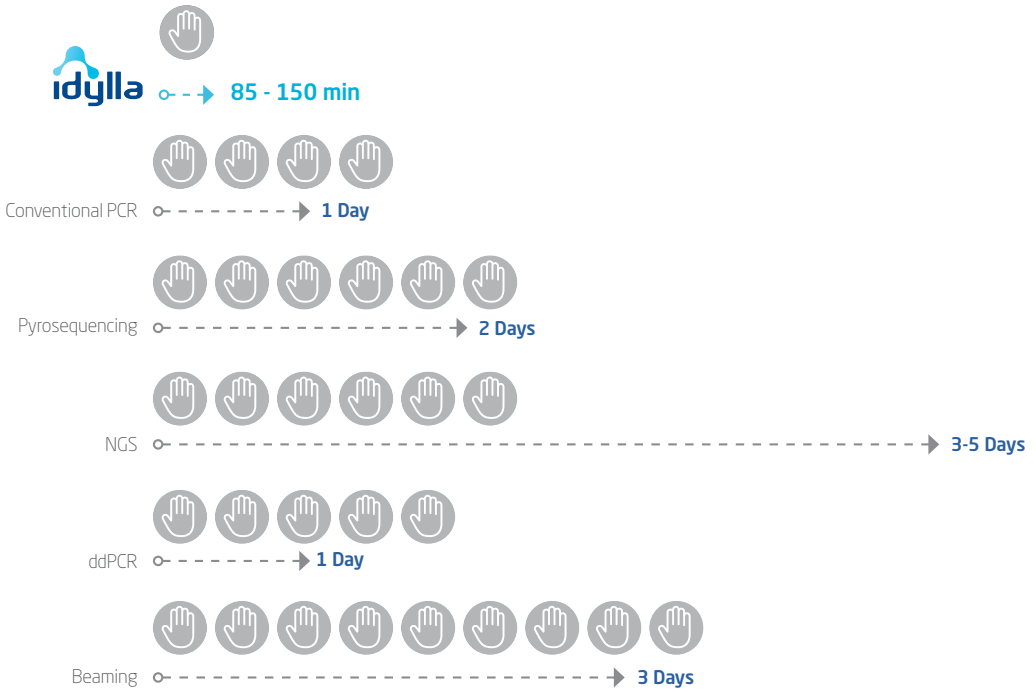
Step 1
The patient sample information is entered via the console by scanning the barcode on the sample container, or by manual entry of the patient sample identification code.

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™ system in combination with the Idylla™ Molecular Oncology Assays differs from other technologies in its outstanding ease-of-use, enabling clinicians to make treatment decisions in a much shorter timeframe.



[28] Biocartis believes Idylla™ has the potential to become a CLIA-Waived platform, i.e., a platform that, in accordance with applicable US rules and regulations (including the CLIA), is authorized for use in the US outside of specialized, dedicated laboratory environments and without the need for technically specialized and highly trained staff.

Idylla™ Explore and Idylla™ Connect

Idylla™ Connect is a web-based, real time service for healthcare monitoring whereby Idylla™ is safely connected to a network[29], allowing remote connectivity, advanced services such as automatic software updates, remote service and support as well as access to Idylla™ Explore. This is a web-based application that allows advanced data analysis by providing for example visualization of PCR curves from Idylla™ test results. Data is transported over a Single TLS (Transport Layer Security) socket between the Idylla™ system and the Biocartis server to secure end-to-end confidentiality of encrypted data. Idylla™ does not require patient identification information. Idylla™ test results only reference to an anonymous sample ID. Idylla™ Connect also enables to create a network between different Idylla™ user sites to share data and knowledge, and even the linking of the real-time molecular diagnostic test data to a disease surveillance grid which can be used to monitor a specific geo-location and sample data.

[29] The Idylla™ Connect and Idylla™ Explore solution complies with the US FDA adopted Cyber Security standards of the CSLI organization, AUTO-9A (Remote Access to Clinical Laboratory Diagnostic Devices via the Internet) and AUTO11-A2 (Remote Access to Clinical Laboratory Diagnostic Devices via the Internet).

3.2.

Menu of molecular diagnostic tests

Idylla™ Molecular Oncology Assays

Solid biopsy

Diagnostic products (CE IVD)

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

Research products (RUO)

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

Liquid biopsy

Research products (RUO)

- Idylla™ ctBRAF Mutation Assay
- Idylla™ ctKRAS Mutation Assay

Idylla™ Molecular Infectious disease Assays

- Idylla™ Ebola Virus Triage Test

(Emergency Use Authorization), co-developed by Biocartis NV, Janssen Diagnostics and the Belgium Institute of Tropical Medicine

- Idylla™ Respiratory (IFV-RSV) Panel, developed by Janssen Diagnostics (CE-IVD)

All CE-IVD tests in Biocartis' menu of tests are reimbursed by third-party payers.

Idylla™ Molecular Oncology Assays

KRAS

Idylla™ KRAS mutation detection on solid and liquid biopsies

RAS gene mutations occur in **9-30%** of all cancers[30] including colorectal cancer, lung cancer and pancreatic cancer. About **46%** of all metastatic **colorectal tumors** harbor mutations in the KRAS gene[31].

Several studies are ongoing to define the predictive impact of KRAS mutations on therapy decision for non-small-cell lung cancer patients[32]. 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[33].

According to ESMO[34], NCCN[35], ASCO[36], and CAP/AMP/ASCO guidelines[37], genotyping of clinically actionable mutations 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) 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 EGFR antibody therapies[38].

Using **liquid biopsies** for KRAS testing is minimally invasive, fast and easy to perform and provides an excellent solution to study the presence of KRAS mutations in different cancer types.

[30] Adrienne D. Cox et al. Drugging the undruggable RAS: Mission Possible? Nature Reviews Drug Discovery Volume: 13, Pages: 828–851 Year published: (2014) DOI:doi:10.1038/nrd4389

[31] 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.

[32] 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 randomized 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.

[33] NCCN Clinical Practice Guidelines in Oncology – NSCLC – Version 4.2016

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

[35] NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016

[36] 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

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

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

DIAGNOSTIC PRODUCT

Idylla™ **KRAS** Mutation Test (CE IVD)

KRAS

Diagnostic use

approx. 120 min. Sample-to-result

Approx. **120 minutes** sample-to-result

FFPE

Directly on FFPE tissue sections (5-10µm) from **metastatic colorectal cancer**

< 2 min. hands-on time

< 2 minutes hands-on time

Mutation detection for **baseline treatment**

RESEARCH PRODUCT

Idylla™ **ctKRAS** Mutation Test (RUO)

ctKRAS

Research Use Only, not for diagnostic use

approx. 130 min. Sample-to-result

Approx. **130 minutes** sample-to-result

1 ml

Directly on 1ml plasma

< 1 min. hands-on time

< 2 minutes hands-on time

Useful in multiple cancers harboring **KRAS mutations**

NRAS

Idylla™ NRAS mutation detection on solid biopsy

RAS gene mutations occur in **9-30%** of all cancers[39] and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.

According to ESMO[40], NCCN[41], ASCO[42] and the CAP/AMP/ASCO guidelines[43], RAS gene mutation testing 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 EGFR antibody therapies[44].

About 5% of all metastatic colorectal tumors harbor NRAS gene mutations[45]. In metastatic colorectal cancer, 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 mutations in mCRC is about 8-15%[46]. Recent data suggest that the EGFR S492R mutation may develop as a mechanism of resistance, in about 16% of patients, as a result of certain anti-EGFR antibody therapies such as cetuximab[47]. The Idylla™ ctNRAS-BRAF- EGFR S492R Mutation Assay can be used for the study of emergence of such mutations.

[39] Adrienne D. Cox et al. Drugging the undruggable RAS: Mission Possible? Nature Reviews Drug Discovery Volume: 13, Pages: 828-851 Year published: (2014) DOI:doi:10.1038/nrd4389

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

[41] NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016

[42] 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

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

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

[45] 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

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

[47] Montagut C. et al., Identification of a mutation in the extracellular domain of the Epidermal Growth Factor Receptor conferring Cetuximab resistance in colorectal cancer. Nature Medicine 2012. Newhall K., Frequency of S492R Mutations in the Epidermal Growth Factor Receptor: Analysis of plasma DNA from Metastatic Colorectal Cancer Patients Treated with Panitumumab or Cetuximab Monotherapy. 16th World Congress on Gastrointestinal Cancer, Barcelona, Spain 2014.

DIAGNOSTIC PRODUCT

Idylla™ **NRAS-BRAF** Mutation Test (CE-IVD)

Diagnostic use

approx. 120 min. Sample-to-result

Approx. **120 minutes** sample-to-result

FFPE

Directly on FFPE tissue sections (5-10µm) from **metastatic colorectal cancer**

< 2 min. hands-on time

< 2 minutes hands-on time

Mutation detection for **baseline treatment**

RESEARCH PRODUCT

Idylla™ **NRAS-BRAF-EGFR S492R** Mutation Assay (RUO)

Research Use Only, not for diagnostic use

approx. 120 min. Sample-to-result

Approx. **120 minutes** sample-to-result

FFPE

Directly on FFPE tissue sections (5-10µm) from **metastatic colorectal cancer**

< 2 min. hands-on time

< 2 minutes hands-on time

Applicable in multiple cancers harboring a **NRAS, BRAF or EGFR S492R mutation**

Together, the Idylla™ KRAS Mutation Test (CE-IVD) and the Idylla™ NRAS-BRAF Mutation Test (CE-IVD) offer a complete testing for metastatic colorectal cancers (mCRC) for clinical use on Idylla™, as recommended by the most recent clinical guidelines of ASCO[48] and ESMO[49]. The ability of Biocartis' RAS test offering to enable same-day results can now open routes towards faster treatment selection for mCRC patients.

[48] 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.

[49] Van Cutsem et al, ESMO consensus guidelines for the management of patients with metastatic colorectal cancer, Annals of Oncology 2016, 8:1386-1422.

EGFR

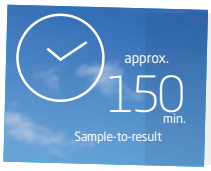
Idylla™ EGFR mutation detection on solid biopsy

EGFR mutations are mainly observed in **lung cancer**. The prevalence of EGFR mutations in NSCLC (non-small cell lung cancer) adenocarcinomas is 10-15% of Western and up to 50% of Asian patients. EGFR mutation testing is recommended in all patients with advanced non-small cell lung cancer (NSCLC) of a non-squamous subtype.

RESEARCH PRODUCT

Idylla™ **EGFR** Mutation Assay (RUO)

Research Use Only, not for diagnostic use



Approx. **150 minutes** sample-to-result

Directly on FFPE tissue sections (5-10µm) from **metastatic non-small cell lung cancer**

< 2 minutes hands-on time

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."

Idylla™ BRAF mutation detection on solid and liquid biopsies

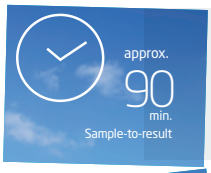
BRAF gene mutations occur in about **8%** of all cancers[50], including melanoma, colorectal cancer, thyroid cancer, lung cancer, hairy cell leukemia and ovarian cancer. BRAF testing is recommended in all patients with **metastatic melanoma and metastatic colorectal cancer** (mCRC).

About 50% of all metastatic melanoma patients harbor mutations in the BRAF gene, making them eligible for BRAF or BRAF/MEK inhibitor therapy[51]. 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%[52].

DIAGNOSTIC PRODUCT

Idylla™ **BRAF** Mutation Test (CE IVD)

BRAF



Approx. **90 minutes** sample-to-result

Directly on FFPE tissue sections (5-10µm) from **metastatic melanoma**

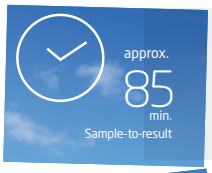
< 2 minutes hands-on time

Mutation detection for **baseline treatment**

RESEARCH PRODUCT

Idylla™ **ctBRAF** Mutation Test (RUO)

ctBRAF



Approx. **85 minutes** sample-to-result

Directly on 1 ml plasma

< 1 minute hands-on time

Useful in multiple cancers harboring a BRAF mutations

[50] Mutations of the BRAF gene in human cancer. Helen Davies et al; Nature 2002, 417, 949-954

[51] Clinical Practice Guidelines - Cutaneous melanoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 26 (Supplement 5): v126–v132, 2015.

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

Idylla™ Molecular Infectious Disease Assays

IFV-RSV

Idylla™ Respiratory (IFV-RSV) Panel (CE-IVD)

The Idylla™ Respiratory (IFV-RSV) Panel has been developed by Janssen Diagnostics and is a highly sensitive and standardized molecular assay that identifies these viruses in as quickly as **50** minutes, and requires less than **1 minute hands-on time**.

Influenza (IFV), commonly known as flu, is a contagious respiratory illness caused by influenza viruses A and B[53]. Respiratory syncytial virus (RSV) is a virus that infects the lungs and respiratory tract and may cause serious illness requiring hospitalization, especially in premature babies, infants and older adults with underlying health conditions.

Accurate and rapid diagnosis of influenza and RSV infection significantly decreases the use of antibiotics, cuts additional laboratory testing thereby saving time and resources and is associated with shorter hospitalization periods[54].

EBOV

Idylla™ Ebola Virus Triage Test (Emergency Use Authorization)

The Idylla™ Ebola Virus Triage Test (Idylla™ EBOV Test) received Emergency Use Authorization[55] by the US FDA on 1 June 2016. The test was co-developed by Biocartis NV, Janssen Diagnostics and the Belgium Institute of Tropical Medicine, and delivers results within 100 minutes on a single cartridge. The test is intended for the detection of the Ebola Zaire virus in patients with signs and symptoms of Ebola from the 2014 West Africa outbreak.

In the test, sample manipulation is reduced to a single step, i.e. entering the blood sample into the Idylla™ cartridge, after which the cartridge becomes a hermetically closed container. This reduces the risk of exposure to the Ebola virus for healthcare workers. Furthermore, the Idylla™ Ebola Virus Triage Test requires only minimal training of healthcare professionals and can be transported and stored at ambient temperature conditions, which enables rapid global deployment during outbreaks.

[53] Hammond SP, Gagne LS, Stock SR, Marty FM, Gelman RS, Marasco WA, Poritz MA, Baden LR. 2012. Respiratory virus detection in immunocompromised patients with FilmArray respiratory panel compared to conventional methods. J Clin Microbiol 50:3216-3221. Jennings LC, Anderson TP, Werno AM, Beynon KA, Murdoch DR. 2004. Viral etiology of acute respiratory tract infections in children presenting to hospital: role of polymerase chain reaction and demonstration of multiple infections. Pediatr Infect Dis J 23:1003-1007.

[54] Landry ML. 2011. Diagnostic tests for influenza infection. Curr. Opin. Pediatr. 23:91–97. doi:10.1097/MOP.0b013e328341ebd9.

[55] The Idylla™ Ebola Virus Triage Test is for use only under Emergency Use Authorisation (EUA) by laboratories in the United States certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity tests, and by laboratories in the United States certified under CLIA to perform high complexity tests, or in similarly qualified non- U.S. laboratories, by clinical laboratory personnel who have received specific training on the use of the Idylla™ Ebola Virus Triage Test on the Idylla™ System.

3.3.

Intellectual property (IP)

Currently, the patent portfolio of Biocartis consists of **38 proprietary families** comprising of issued and pending patents worldwide. The portfolio further includes multiple in-licensed patent families.

The protection of our intellectual property rights, which form the basis of our products and technologies, is a critical factor for our success. Biocartis' intellectual property is predominantly held by Biocartis NV. Our internal IP department overlooks the different IP related activities:

- We have built our current patent portfolio through acquisitions of third-party patents, patent applications and know-how, as well as through internal creation. It has also exclusively licensed specific third-party technologies.

- In addition to patents, we also rely on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements, non-exclusive licenses and other contractual provisions and technical measures that help us maintain and develop our competitive IP position. Based on these protections, competitors are not able to produce tests or cartridges that operate on the Idylla™ system. Our intellectual property rights form the basis of our products and technologies.

CHAPTER 4

Our stakeholders

4.1.

Society

4.1.1

Contributing to sustainable healthcare

Biocartis aims to create value for its shareholders and for society by contributing to sustainable healthcare, accessible to all patients worldwide. Biocartis' molecular diagnostic products enable fast, early and accurate molecular information to be available to clinicians and thereby open doors to better, faster and more efficient diagnostic and treatment selection. As such Biocartis aims to contribute towards a more sustainable healthcare model, bringing benefits for patients, clinicians, payers and the healthcare industry.

Biocartis' products support the development of globally accessible, sustainable healthcare:

- **Fast diagnostics**: Today, many hospitals do not perform molecular tests in-house, but send the test samples out to specialized labs, which can take up to several weeks before results are available, thereby delaying treatment decisions, which are often crucial to save patients' lives.
- **Easy diagnostics:** Thanks to the easy workflow of Idylla™, our platform and tests can be used in hospitals that today do not have a specialized laboratory infrastructure or highly trained personnel. This allows helping patients on a broader scale.
- **Highly accurate diagnostics:** Today, to move away from the one-drug-fits-all paradigm towards new treatments matching the genetic profile of a patient which ensures a better health outcome and lower healthcare costs, detailed molecular diagnostics information is needed to help a clinician determine what drug the preferred treatment is for example for a melanoma patient whose tumor carries a specific genetic mutation.do not have a specialized laboratory infrastructure or highly trained personnel. This allows helping patients on a broader scale.

The growth of our Idylla™ installed base and cartridges represents the positive impact of rapid, easy and highly accurate molecular diagnostics testing:

- 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 access to accurate molecular information to better guide treatment selection with potentially less adverse effects.
- For the payer, it could mean reduced hospital costs, more predictable reimbursement costs and more certainty that the treatment will work efficiently for the patient, as such avoiding unnecessary costs relating to treatments that might not work.
- For the healthcare industry, it could mean a higher success rate of treatments, a better selection of the right patient population and a more predictable reimbursement.
- For society, it could mean improved access to healthcare with the best possible outcome for all patients, as such improving general health economics, a high level of standardized care and global health and longevity.

Biocartis believes that its approach will create long term positive impact for all stakeholders in the sustainable healthcare ecosystem, including patients, care providers, payers, industry and society as a whole. Biocartis' goal is to improve clinical practice and ultimately, contribute to better patient outcome.

4.1.1

Market access and regulatory environment

In each of the countries in which Biocartis markets its products, it must comply with local regulations affecting, among other things, design and product standards, packaging, advertising and labelling requirements.

- In the European Union, CE-marking is required. As such, Biocartis is compliant with the IVD Directive for manufacturers who place IVD devices on the EU market. The Idylla™ platform and the Idylla™ BRAF Mutation Test were initially launched in 2014 as CE-marked IVDs. Since then Biocartis has added the Idylla™ KRAS Mutation Test, Idylla™ NRAS-BRAF Mutation Test, and the Idylla™ Respiratory (IFV-RSV) Panel to the CE-marked IVD product portfolio, allowing Biocartis to market these products in the European Union, as well as in countries accepting CE-marked IVD devices, which allows sales in a number of additional countries.
- In addition, Biocartis has obtained registration or marketing approval for the Idylla™ platform and some of its tests in several other markets, including Australia, Canada, South Korea, Brazil, Mexico, Saudi Arabia, and others.
- The US requires more rigorous product clearance efforts, including Pre-Market Approvals for most oncology products and 510(k) clearance for infectious disease products. The regulatory strategy for the US market was outlined in 2016 and implementation is underway.
- China and Japan also employ rigorous product clearance regulations. The regulatory strategy for these markets will be assessed in 2017.

In addition to IVDs, Biocartis also offers products for Research Use Only (RUO), meaning they may be used only for research purposes, not for use in diagnostic procedures. Biocartis currently offers the following RUO devices: Idylla™ BRAF Mutation Assay, Idylla™ KRAS Mutation Assay, Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, Idylla™ EGFR Mutation Assay, Idylla™ ctBRAF Mutation Assay and the Idylla™ ctKRAS Mutation Assay.

The RUO products may be offered for sale in markets where similar IVD products are not yet approved for sale or distribution. They may be used in research applications to evaluate or confirm the prevalence of certain mutations, or other research-oriented applications.

Healthcare policy makers, governments, insurers and other payers are implementing price control systems that favor early diagnosis, better screening and monitoring and cost-effective therapies driven by rising healthcare costs and budget constraints. As such, diagnostic testing is increasingly being accepted as a critical tool to reduce healthcare costs. In order to increase market access, Biocartis' focuses on:

- **Reimbursement:** Biocartis' initial focus is on tests that are already reimbursed by third-party payers in most developed countries. End of 2016, Biocartis had three CE-marked IVD tests on the market which are reimbursed by third-party payers. Additionally, the coverage of Biocartis' tests has expanded in several countries in 2016, such as for outpatient testing in Germany, and from a smaller network of research institutes to all laboratories in France.
- **Competitive pricing:** Biocartis' products have price levels competitive to existing regulator-approved tests in the EU, taking into account the total cost of ownership. Compared to competition, Biocartis' sample-in result-out technology substantially reduces the need for extra consumables, inefficient kit usage and labor. On top, customers save in lab infrastructure, accreditation and other lab running costs.
- **Health economics and outcomes research:** the Idylla™ platform and tests provide clinicians with accurate and fast information, which allows for improved care and faster targeted treatment. To demonstrate the related impact, Biocartis in collaboration with several of its (research) partners is performing studies to measure amongst others the impact of the Idylla™ platform on time-to-therapy and consequent positive impact on patient treatment.

Molecular biologist, UK: "The speed of testing which far outstrips alternatives will translate in to reduced patient care time as delays before treatment are reduced. Although hard to capture, in-patient care is one of the most expensive costs to Healthcare providers and any reduction in this provides a considerable cost benefit."

4.2.

Partners

Partnerships aimed at enabling personalized medicine for patients across the globe through rapid, highly accurate and easy to use high precision diagnostic solutions, are a key element in Biocartis' strategy. As such, Biocartis ensures accelerated growth of its test menu as well as commercial expansion. End of 2016, Biocartis had several strategic partnerships in place with large pharmaceutical companies and key players in the healthcare industry.

Johnson & Johnson - Janssen Pharmaceutica

Janssen Pharmaceutica NV (JPNV) signed a strategic partnership with Biocartis in December 2010 with the aim to co-develop assays for the Idylla™ platform and collaborate commercially. In November 2015, the Idylla™ Respiratory (IFV-RSV) Panel Test was launched as a CE-marked IVD test 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). In June 2016, Biocartis received Emergency Use Authorization (EUA) by the US Food and Drug Administration (FDA) for the Idylla™ Ebola Virus Triage Test for detection of the Ebola Zaire virus and which was co-developed by Biocartis NV, Janssen Diagnostics and the Belgian Institute of Tropical Medicine that co-discovered the Ebola virus 40 years ago.

Abbott Molecular

Biocartis has a strategic collaboration with Abbott Molecular since November 2014 to develop and commercialize novel companion diagnostics tests.

Merck KGaA

Biocartis announced a partnership with Merck KGaA (Merck, Darmstadt, Germany) in January 2016 for the development and commercialization of new Idylla™-based liquid biopsy RAS biomarker tests, the Idylla™ ctKRAS Mutation Assay and the Idylla™ ctNRAS Mutation Assay for patients with metastatic colorectal cancer (mCRC). The partnership is aimed at implementing Idylla™ liquid biopsy RAS test in numerous medical centers across the world, excluding the U.S., China and Japan.

Amgen

In February 2016, Biocartis announced its collaboration with Amgen to offer its new RAS biomarker tests to hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey. The aim of the partnership is to accelerate access to RAS biomarker information in the selected countries. In December 2016, the partnership was expanded to accelerate access to RAS biomarker information in up to 10 European countries.

Thermo Fisher Scientific

Biocartis announced in November 2016 to have granted rights in the US to Thermo Fisher Healthcare (part of Thermo Fisher Scientific Inc.) to distribute its Idylla™ platform and accompanying assays, with a first focus on oncology products. Thermo Fisher is a global company with annual revenues of $17 billion and more than 50,000 employees in 50 countries.

In addition, Biocartis actively pursues collaborations with companies that have considerable knowledge of MDx in specific disease areas to (co)develop tests. To facilitate joint test development, Biocartis developed a 'Developer's Suite', a unique test development toolkit, for partners containing all required information to develop Idylla™ compatible tests.

Emilie Charlot, Vectibix EU Brand Director Amgen: "The vision of Panitumumab is to be the first-line market share leader in Europe in 2019. Therefore we have developed long term collaborations, in which the Biocartis partnership is key."

Microbiome

Biocartis and Microbiome, a spin-off of the VU University Medical Center Amsterdam, have announced a collaboration in March 2015 within a worldwide license and collaboration agreement for the development of an integrated multiplex real-time polymerase chain reaction (PCR) test for rapid detection of bloodstream infections.

Fast-track diagnostics

In May 2015, Biocartis announced a partnership with Fast-track diagnostics, a leading provider of multiplex polymerase chain reaction (PCR) test kits for infectious diseases, to develop a range of syndromic multiplex infectious disease tests for the Idylla™ platform. Syndromic multiplex testing enables the identification of a broader range of disease pathogens in a single test, as such significantly decreasing the time to result of infectious disease testing. The first test to be developed under the collaboration is a multiplex respiratory panel for the detection of viral and bacterial targets in upper respiratory tract infections, to be launched in 2017.

A*STAR

Biocartis signed an agreement with A*STAR[56], Singapore's lead public sector agency that spearheads economic oriented research to advance scientific discovery and develop innovative technologies, aimed at the joint development of a range of proprietary tests for the Idylla™ platform, with a main focus on cancer biomarkers.

Read more on our partner-distributors and our Go to market strategy under 'Our stakeholders', 'Customers'.

Rehan Verjee, Chief Marketing and Strategy Officer of Merck's biopharma business: "Through this collaboration, our desire is to have more metastatic colorectal cancer patients gain access to liquid biopsy RAS testing, regardless of their geographical location. As the first pharmaceutical company to collaborate with multiple diagnostic providers of liquid biopsy RAS testing, we are living our commitment to supporting patients and physicians by going beyond treatment. The Biocartis technology will be complementary to other technology previously developed, and will allow for liquid biopsy RAS offerings to a wide range of lab segments, regardless of size and expertise levels."

[56] The partnership agreement was signed with ETPL (Exploit Technologies Pte. Ltd.), the commercialization arm of the Agency for Science, Technology and Research (A*STAR, based in Singapore).

4.3.

Customers

4.3.1.

The need for improved, standardized and faster diagnostics

95% of the patients have to wait more than a week in order to receive the biomarker results. 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[60].

Cancer can hit anyone at any time and treatment remains a real challenge. Because cancer doesn't follow rules. It fights back against therapies. It adapts. It changes its path. It does whatever it can to stay ahead of us. At the advanced edge of oncology, rapid access to accurate data about relevant cancer mutations and treatment resistance is vital and creates the opportunity for early disease interception[57], 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[58]. 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 targeted therapy or immunotherapy as first-line treatment is crucial for cancer patients, as it increases overall survival rates[59]. 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 biomarker results[60]. 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.

Molecular biologist, UK: "The number one argument for our setting is the short turn- around time. Patients' lives are affected if not treated quickly; some patients only have months to live. A result in 1.5 hours means decisions can be made quickly and these decisions are well informed."

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

[58] 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.

[59] 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 4.2016. M. Reck et al. Metastatic non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology, 2014. 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

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

4.3.2.

Empowering our customers to improve health outcome

Within oncology as Biocartis' first focus area, our high precision diagnostic products have direct potential to improve the work of the oncologist and the pathologist. The molecular pathologist or biologist today often operates in a (large) laboratory setting, running a high volume of tests in which they analyze a specific gene mutation related to the diagnosis of certain cancers. The oncologist operates from a hospital setting and is in contact with the patient, as such in a key position to impact the treatment plan. Both benefit from more rapid, easy and high precision cancer diagnostics.

In terms of customer segmentation, the Biocartis products today already impact different types of settings.

- In a first wave, Biocartis focused on the molecular pathologists within central, highly skilled laboratories, which represent a setting characterized by a higher expertise in molecular diagnostics and a larger volume of tests.
- In a second wave, Biocartis now increasingly expands towards more non-expert, decentralized settings such as large and smaller hospitals which benefit from fully automated solutions:
  - The academic and non-academic large hospitals, representing high testing volume and clear needs in fast and easy MDx solutions.
  - The small to medium-sized hospitals, representing an ideal target group for routine testing with Idylla™. Here, the oncologist's focus is to improve patient outcome through a fast treatment start and potential monitoring of treatment efficiency. Idylla™'s unique combination of speed and accuracy in 2016 confirmed to be an appealing value proposition for the oncologist, delivering actionable outcomes enabling them to start treatments faster and with the best possible outcome for their patients.

Molecular biologist, UK: "The Idylla™ is really easy to implement. It just needs a plug and a qualification run."

4.3.3.

Go to market

In our goal to be a leader in MDx with a first focus on oncology, the continuous expansion of our commercial network is key. Biocartis operates through three different pillars: its direct sales network, its indirect sales network (distributors) and a network of partners mainly consisting of large pharmaceutical and biotech companies who are today driven by the increased need for high precision diagnostics.

Go to market strategy

- **Direct sales channels:** Biocartis operates in Europe through a direct sales force covering key European countries.
- **Indirect sales channels:** outside of Europe, Biocartis operates through collaborations with distributors and strategic partners. In 2016, Biocartis expanded its distributor's network with 9 new distributor agreements towards a total of 35 distributor agreements in 51 countries end of 2016, adding to its network of distributors several countries including in Latin-America and Asia.
- **Collaborations** with large pharmaceutical and biotech companies driven by their needs to match diagnostic testing with their targeted therapies.

For a full overview of current partnerships, see under 'Our stakeholders', 'Partners'.

We connect with our customers through a variety of channels, including:

- **Conferences:** with a focus on large conferences aimed at pathologists and oncologists.
- **Biocartis sales team:** with many people in the sales team benefitting from extensive backgrounds and experience in molecular biology or oncology, Biocartis ensures a professional and high quality dialogue with its customers.
- **Customer trainings:** provided directly by the sales team. As a minimum, every customer receives the Idylla™ User training at the start of the collaboration.
- **Regular communications on the product menu and commercial activities:** including a direct newsletter at every product launch and for the announcement of key international conferences where Biocartis is represented, and a direct emailing to announce product launches, updates or attendances at international conferences.
- **Website:** continuous updates through the website.

Customer satisfaction

In October 2016, for the first time, Biocartis organized a Customer Feedback Survey in collaboration with InSites, addressing oncologists, pathologists, molecular biologists and lab technicians. The customer panel included Idylla™ users from six different nationalities, of which 82% have been using Idylla™ for a longer period of time (> 1 year)[61]. The outcome was a satisfaction score of 9/10 in terms of likelihood to recommend Idylla™ to professionals.

Other key conclusions included:

- Different contract forms possible.
- Positive feedback on the quality of the demo and training by the Biocartis sales team, and the Customer service communication
- The Idylla™ test result report is praised for the ease of interpretation; more quantitative data (i.e. real-time PCR data, frequency and relevance of mutations) would be appreciated, highlighting the importance of Idylla™ Connect
- Key arguments to use Idylla™: short turnaround time, sensitivity and portfolio extension

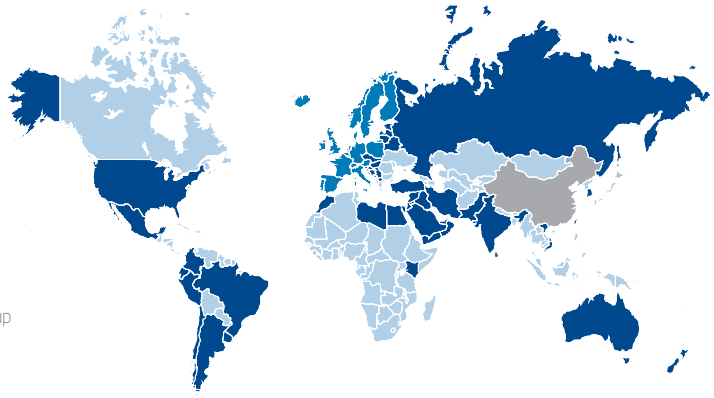
Key takeaways for the future included expansion of the test menu, sharing scientific publications and the general need for Idylla™ users to be part of a global network where they can share experiences with peers.

Molecular biologist, France: "The Idylla™ system only requires inputting the sample directly in the cartridge and doesn't require DNA extraction, which is not the case for almost all commercial PCR kits."

Biocartis engages 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's newsletters with key updates on the Biocartis products
- Regular distributor update meetings
- 24/7 access to an online marketing platform, a one-stop-shop for all product marketing materials

Biocartis strengthened its commercial footprint in 2016, covering over 60 countries, worldwide at the end of 2016, of which over 50 countries covered by distribution agreements.



[61] Before January 2016.

Pharmaceutical partner companies

The pharmaceutical industry's 20 top-selling cancer drugs generate sales over $50 billion, worldwide[62].

On our path towards MDx leadership in oncology, a vital part of Biocartis' strategy is to collaborate with pharmaceutical and biotech companies active in targeted, oncology treatments. The pharmaceutical industry's 20 top-selling cancer drugs generate sales over $50 billion worldwide[63]. With an increasing worldwide demand for oncology medications, pharmaceutical companies are increasingly focusing their efforts on developing, testing and launching new medications in the oncology therapeutic area to meet customer demand. From the payers' side, there is an increased pressure on the rising healthcare costs and reimbursement. In combination with the rising awareness that without diagnostics resulting in actionable mutations to address, there is no connection with targeted oncology treatments or reimbursement thereof, pharmaceutical companies today are aiming to offer a broader value package towards the healthcare professional, and as such diagnostics has conquered a clear place on the pharma company radar. More concretely, Biocartis' molecular diagnostic products enable a quick response to the question if a cancer patient is eligible for a specific treatment or not. As such, spending money on expensive and inefficient treatments can be avoided, which also means a better spending of healthcare budget, while improving health outcome for the patient.

Caroline Collard, Marketing Director Biocartis: "Biocartis' molecular diagnostic products enable a quick response to the question if a cancer patient is eligible for a specific treatment or not. As such, spending money on expensive and inefficient treatments can be avoided, which also means a better spending of healthcare budget, while improving health outcome for the patient."

On the one hand, Biocartis can collaborate with partners on tests. Example here is the agreement between Amgen and Biocartis which was signed in 2016, and where Biocartis' existing Idylla™ KRAS Mutation Test, because of its speed and accuracy, clearly accelerates treatment decisions of oncologists. As such, it is perceived to have a high value by both the oncologist and Amgen. On the other hand, Biocartis is also capable of developing on-demand diagnostic tests. In the case of the Merck KGaA collaboration, the Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test are being developed as a CE IVD test. The development of collaborations can be linked to treatments already on the market such as Erbitux (Merck) or treatments in clinical trials, where Idylla™ is used as reference diagnostic.

Ulrik Cordes, VP Pharma Collaborations and CDx Business: "Strong partnerships with a diverse range of pharmaceutical companies will strengthen Biocartis' footprint, not only on a European but also on a global level. Our ultimate goal is improving patient outcome by providing fast and accurate biomarker information, and therefore the pharmaceutical industry and MDx go hand in hand."

In 2016, Biocartis signed four new collaboration agreements with three different partners. For more information, see 'Business Review 2016'.

[62] https://www.thebalance.com/top-cancer-drugs-2663234

[63] https://www.thebalance.com/top-cancer-drugs-2663234

Key Opinion Leaders in molecular diagnostics

To improve the quality of our products, enhance the Idylla™ experience and stay on top of innovations and trends in the molecular diagnostics landscape, Biocartis further continued its dialogue with several Key Opinion Leaders (KOLs) through a number of activities in 2016:

- **Abstracts and publications:** Biocartis collaborated with KOLs on the generation of research and clinical data that translated into more than 20 abstracts presented at national and international conferences and 12 publications in key journals demonstrating the quality and high performance of the Idylla™ products.
- **Key Expert Meetings:** on 6 October 2016, Biocartis organized its second Key Expert Meeting in Oncology. The meeting was attended by 13 experts, 5 oncologists and 8 pathologists from different European countries to discuss new trends and needs in the oncology space. The outcome of the meeting was very positive. It was recognized that Biocartis is pursuing several important projects in the field of molecular oncology that ultimately will allow a broaden access to personalized medicine. In order to reach this goal, several experts emphasized the importance of collaborating with large pharmaceutical companies working in rapidly emerging and evolving fields such as immunotherapy and liquid biopsy. Several events such as symposia where KOLs shared their user experience on Idylla™ products, supported by several research studies.

Richard Colling, University of Oxford, UK: "Idylla™'s unique fully automated and on-demand process has proven to be accurate, reliable and fast."

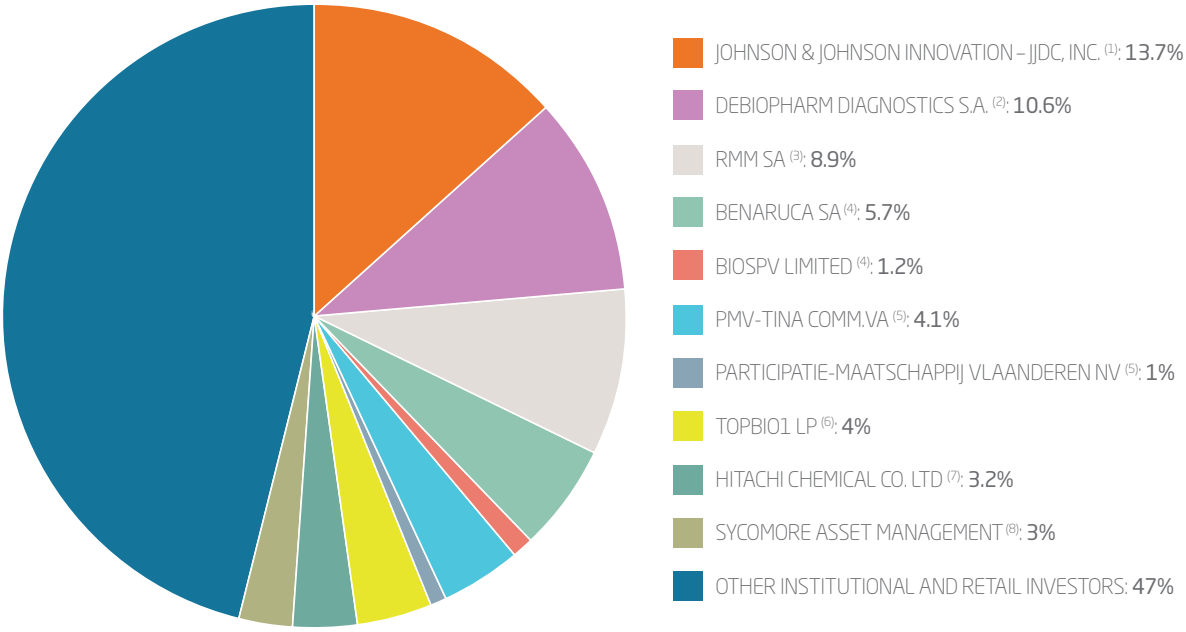
4.4.

Shareholders

4.4.1.

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 2016 and the transparency notifications received until such date, the shareholder structure of the Company is as follows:



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.

(1) Johnson & Johnson Innovation-JJDC, Inc., is a wholly owned subsidiary of Johnson & Johnson. Johnson & Johnson is not a controlled entity.

(2) Debiopharm Diagnostics SA is controlled by Debiopharm Holding SA, which is controlled by Rolland-Yves Mauvernay.

(3) RMM SA is controlled by Rudi Mariën.

(4) BioSPV Limited and Benaruca SA are controlled by Rudi Pauwels.

(5) PMV-Tina Comm. VA is controlled by ParticipatieMaatschappij Vlaanderen NV, which is controlled by the Flemish Region (het Vlaamse Gewest).

(6) Topbio 1 LP is not a controlled entity.

(7) Hitachi Chemical Co., Ltd. is controlled by Hitachi, Ltd., which is not a controlled entity.

(8) Sycomore Asset Management is not a controlled entity.

4.4.2.

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 2016, the share capital of the Company amounted to EUR 446,481.05 represented by 44,648,105 shares. In addition, as at such date, 5,676,884 shares could still be issued by the Company as follows:

- 838,951 shares can be issued upon the exercise of 838,951 outstanding stock options (each stock option having the form of a warrant) that were still outstanding under the '2013 Plan' for employees, consultants, management members and directors, entitling the holders thereof to acquire one new share per option.
- 262,934 shares can be issued upon the exercise of 262,934 outstanding stock options (each stock option having the form of a warrant) that were still outstanding under the '2015 Plan' for employees, consultants, management members and directors, entitling the holders thereof to acquire one new share per option.
- 4,574,999 shares can be issued pursuant to a conversion option agreement entered into between Koninklijke Philips NV and the Company[64].

The total number of fully diluted shares consequently amounted to 50,324,989 as of 31 December 2016. More information on the Company's stock options and warrants can be found under 'Stock options and warrants' in this chapter and the 'Remuneration Report'.

4.4.3.

Warrant plan

4.4.3.1

Stock based incentive plans

The Company currently has three stock based incentive plans:

- the 2008 Plan
- the 2013 Plan
- the 2015 Plan

The stock options under the 2013 Plan and the 2015 Plan have the form of warrants with respect to new shares of the Company (i.e. these plans are dilutive plans). The stock options under the 2008 Plan are stock options with respect to existing shares and do not have the form of warrants (i.e. this plan is a non-dilutive plan). More information on these plans can be found in the 'Remuneration Report'.

[64] The conversion option agreement allows Koninklijke Philips NV to convert certain royalty and other payments due to it up to a maximum of 10% of the then outstanding capital of the Company on a fully diluted post-money basis, but only if the Company has not yet made a lump sum payment in lieu of such royalty and other payments, and the conversion can only be exercised by Koninklijke Philips NV upon the acceptance of the exercise by the Company at its sole discretion. The number of 4,578,399 shares that can still be issued assumes that all outstanding warrants (entailing the issue of up to 1,135,885 new shares) have been exercised, it being understood that the actual number of shares issuable depends on a number of factors.

4.4.3.2

Philips conversion option agreement

On 15 August 2011, Biocartis SA and Koninklijke Philips NV ('Philips') entered into a conversion option agreement, as amended and restated, on the basis of which shares of Biocartis may be acquired subject to the terms and conditions of the conversion option agreement. The conversion option is stipulated as follows: "At Biocartis' sole discretion, Philips shall be granted the right to convert all or part of the Third Milestone Payment, Royalties and Initial Revenue Sharing Payments, all as specified in the Polaris IP Agreement, into Biocartis shares it being understood that:

- Under all circumstances Philips can only convert up to a maximum of 10% of the then outstanding capital of the Company on a fully diluted post-money basis, and Philips hereby accepts the options pursuant to the terms and conditions of the conversion option agreement; and
- The conversion of the Initial Revenue Sharing Payments and/or Royalty Payments as specified under the Polaris IP Agreement can only take place in so far as the Company has not exercised the buy-out right granted to it under clause 3.2 of the Polaris IP Agreement." The Polaris IP Agreement refers to the intellectual property assignment and intellectual property license agreement pursuant to which Philips assigned certain patents and patent applications and know-how in relation to the Idylla™-Enrich technology to Biocartis, and the buy-out right refers to the option of Biocartis to make a lump sum payment in lieu of all further revenue sharing payments and royalties to Philips under this agreement.

On 25 November 2014, the conversion option agreement was rolled up in order to relate to the Company and the Company's shares. This conversion right can only be exercised by Philips upon acceptance of the exercise by the Company. The price to be paid in relation to the shares upon conversion shall be the underlying stock price of the Biocartis shares.

4.4.3.3

WHC Warrants

In execution of a decision of the board of directors of Biocartis SA of 24 April 2014, 100,000 options on shares of the Company were granted by Biocartis SA to Whitemarsh Capital LLC, a company that provides assistance in brokering agreements with US governmental institutions. On 25 November 2014, the option grant was rolled up in order to relate to the Company and the Company's shares instead of shares in Biocartis SA. The options, called 'WHC Warrants', were formally granted by an award letter on 14 April 2015. The WHC Warrants have the following features: (i) each WHC Warrant can be exercised into one share of the Company, (ii) the WHC Warrants were granted for no additional consideration, (iii) the WHC Warrants have a term of five years as from 25 November 2014, (iv) the exercise price of the WHC Warrants is EUR 8.1308, and (v) the WHC Warrants are not transferable by Whitemarsh Capital LLC. The board of directors could decide to accelerate the exercisability of the WHC Warrants in the event of a change of control. The WHC Warrants could only be exercised if certain conditions were met. As at 31 December 2016, none of the conditions for exercisability of any of the WHC Warrants were met, nor could they still be met.

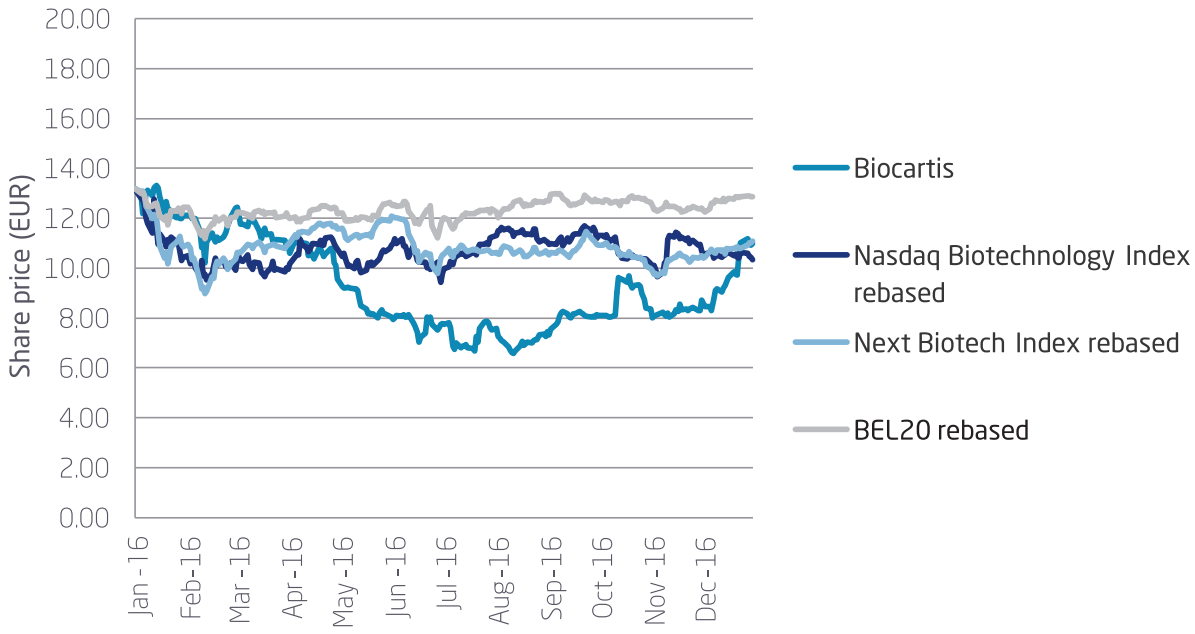
4.4.4.

Share performance

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

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

Biocartis share performance 2016



* Rebased at Biocartis share price on 31 December 2016 / Source: Bloomberg

The closing price of the Biocartis share on 30 December 2016 was EUR 10.97.

4.4.5.

Trading volume

Below is a summary of the 2016 trading volumes of Biocartis' share.

BCART	2016	2015	% Change
Average daily volume in shares	43,539	46,059	-5%
Average daily value in euro	9.3	12.87	-28%
Total traded volume in shares	11,232,944	8,152,448	38%
Total traded value in euro	97,176,297	106,367,526	-9%

Source: Euronext

4.4.6.

Analyst coverage

The Biocartis share is actively covered by three renowned brokers:

BROKER	ANALYST	RATING END 2016	TARGET PRICE END 2016
KBC Securities	Michaël Vlemmix/Sandra Cauwenberghs	Buy	EUR 16.50
Kempen & Co	Alexandru Cogut	Buy	EUR 16.00
Degroof Petercam	Stéphanie Put	Buy	EUR 17.00

4.4.7.

Financial calendar 2017

Full year results 2016	2 March 2017
Publication annual report 2016	30 March 2017
Q1 Business Update 2017	27 April 2017
Annual General Meeting	12 May 2017
H1 2017 results	7 September 2017
Q3 2017 Business Update	16 November 2017

4.4.8.

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.

4.5.

Employees

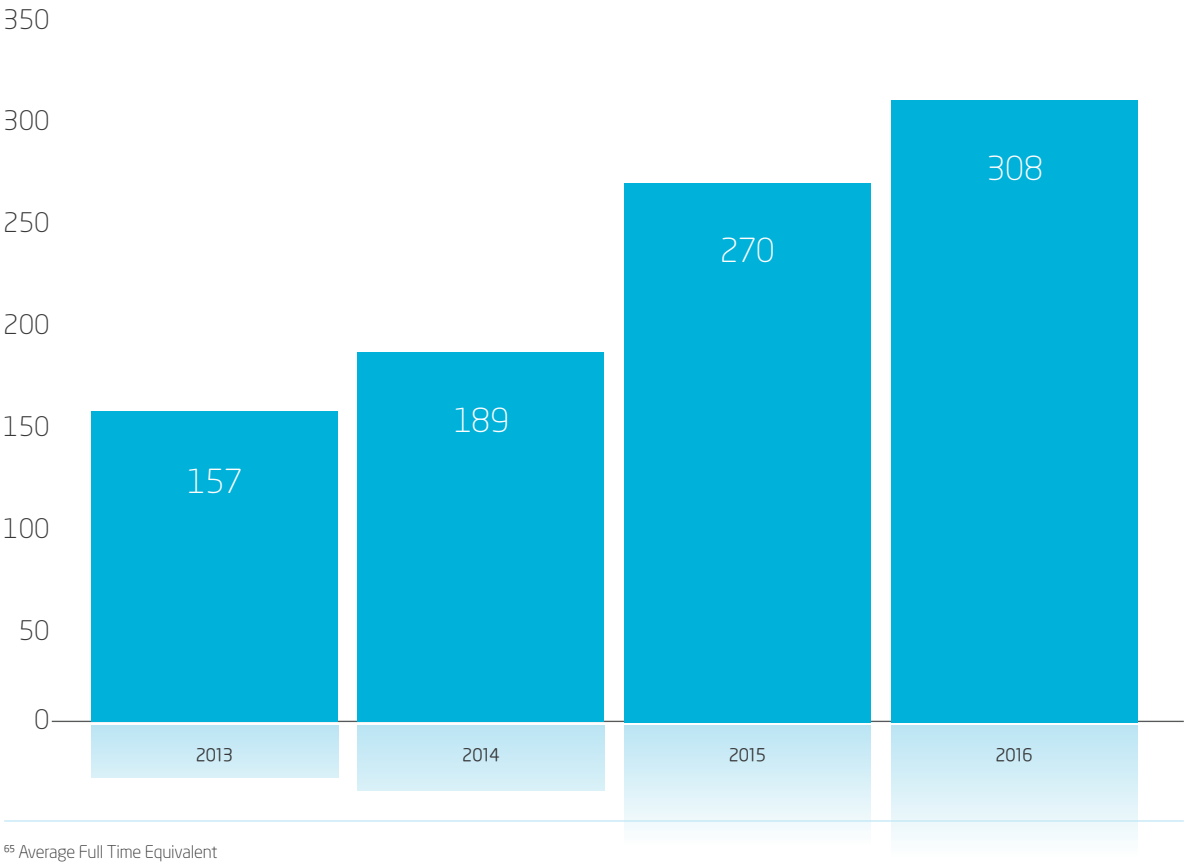
In realizing its vision, Biocartis wants to facilitate an environment for our employees where people are committed every day to improve other people's lives. 'Sense, think, share, do' summarizes the Biocartis DNA and how we work as a team:

- surface tensions, think solutions
- work hard, have fun
- put your heart into what you do
- take responsibility
- respect is an attitude
- dare to fail

308 employees (in FTE[65]) / 25 nationalities / 50% male, 50% female

Our employees are essential to the success of Biocartis. The Biocartis workforce counted 308 FTEs on 31 December 2016, composed of 25 different nationalities with a balanced level of gender diversity of 50% male and 50% female, stable versus 2015. 92% of our employees work full-time.

Employee evolution (FTE)[65]



[65] Average Full Time Equivalent

Training and development

Training and development is an essential part of Biocartis' HR management as it supports our employees to develop their full potential. It includes different training and development initiatives:

- **Induction training:** for all new employees, within the first few weeks after joining Biocartis. A Welcome Package is also provided, containing a wide range of information varying from travel policy, to health, safety and environment topics.
- **Biocartis School:** these regular 'lunch & learn sessions' for employees stimulate continuous learning on different topics. In 2016, Biocartis organized seven sessions, including on the Biocartis partnerships, the quality management software 'Master Control' and the technology of Next-Generation Sequencing.
- **Specific job training:** depending on the specific job requirements, this can be discussed upon request.

Biocartis furthermore engages with its employees in a participative manner, in which regular two-way communication is crucial. Internal communication with employees takes place through several channels:

- Monthly staff meetings with all employees, at which different operational topics, company updates on key progress and projects are presented
- Roundtable meetings to discuss important topics across different departments
- Department meetings
- Project team meetings
- Intranet

Every year, Biocartis organizes a Corporate Day at which Biocartis reflects on its strategy and the progress made. In the 2016 edition, Biocartis employees organized a fundraising for Music for Life, resulting in close to EUR 10,000 fundraising which was donated to three not-for-profit organizations chosen by Biocartis employees:

- **Think Pink organization**, supporting breast cancer initiatives
- **Verburght organization**, supporting the integration of people with a disability
- **Vecarfa organization**, supporting parents with children carrying a disease related to a chromosome aberration

One Biocartis colleague even participated in the Antarctic Ice Marathon in December 2016, for which he raised funds to support children at Gdynia, Children Hospice in Poland.

Health & safety

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

- Ensuring compliance with the most recent 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
- Taking into account EHS requirements in every new business initiative, infrastructural as well as organizational
- 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

No legal EHS regulation breaches were reported in 2016.

In 2016, Biocartis staff followed several trainings, including basic rescue trainings, first-aid refreshment trainings, a safety training on chemical agents and a training on portable extinguishing tools.

Biocartis is striving for a zero-tolerance when it comes to accidents at work. In 2016, Biocartis reported no lethal accidents. Four working accidents occurred, of which three happened when travelling to or from work.

Quality management

Biocartis has established, documented and implemented a quality management system ('QMS') compliant with the international standards and regulations for design and development, for manufacturing and testing and for customer facing processes. The quality system covers all of Biocartis' products and tests.

In 2016, Biocartis worked on the preparation of its quality system to cover the regulatory requirements in the US. In the future, Biocartis intends to further develop the quality system to cover the regulatory requirements of other major territories, including China, Japan, Brazil and Russia.

More information can be found in the chapter 'Corporate Governance', under 'internal and external control'.

Environmental management

One of the key aspects of our environmental impact as a company manufacturing MDx materials is related to our cartridge and instrument production. As a producer of equipment, Biocartis complies with three directives that have been installed to address environmental impact:

- 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 REACH regulation which restricts the use of chemical substances that could have an impact on human health and the environment[66]

Supply chain

We work closely with our suppliers to ensure that they meet Biocartis' requirements in terms of quality, safety and environment compliance.

- Risk assessments: we perform thorough Risk Assessments to get an overview of potential risks, before starting supplier collaboration.
- Quality agreements: we enter into quality agreements with our suppliers. These outline our expectations in terms of technical specifications, quality, safety and environment.
- Performance audits: we perform regular performance audits to ensure that the materials from our suppliers meet our expectations for technical specifications, quality, safety and environment.
- Supplier performance: we monitor and support our suppliers through various other actions, e.g. product specification documents and audit action plans, to help our suppliers meet our performance criteria.

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

CHAPTER 5

Corporate governance

5.1.

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 came into effect upon the public listing of the Company's shares on 27 April 2015.

The Company's corporate governance charter was last updated at the meeting of the board of directors held on 1 September 2016. The main changes related to the dealing code, which was adopted with the aim of preventing market abuse and which is attached to the corporate governance charter. The dealing code sets out, among others, the notification and conduct obligations of directors, members of the executive management team and staff members of the Company with respect to transactions in shares or other financial instruments of the Company. The amendments to the dealing code were made to bring this code in line with the new European market abuse regulation which entered into force on 3 July 2016.

The corporate governance charter 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 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 our activities, the size of the Company and the specific circumstances in which the Company operates. The Company deviates from the provisions of the Corporate Governance Code in relation to the following two matters:

- Upon advice of the remuneration and nomination committee, the Company awards stock based incentives (under the form of warrants of the Company) to the independent directors. The Company does not consider the warrants as variable remuneration as they are not subject to any performance related criteria. 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 audit committee of the board of directors is composed exclusively of non-executive directors, of which two are independent directors. However, as the audit committee is composed of four members it does not have a majority of independent directors. This is contrary to provision 5.2/4 of the Corporate Governance Code which provides that at least a majority of the audit committee's members should be independent. The chairman of the audit committee, however, is an independent director and has a casting vote. The Company justifies this as it allows the audit committee to draw on the additional (sector) expertise of the members of the board of directors who have financial and auditing expertise.

The articles of association and the corporate governance charter are available on the Company's website (https://investors.biocartis.com/en/corporate-governance-overview).

5.2.

Board of directors

5.2.1.

Composition

The board of directors is composed of eight directors. The table below gives an overview of the members of the Company's board of directors as at 31 December 2016.

NAME	AGE	POSITION	START OF TERM	END OF TERM
Rudi Mariën[1]	71	Chairman, non-executive director	2015	2017
Rudi Pauwels[2]	57	Chief executive officer, director	2015	2018
Hilde Windels[3]	51	Deputy chief executive officer, director	2015	2018
Hilde Eylenbosch[4]	53	Chief commercial officer, director	2016	2019
Roald Borré	44	Non-executive director	2015	2018
Peter Piot	68	Non-executive, independent director	2015	2018
Renaat Berckmoes[5]	50	Non-executive, independent director	2015	2018
Mark Shaffar[6]	61	Non-executive, independent director	2015	2018

Mr. Rudi Pauwels (permanently representing Valetusan Ltd.) resigned as chief executive officer of the Company with effect as from 2 March 2017. Hilde Windels (permanently representing Hilde Windels BVBA) took over the role of chief executive officer on an interim basis until a successor is on board.

Notes:

[1] Permanently representing Gengest BVBA.

[2] Permanently representing Valetusan Ltd.

[3] Permanently representing Hilde Windels BVBA.

[4] Permanently representing Citros vof. Mrs. Hilde Eylenbosch was appointed as director by the annual shareholders' meeting held on 13 May 2016. Mrs. Hilde Eylenbosch resigned as director with effect as of 18 November 2016. Following her resignation, Citros vof, permanently represented by Mrs. Hilde Eylenbosch, was coopted as director of the Company with effect immediately after the resignation of Mrs. Hilde Eylenbosch.

[5] Permanently representing Be@dvised BVBA.

[6] Permanently representing Shaffar LLC. Mr. Mark Shaffar resigned as director with effect as of 22 June 2016. Following his resignation, Shaffar LLC, permanently represented by Mr. Mark Shaffar, was coopted as director of the Company with effect immediately after the resignation of Mr. Mark Shaffar.

Rudi Mariën is President and Managing Director of Gengest BVBA and Biovest Comm.VA. He was the Vice President of Cerba European Lab. Through his management company, Gengest BVBA, Mr. Mariën has board mandates in different listed and private biotech companies. Mr. Mariën was co-founder, reference shareholder and Chairman of Innogenetics, and has been the founder, shareholder and Managing Director of several clinical reference laboratories including the Barc Group, a leading international centralized clinical laboratory, exclusively dedicated to pharmaceutical studies. Mr. Mariën holds a degree in pharmaceutical sciences from the University of Ghent, Belgium and a degree in clinical biology from the University of Ghent, Belgium.

Rudi Pauwels founded Biocartis in 2007. Mr. Pauwels is a serial entrepreneur who also co-founded several other European biotech companies, including Tibotec, Virco and Galapagos Genomics. Starting his career as a researcher at the internationally renowned Rega Institute for Medical Research in Leuven, Mr. Pauwels has focused for more than two decades on the search and development of anti-HIV drugs and the development of diagnostic tools that enable personalized HIV treatment. He is (co)-author of more than 150 papers in peer-reviewed journals and is the recipient of several awards for his scientific and entrepreneurial accomplishments. Mr. Pauwels holds a PhD in Pharmaceutical Sciences from the Katholieke Universiteit Leuven, Belgium.

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) as of 2 March 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, MDxHealth and FlandersBio and currently serves as a board member of VIB and Erytech SA. Mrs. Windels holds a Masters in Economics from the University of Leuven, Belgium.

Hilde 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. Over the last five years, she held the roles of chief commercial officer at Alere Inc. and was President of Alere International reporting to the COO. Hilde Eylenbosch holds a degree as Medical Doctor (University of Ghent, Belgium) and successfully completed the General Management Program at Harvard Business School.

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 focuses on industrial projects with a high degree of innovation and the potential to transform, now adding Head of Equity Investments and statutory manager of PMV-TINA Comm. VA 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.

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 Programme 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 amongst 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.

Renaat Berckmoes is non-executive director at FPIM-SFPI and a partner at Fortino CVA. Mr. Berckmoes has also held finance positions at Telenet, being CFO from 2006 to 2013. Mr. Berckmoes holds a Master in Business Economics and a Master in Maritime Economics from the University of Antwerp, Belgium and a Master in Political and Social Sciences from the Katholieke Universiteit Leuven, Belgium.

Mark Shaffar has around 40 years of experience in the biotechnology sector, having held numerous positions at Abbott Laboratories from 1977 to 2014, including Divisional Vice-President of Acquisitions and Licensing. Mr. Shaffar holds an MM in Management Policy, Finance from Northwestern University—Kellogg Graduate School of Management, the United States and a BS in Biochemistry from the University of Wisconsin-Madison, US

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

5.2.2.

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 of 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.

5.2.3.

Changes to the composition of the board of directors

Mr. Mark Shaffar resigned as director with effect as of 22 June 2016. As a result of the vacancy that was created by this resignation, the board of directors coopted Shaffar LLC, having its registered office at 6334, 3rd Ave, Kenosha, Wisconsin 54143, US, with as permanent representative Mr. Mark Shaffar, as independent director within the meaning of Article 526ter of the Belgian Companies Code and provision 2.3 of the Corporate Governance Code. It was further decided that Shaffar LLC, with as permanent representative Mr. Mark Shaffar, shall complete the term of the resigning director. The board of directors will therefore propose to the annual shareholders' meeting of 2017 to confirm the appointment of Shaffar LLC, with as permanent representative Mr. Mark Shaffar, for a term up to and including the closing of the annual shareholders' meeting to be held in 2018 which will resolve on the financial statements for the financial year ending on 31 December 2017.

Mrs. Hilde Eylenbosch was appointed as independent director by the annual shareholders' meeting held on 13 May 2016. She resigned as director with effect as of 18 November 2016. As a result of the vacancy that was created by this resignation, the board of directors coopted Citros vof, having its registered office at Pontstraat 87, 9831 Deurle, Belgium, with as permanent representative Mrs. Hilde Eylenbosch, as director. It was further decided that Citros vof, with as permanent representative Mrs. Hilde Eylenbosch, shall complete the term of the resigning director. The board of directors will therefore propose to the annual shareholders' meeting of 2017 to confirm the appointment of Citros vof, with as permanent representative Mrs. Hilde Eylenbosch, for a term up to and including the closing of the annual shareholders' meeting to be held in 2019 which will resolve on the financial statements for the financial year ending on 31 December 2018. On 18 November 2016, Citros vof, with as permanent representative Mrs. Hilde Eylenbosch, has taken up the position of chief commercial officer and is consequently no longer considered as an independent director of the Company.

The mandate of Gengest BVBA, permanently represented by Mr. Rudi Mariën, will end after the annual shareholders' meeting of 2017. The board of directors will propose to the annual shareholders' meeting that the mandate of this director be renewed for a term of one year as non-executive director.

5.2.4.

Gender diversity

The board of directors must be composed in a manner compliant with the principles of gender diversity as well as of diversity in general. The board of directors is currently composed of six men and two women with very diverse and complementary knowledge bases, experience and fields of expertise.

The board of directors 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 (one of whom was appointed in 2016) on a total of eight directors. 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. More information on (gender) diversity at Biocartis can be found under 'Our stakeholders', 'Employees'.

5.2.5.

Activity report

In 2016, the board of directors held six regular meetings, two meetings by telephone conference to discuss specific matters and one meeting in the presence of a notary relating to the launch of the private placement via an accelerated bookbuild offering.

The attendance rate (in person or by written proxy to a fellow director) for the board members in function at 31 December 2016 was 100%. All directors attended all physical board meetings in person, save for (i) one board member who attended one of these meetings by telephone and (ii) the board meeting held before the notary which was attended in person by two directors on the basis of written proxies from the other board members who already approved the private placement via an accelerated bookbuild offering during a private board meeting held by telephone conference. During such private board meeting, one member was represented on the basis of a written proxy.

During the meetings of the board of directors, the board among others reviewed the Group's overall strategy, discussed and approved the Company's new debt and equity financings, reviewed its corporate governance and adopted a new version of its corporate governance charter and dealing code, discussed the regular updates of the financial data and approved the budget for the financial year 2017. 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, as well as the strengthening of the executive management team. As the board of directors has only been officially installed since the IPO on 27 April 2015, it has not yet carried out an internal evaluation procedure to discuss its size, composition, performance and interaction with the executive management and the board committees.

5.2.6.

Other board mandates

Apart from their functions within Biocartis, the directors of the Company hold the following board mandates:

Rudi Mariën[1]	Gengest BVBA	Quest For Growth NV[2]
	Biovest Comm.VA	Oystershell NV[2]
	DSJ Bruxelles NV	Bio-Incubator Gent II NV[2]
	LMA BVBA	Argon CVA
	Immo St-Michel NV	Jenavalve
	MyCartis NV[2]	4Tech
	MDxHealth[2]	Agrosavfe NV
	myoscience[2]	
Rudi Pauwels[3]	Valetusan Ltd.	Riverwells Investments SA
	Benaruca SA	Calimontes SL
	Cambenes SA	Caruso Inversiones SL
Hilde Windels[4]	Hilde Windels BVBA	
	Erytech	
	VIB	
Hilde Eylenbosch[5]	Citros vof	
Roald Borré	High Wind NV[6]	Future Foundations NV
	miDiagnostics nv	Laboratoria Smeets NV
	PMV-TINA Comm.VA[6]	Newtec Cy NV
	Trividend CVBA	Zoefff! BVBA
	Capricorn Cleantech Fund NV	
Peter Piot	Geen	
Renaat Berckmoes[7]	Fortino	
	FPIM-SFPI	
	Savaco NV	
Mark Shaffar[7]	Shaffar LLC	
	MDxHealth[9]	
	MyCartis NV[9]	

Notes:

[1] Acting as permanent representative of Gengest BVBA / [2] Acting through Gengest BVBA / [3] Acting as permanent representative of Valetusan Ltd. / [4]Acting as permanent representative of Hilde Windels BVBA / [5] Acting as permanent representative of Citros vof / [6] Acting as permanent representative of ParticipatieMaatschappij Vlaanderen NV / [7] Acting as permanent representative of Be@dvised BVBA / [8] Acting as permanent representative of Shaffar LLC / [9] Acting through Shaffar LLC.

5.2.7.

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 twice in 2016. The extract of the minutes of those meetings is as follows:

- **The conflicts of interest procedure pursuant to Article 523 of the Belgian Companies Code was applied for the first time during the board meeting held on 18 February 2016:**

"Prior to the deliberation of the next item by the board of directors, Rudi Pauwels and Hilde Windels, each director of the Company, made the following declarations as far as needed and applicable in accordance with Article 523 of the Belgian Companies Code:

The meeting of the board of directors is asked to deliberate and decide on the contemplated modifications in the compensation of the CEO and Deputy CEO of the Company.

Rudi Pauwels and Hilde Windels therefore inform the board of directors, in accordance with the provisions of Article 523 of the Belgian Companies Code, that they may have a conflicting interest of a monetary nature with the Company in respect of the decisions that the board of directors may take in relation hereto. Rudi Pauwels and Hilde Windels further explain that they are the respective owners of the majority of the shares in Valetusan Ltd. respectively Hilde Windels BVBA and that the variable compensation for Valetusan Ltd. as CEO and for Hilde Windels BVBA as Deputy CEO is the subject that will be discussed by the board of directors. Therefore, in accordance with the provisions of the aforementioned Article 523 of the Belgian Companies Code, both Rudi Pauwels and Hilde Windels leave the meeting and do not take part in the further discussion, deliberation and voting.

Following the recommendation of the remuneration and nomination committee, the board of directors discusses and deliberates the variable remuneration for the CEO and the Deputy CEO.

The chairman of the remuneration and nomination committee reports on the meeting of the committee with regards to the variable compensation and KPIs for the CEO and the Deputy CEO for the current year.

The proposal is to fix the maximum variable compensation for the CEO and the Deputy CEO to 15% of their respective annual fixed compensation. In order to measure the performance of the CEO and the Deputy CEO, the proposal is to align the performance goals for the variable compensation (KPIs) with the overall Company goals sets by the board of directors for 2016. These company goals are translated into five specific, measurable, attainable, realistic and timely goals for the CEO and Deputy CEO. Each of the goals accounts for 20% of the variable compensation.

The board of directors considers the proposed KPIs that will be used to measure and determine the variable compensation for the CEO and Deputy CEO to be fully in line with the Company's interests as they are 100% aligned with the overall Company goals. Therefore after discussion the board of directors RESOLVES to approve the variable compensation mechanism for the CEO and Deputy CEO and the KPIs for 2016 as discussed.

Rudi Pauwels and Hilde Windels re-enter the meeting room."

For detailed information on the remuneration of the CEO in 2016, reference is made to the Remuneration Report below. The annual fixed compensation of the Deputy CEO in 2016 which is the basis for the variable compensation of the Deputy CEO was determined on the basis of the Biocartis remuneration policy and is materially in line with the remuneration of the other members of the executive management (other than the CEO) in terms of total cost to Biocartis. More information on the remuneration of the Deputy CEO and other members of the executive management in 2016 can be found in the Remuneration Report below.

- **The conflicts of interest procedure pursuant to Article 523 of the Belgian Companies Code was applied for a second time during the board meeting held on 16 November 2016:**

Prior to discussing this item on the agenda, Mrs. Hilde Eylenbosch, today director of the Company and permanent representative and shareholder of Citros vof, director of the Company with effect as from 18 November 2016, declares to have an interest of a patrimonial nature which is conflicting with the decisions that fall within the scope of the powers of the board of directors, in respect of the entry into of the consultancy agreement and stock option agreement with Citros vof (together the 'Agreements').

This conflict of interest results from the fact that Citros vof shall, with effect as from 18 November 2016, be both a director of the Company and a party to the Agreements. The Agreements will have financial consequences for the Company as (i) the consultancy agreement will require the Company to pay a fee to Citros vof as compensation for the provision of its services under such agreement, and (ii) the stock option agreement will require the Company to grant stock options (taking the form of warrants) to Citros vof.

In accordance with Article 523 of the Belgian Companies Code, Mrs. Hilde Eylenbosch has decided that she will refrain from taking part in the deliberations and from voting on this agenda point. Mrs. Hilde Eylenbosch has left the conference call.

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, has been 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.

The board of directors took note of the proposal of the remuneration and nomination committee of the Company regarding (i) the appointment of Citros vof, permanently represented by Mrs. Hilde Eylenbosch, as chief commercial officer, and (ii) the entry into of the Agreements with, and the remuneration of, Citros vof.

The Company requires highly qualified specialists with extensive experience and expertise in its field of business and requires someone with the required expertise, know how, background and passion to lead the Sales and Marketing team. The board of directors is of the opinion that Citros vof, permanently represented by Mrs. Hilde Eylenbosch, has these skills.

The board of directors is of the opinion that the provisions of the Agreements are proportionate for the services to be provided, and the role to be fulfilled, by Citros vof. The board has resolved that the appointment of Citros vof, permanently represented by Mrs. Hilde Eylenbosch, as chief commercial officer, and the entry into of the Agreements with Citros vof are in the interest of the Company.

Informed of the existence of a conflict of interest with respect to the aforementioned items, the board of directors has resolved to approve, with effect as from 18 November 2016, the appointment of Citros vof, permanently represented by Mrs. Hilde Eylenbosch, as chief commercial officer, and the entry into of the Agreements with Citros vof. Citros vof shall be an executive director with effect as from 18 November 2016."

The remuneration of Citros vof for the performance of its services under the consultancy agreement consists of a daily fee for each service day performed, which was determined on the basis of the Biocartis remuneration policy and is materially in line with the remuneration of the other members of the executive management (other than the CEO) in terms of total cost to Biocartis. As a member of the executive management, the remuneration of Citros vof includes a variable remuneration, and Citros vof is also granted stock options on shares of the Company. More information on the variable remuneration mechanism and the stock options granted to Citros vof can be found in the Remuneration Report below.

5.3.

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 board of directors has established a third committee with effect as from 2 March 2017, namely the strategy committee. The terms of reference of these board committees are set out in the Company's corporate governance charter.

5.3.1.

Audit commitee

5.3.1.1

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 four directors are members of the audit committee: Be@dvised BVBA, permanently represented by Mr. Renaat Berckmoes (chairman), Mr. Roald Borré, Gengest BVBA, permanently represented by Mr. Rudi Mariën and Shaffar LLC, permanently represented by Mr. Mark Shaffar. While the audit committee is composed exclusively of non-executive directors, of which two are independent directors, the audit committee does not have a majority of independent directors. This is contrary to provision 5.2/4 of the Corporate Governance Code which provides that at least a majority of the audit committee's members should be independent. The chairman of the audit committee, however, is an independent director and has a casting vote. The Company justifies this as it allows the audit committee to draw on the additional (sector) expertise of the members of the board of directors who have financial and auditing expertise.

The members of the audit committee have sufficient expertise in financial matters to discharge their functions and have a collective expertise relating to the activities of the Company. The chairman of the audit committee is competent in accounting and auditing as evidenced by his previous and current roles. The other members of the audit committee also satisfy this requirement, as evidenced by the different senior management and director mandates that they have held in the past and currently hold.

5.3.1.2

Activity report

In 2016, the audit committee held four regular meetings which were attended by all four 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. It analyzed and discussed the full year and half year financial statements and reports and the Q1 and Q3 business updates, as well as the communication in relation to these figures. The external auditor of the Company, Deloitte Bedrijfsrevisoren BV ovve CVBA, represented by Gert Vanhees, attended the meetings of the audit committee that reviewed the full year and half year figures and reports. The external auditor also presented the audit plan 2016 during the last meeting of the audit committee which was held in 2016. The audit committee further reviewed the performance of the Group presented through the management reporting documentation and it discussed the 2017 budget prepared by the executive management team. The audit committee reported systematically to the board of directors and ensured the co-operation of the executive management team and the financial department of the Company where required.

5.3.2.

Remuneration and nomination committee

5.3.2.1

Composition

The remuneration and nomination committee consists of three directors: Gengest BVBA, permanently represented by Mr. Rudi Mariën (chairman), Be@dvised BVBA, permanently represented by Mr. Renaat Berckmoes and Shaffar LLC, permanently represented by Mr. Mark Shaffar. All members of the remuneration and nomination committee are non-executive directors. In line with Article 526quater of the Belgian Companies Code, the remuneration and nomination committee consists of a majority of independent directors and has the necessary expertise on remuneration policy, which is evidenced by the experience and previous roles of its members. The chief executive officer and deputy chief executive officer participate 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 being discussed.

5.3.2.2

Activity report

In 2016, the remuneration and nomination committee held two meetings which were attended by all three members, resulting in a 100% attendance rate for the remuneration and nomination committee meetings. During its meetings, the remuneration and nomination committee among others prepared the remuneration report 2016, reviewed and discussed the remuneration of the members of the executive management team and proposed to appoint Hilde Eylenbosch (through Citros vof) as chief commercial officer while having Ulrik Cordes transition into the function of EVP Pharma Collaborations and Companion Diagnostics. 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.

5.4.

Executive management

Biocartis' executive management is composed of the chief executive officer and the other members of the executive management. On 31 December 2016, the executive management team was composed as follows [1]:

NAME	AGE	FUNCTION
Rudi Pauwels[2]	57	Chief executive officer (CEO)
Hilde Windels[3]	51	Deputy chief executive officer(Deputy CEO)
Hilde Eylenbosch[4]	53	Chief commercial officer (CCO)
Ewoud Welten	33	Chief financial officer (CFO)
Ulrik Cordes	46	EVP Pharma Collaborations and Companion Diagnostics
Erwin Sablon	52	Head of R&D and Alliance Management
Susy Spruyt	49	Human Resources Director
Erik Vossenaar[5]	44	VP Business Development
Reginald Van Genechten[6]	51	Head of Manufacturing and Supply Chain

Mr. Rudi Pauwels (permanently representing Valetusan Ltd.) resigned as chief executive officer of the Company with effect as from 2 March 2017. Hilde Windels (permanently representing Hilde Windels BVBA) took over the role of chief executive officer on an interim basis until a successor is on board.

Notes:

[1] Mr. Patrick Hofkens left Biocartis on 8 April 2016.

[2] Permanently representing Valetusan Ltd.

[3] Permanently representing Hilde Windels BVBA.

[4] Permanently representing Citros vof. Citros vof, permanently represented by Mrs. Hilde Eylenbosch, was appointed as chief commercial officer with effect as of 18 November 2016.

[5] Mr. Erik Vossenaar joined the executive management team on 1 January 2016.

[6] Mr. Reginald Van Genechten joined the executive management team on 1 March 2016 replacing Mrs. Caroline Collard who however remained Marketing Director of Biocartis.

Rudi Pauwels was the chief executive officer until 2 March 2017 and is a director of the Company. See his biography under 'board of directors'.

Hilde Windels was the deputy chief executive officer until 2 March 2017 and is currently the chief executive officer (ad interim) and a director of the Company. See her biography under 'board of directors'.

Hilde Eylenbosch is the chief commercial officer and a director of the Company. See her biography under 'board of directors'.

Ewoud Welten is the chief financial officer. 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. Ewoud holds a Master Degree in Financial Economics (distinction) from the Erasmus University Rotterdam, the Netherlands.

Ulrik Cordes is EVP Pharma Collaborations and Companion Diagnostics. Mr. Cordes has special experience in strategy, commercial partnering, global go-to market strategies and M&A activities. Prior to joining Biocartis, he held the position of Global Sales & Marketing Director Slides & Specialty Glass at Thermo Fisher Scientific. He has also held a number of positions at Dako, including that of Vice President Marketing Operations and Vice President Asia Pacific & Export Region. At Dako, Mr. Cordes spearheaded M&A transactions including the Dako-Cytomation merger and the Cytologix acquisition. He also successfully led Dako's market expansion through commercial partnering and the establishment of subsidiaries in amongst others China and Brazil. Mr. Cordes holds a Master of Science in Biochemistry from the University of Copenhagen, Denmark and a Bachelor of Commerce from Copenhagen Business School, Denmark.

Erwin Sablon is the head of R&D and Alliance Management. He joined Biocartis as Director of Diagnostics Development and Alliance Management in June 2010. In August 2012, he took on the role of Head of Applied Research and Development. He is now responsible for all Biocartis' internal and external life sciences R&D activities, and for managing the relationships with the Company's development partners. Prior to joining Biocartis, Mr. Sablon held the position of Director Project Management at Ablynx NV (Gent, Belgium) from 2008-2010. He also gained extensive experience in in vitro diagnostics (IVD) development of molecular diagnostic assays during his 18 years at Innogenetics NV (Gent, Belgium), where he held various R&D management positions, including at the departments of infectious diseases, virology and microbiology. Mr. Sablon holds a PhD in Molecular Biology from the University of Ghent and an Executive MBA from the Vlerick Business School.

Susy Spruyt is the Human Resources Director. She joined Biocartis in 2015. Prior to joining Biocartis, Mrs. Spruyt held progressive local and international HR roles primarily in the biotech and pharmaceutical industry where she worked with client groups in Sales and Marketing, R&D, Operations and General Services. She holds a Master Degree in Law from VUB University of Brussels.

Erik Vossenaar joined Biocartis in 2010. As VP Business Development his responsibilities include partnering and licensing. He played a key role in establishing the Company's partnership model since the very beginning. Mr. Vossenaar has a proven track record in the development of molecular diagnostic platforms. Before joining Biocartis, he worked at Philips where he headed the molecular diagnostic assay development team, and afterwards became responsible for Business Development and Technology Strategy for Philips' Molecular Diagnostics Business Unit. Mr. Vossenaar had a pivotal role in the development of Philips' Molecular Diagnostics platform, which was acquired by Biocartis in 2010. Mr. Vossenaar obtained his Master's degree in Chemistry from the Radboud University Nijmegen (1999). In 2004, he obtained his PhD at the department of Autoimmune Biochemistry at the same university.

Reginald Van Genechten joined Biocartis as Head of Manufacturing and Supply Chain in March 2016. Prior to joining Biocartis, Mr. Van Genechten held positions as, amongst others, Head of Technical Operational Excellence at McNeil (US based, part of J&J) and Senior Director Johnson&Johnson Global Supply Chain. He has over 25 years of cross-cultural healthcare experience in Operational Excellence, with an outstanding track record of improving processes to excellence, extensive compliance knowledge (including Consent Decree), achieving superior business results and building competency and sustainable capabilities. Mr. Van Genechten holds a Master Degree in Engineering from VUB University of Brussels and is a certified Master Black Belt in Lean and Black Belt in Six Sigma.

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.

5.5.

Share capital and shares

5.5.1.

Issue of shares by the Company in 2016

On 1 January 2016, the share capital of the Company amounted to EUR 405,441.88, represented by 40,544,188 shares. In the course of 2016, there was one capital increase resulting from the exercise of warrants under the stock option plan 2013, resulting in the issuance of 45,000 new shares, an increase of the share capital of EUR 450 and an increase of the issuance premium account of EUR 365,440.50. In addition, on 21 November 2016, the Company issued 4,058,917 new shares 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, resulting in an increase of the share capital of EUR 40,589.17 and an increase of the issuance premium account of EUR 32,633,692.68. Consequently, on 31 December 2016, the total share capital of the Company amounted to EUR 446,481.05, represented by 44,648,105 shares. An overview of the major shareholders of the Company on 31 December 2016 based on the transparency notifications received until that date can be found in the section 'Major Shareholders'. The Company is not aware of any shareholders' agreements with respect to the Company.

5.5.2.

Number and form of shares of the Company

Of the 44,648,105 shares of the Company outstanding at 31 December 2016, 11,179,881 were registered shares and 33,468,224 were dematerialized shares. All shares belong to the same class and are freely transferable. All shares are issued and fully paid-up.

5.5.3.

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 to 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.

5.5.4.

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, 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. As a result, the board of directors still has the authority under the authorized capital to increase the Company's share capital with an aggregate amount of EUR 350,850.96.

5.5.5.

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 and a majority of at least 75% of the votes cast. An amendment of the Company's corporate purpose requires the approval of at least 80% of the votes cast at a general shareholders' meeting, 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 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.

5.5.6.

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 the 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 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 has currently not been authorized by an extraordinary shareholders' meeting to purchase or sell its own shares. On 31 December 2016, neither the Company nor any subsidiary of the Company held any shares in the Company.

5.5.7.

Public takeover bids

Public takeover bids for the Company's shares and other securities giving access to voting rights (such as warrants) are subject to supervision by the Belgian Financial Services and Markets Authority (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 Takeover Act 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 Takeover Decree of 27 April 2007. 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 Belgian Takeover 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 that may apply to the Company and 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 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 important agreements which take effect, alter or terminate upon a change of control over the Company following a takeover bid:

- Outstanding WHC Warrants (see 'Whitemarsh capital warrants', WHC Warrants) for which the board of directors can decide to accelerate the exercisability of (all or part of) the WHC Warrants in the event of a change of control over the Company, it being understood that the deadline for satisfaction of the criteria for exercisability of WHC Warrants has lapsed on 1 January 2017.
- The EUR 25.0m credit contract dated 19 July 2016 entered into between KBC Bank NV and the Company, of which the change of control clause will be submitted for approval by the annual shareholders' meeting of 2017 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 framework agreement dated 19 July 2016 entered into between Gigarant NV and the Company in the presence of Biocartis NV and KBC Bank NV, of which the change of control clause will be submitted for approval by the annual shareholders' meeting of 2017, which stipulates that a change of control in respect of the Company would entail a breach of covenant in which case the Company must indemnify Gigarant NV for any costs, expenses, losses, liabilities and damages it may suffer as a consequence thereof.
- The EUR 15.0m subordinated loan agreement dated 19 July 2016 entered into between PMV-Tina Comm.VA, FPIM Federale Participatie- en Investeringsmaatschappij NV, the Company and Biocartis NV, of which the change of control clause will be submitted for approval 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).

In addition, the Company's warrant plans (2013 Plan and 2015 Plan) provide for an accelerated vesting of the warrants in case of a change of control event. The 2013 Plan and 2015 Plan are described in more detail in the Remuneration Report (see 'Characteristics of the Stock Options').

5.6.

External and internal control

5.6.1.

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 appointed for the statutory term of three years at the Company's incorporation on 24 November 2014 and thus the auditor's term will end at the closing of the annual shareholders' meeting to be held in 2018.

In 2016, a total amount of EUR 120,210.51 was paid to the statutory auditor. This amount includes the following elements: EUR 95,000 for audit fees, EUR 10,500 for work performed in relation to legal mission work of the Company (warrant plans and the Company's private placement via an accelerated bookbuild offering), EUR 4,210.51 for tax related work and EUR 10,500 for IFRS accounting advice.

5.6.2.

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 its risks, e.g. property and material damage, business interruption and cyber risk 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 financials accounts of the Company, the management reporting and budgets and gives its recommendation with regards to these documents to the board of directors.

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. Hereto, 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 a very 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.
- **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 the above mentioned accounts at least every six months.

In 2016, the Company requested a review by a third party of amongst others its existing internal control processes with the goal to identify improvements based on the principles as outlined in the frameworks and guidance on enterprise risk management, internal control and fraud deterrence as outlined by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company is currently further improving its internal environment based on the recommendations that were obtained from this review.

In order to ensure the quality and reliability of the financial information, Biocartis has established different 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 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 below (see 'Quality management system').

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.

5.6.3.

Quality management system

Biocartis has established, documented and implemented a quality management system ('QMS') compliant with the international standards and regulations for design and development, for manufacturing and testing and for customer facing processes. The quality system covers all of Biocartis' products and tests.

Biocartis currently holds ISO 13485:2012 (Medical devices—Quality Management Systems—Requirements certification for regulatory purposes), ISO 13485:2003 as for CMDCAS (Medical Devices and QMS for Canadian Medical Devices Conformity Assessment System) and ISO 9001:2008 (Quality Management Systems) certificates covering its design and development activities, its manufacturing and testing activities and its customer related processes, in Mechelen (Belgium). It has elected TÜV Rheinland as its registrar and notified body. Biocartis also complies with the following standards:

- The IVD Directive
- EN ISO 14971:2012(C) (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)

In 2016, Biocartis has been audited by Belarus and South Korean authorities and has been granted approval for its Idylla™ platform and tests. In addition, Biocartis has implemented the requirements of FDA QSR 21 CFR chapter 820 (Quality System Regulation) to comply with the FDA regulations governing IVD devices and has initiated the regulatory approval process of its Idylla™ platform with the US FDA.

All processes needed for the QMS and their application throughout the organization are defined in the QMS process. It describes the key processes to develop, manufacture and deliver high quality products to our customers and the leverage of 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, planned arrangements for product realization, requirements from standards and regulations for QMS (like ISO13485 and 21CFR820) and internal requirements established as per 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.

CHAPTER 6

Remuneration report

6.1.

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.

6.2.

Remuneration policy

6.2.1.

Principles

Biocartis' remuneration policy is designed to enable Biocartis to (i) attract and retain talented individuals, (ii) promote continuous commercial and operational improvements, and (iii) link remuneration and performance, motivating people to deliver increased shareholder value through superior business results.

The remuneration of the non-executive directors was based on a benchmarking performed by the Company in 2015 and will be reviewed against market practice at regular occasions. Their remuneration is composed of a fixed fee and an attendance fee. Their remuneration does not contain a variable part. 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, the Deputy CEO and the other members of the executive management team consists of an annual fixed base salary, a variable remuneration (cash bonus), participation in stock option plans and certain other components. The variable remuneration is structured so as to link rewards to corporate and individual performance of the executives. The corporate and individual 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.

6.2.2.

Relative importance of each component of the remuneration

For 2016, the CEO's and Deputy CEO's variable remuneration could be maximum 15% of their respective annual fixed remuneration of the year for which the variable remuneration is awarded. For the other members of the executive management team the variable remuneration for 2016 could be maximum 10% of their respective annual fixed remuneration of the year for which the variable remuneration is awarded. In addition, the Deputy CEO and the other members of the executive management team (excluding the CEO) participate in stock option 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.

6.2.3.

Performance-related premiums in shares, options or other rights to acquire shares

The Company does not provide any performance-related premiums in shares, options or other rights to acquire shares. The stock options granted under the SOP 2008 and the warrants granted under the SOP 2013 and SOP 2015 are not considered to be variable remuneration as they are not linked to any performance criteria.

6.2.4.

Remuneration policy for the next two financial years (2017-2018)

During the meetings of the remuneration and nomination committee and the board of directors held on 18 February 2016, it was decided that the remuneration of the executive management team should include a variable component as further set out in this Remuneration Report. The Company currently has no plans to substantially deviate from the general principles of the remuneration policy used in 2016 as described in this Remuneration Report, in the next two financial years. The remuneration of the new chief executive officer who will be announced in 2017 and the remuneration (if any) of the members of the strategy committee that was established with effect as at 2 March 2017 will be determined by the board of directors and, if required, presented to the general shareholders' meeting of the Company for its approval.

6.3.

Remuneration of the Directors

6.3.1.

Principles

The remuneration of the non-executive directors has been determined by the general shareholders' meeting of 13 April 2015 and is composed of a fixed fee and an attendance fee. The directors who are also a member of the executive management team are remunerated for the executive management mandate only, and not for their director mandate. This concerns Valetusan Ltd. (permanently represented by Mr. Rudi Pauwels) until 2 March 2017, Hilde Windels BVBA (permanently represented by Mrs. Hilde Windels) and, since 18 November 2016, Citros vof (permanently represented by Mrs. Hilde Eylenbosch).

Annual fixed fees:

- The chairperson of the board of directors receives a fixed fee of EUR 14,000 per year.
- The chairperson of the audit committee receives a fixed fee of EUR 12,000 per year.
- The chairperson of the remuneration and nomination committee receives a fixed fee of EUR 10,000 per year.
- The other non-executive directors receive a fixed fee of EUR 8,500 per year.

Attendance fees:

In addition to the annual fixed fees mentioned above, each non-executive director receives an attendance fee of EUR 2,000 per meeting of the board of directors attended in person (or EUR 1,000 per meeting of the board of directors attended per conference call), EUR 1,000 per meeting of the audit committee attended by the director who is a member of such committee, and EUR 500 per meeting of the remuneration and nomination committee attended by the director who is a member of such committee.

Share based awards:

Upon advice of the remuneration and nomination committee and pursuant to the approval by the general shareholders' meeting of 13 April 2015, the Company awards 5,000 warrants on an annual basis to the independent directors (see also 'Corporate Governance', Introduction). Part of the warrants under the 2015 Plan which is described below is used for this purpose. In accordance with the decision of the general shareholders' meeting of 13 April 2015, the warrants under the 2015 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 Company also reimburses reasonable out of pocket expenses of directors (including travel expenses) incurred in performing their mandate.

6.3.2.

Remuneration of the members of the Board of Directors in 2016

Based on what is set out above under Section 'Principles', the remuneration of the directors for the performance of their director mandate in 2016 is as follows:

DIRECTOR	ANNUAL FIXED FEES	ATTENDANCE FEES	TOTAL
Gengest BVBA, represented by Mr. Rudi Mariën	EUR 24,000	EUR 19,000	EUR 43,000
Be@dvised BVBA, represented by Mr. Renaat Berckmoes	EUR 12,000	EUR 17,000	EUR 29,000
Mr. Roald Borré	EUR 8,500	EUR 20,000	EUR 28,500
Mr. Mark Shaffar(1)	EUR 4,041	EUR 8,500	EUR 12,541
Shaffar LLC, represented by Mr. Mark Shaffar(1)	EUR 4,459	EUR 10,500	EUR 14,959
Mr. Peter Piot	EUR 8,500	EUR 14,000	EUR 22,500
Mrs. Hilde Eylenbosch(2)	EUR 4,389	EUR 6,000	EUR 10,389

Notes:

(1) Mr. Mark Shaffar resigned as director with effect as of 22 June 2016. Following his resignation, Shaffar LLC, permanently represented by Mr. Mark Shaffar, was coopted as director of the Company with effect immediately after the resignation of Mr. Mark Shaffar. The director's fee was proportionally split between Mr. Mark Shaffar and Shaffar LLC.

(2) Mrs. Hilde Eylenbosch was appointed as director by the annual shareholders' meeting of 13 May 2016. Mrs. Hilde Eylenbosch resigned as director with effect as of 18 November 2016. Following her resignation, Citros vof, permanently represented by Mrs. Hilde Eylenbosch, was coopted as director of the Company with effect immediately after the resignation of Mrs. Hilde Eylenbosch, and appointed as chief commercial officer of the Company. The director's fee was only paid to Mrs. Hilde Eylenbosch for the period between 13 May 2016 and 18 November 2016. As from 18 November 2016, Citros vof was an executive director who was not remunerated for its director mandate

As indicated above, Valetusan Ltd., Hilde Windels BVBA and Citros vof (since 18 November 2016) are not remunerated for their director mandate.

As of 31 December 2016, each of Mr. Peter Piot, Mr. Mark Shaffar and Be@dvised BVBA (permanently represented by Mr. Renaat Berckmoes), independent directors of the Company, were granted 5,000 warrants under the 2015 Plan. All three independent directors accepted all warrants granted to them. As at 31 December 2016, none of the independent directors exercised any warrants granted to them. It was decided not to grant Citros vof (permanently represented by Mrs. Hilde Eylenbosch) warrants for its role as independent director given that this director ceased to be an independent director on 18 November 2016. Citros vof was however granted warrants for its role as chief commercial officer of the Company (see 'Remuneration of the members of the executive management team').

6.4.

Remuneration of the members of the executive management team

6.4.1.

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 stock option plans (excluding for the CEO)
- Group and hospitalization insurance
- Other components

For 2016, the variable remuneration of the CEO, Deputy CEO and CFO is structured so as to link rewards 100% to company goals (no individual goals). The CEO's and Deputy CEO's variable remuneration can be maximum 15% of their respective annual fixed remuneration of the year for which the variable remuneration is awarded (i.e. 2016). The CFO's variable remuneration can be maximum 10% of his annual fixed remuneration of the year for which the variable remuneration is awarded (i.e. 2016). The variable remuneration of the other members of the executive management team is structured so as to link rewards to company goals (60%) and individual goals of the respective executives (40%). Their variable remuneration can be maximum 10% of their respective annual fixed remuneration of the year for which the variable remuneration is awarded (i.e. 2016).

The company and individual goals are established annually by the board of directors upon recommendation of the remuneration and nomination committee. The company goals for the purposes of the variable remuneration are aligned with the overall company objectives as set by the board of directors and are translated into specific, measurable, attainable, realistic and timely goals. For 2016, the company goals related to the financial position of the Company, the assay launches of the Company and certain milestones to be achieved with respect to commercial revenue development, manufacturing and strategic imperatives. Each of these goals accounted for 20%. The individual goals for the respective members of the executive management related to a business critical objective that these individuals, from a company perspective, would most attribute to given amongst others their respective focus areas and leadership position.

The level of achievement of the objectives of the members of the executive management team and the corresponding amount of the variable remuneration is assessed in the beginning of the first subsequent year (i.e. 2017) by the remuneration and nomination committee and finally established by the board of directors.

The members of the executive management team (excluding the CEO) are also eligible to participate in the stock option plans of the Company and are reimbursed for certain costs and expenses made in the performance of their function. The members of the executive management that have an employment contract can also benefit from a group insurance, hospitalization plan, company car with fuel card, meal vouchers, mobile phone and laptop. Finally, one member of the executive management team also receives certain housing and relocation costs, school allowance, tax assistance and statutory accident and disease insurance.

6.4.2.

Remuneration of the members of the executive management team in 2016

The following remuneration and compensation was paid to the CEO and the other members of the executive management with respect to 2016:

Amounts in EUR[1]	CEO	OTHER MEMBERS OF THE EXECUTIVE MANAGEMENT TEAM
Annual base salary	EUR 351,000.00	EUR 1,283,928.72
Variable remuneration	EUR 34,125.00	EUR 85,236.00
Company car	-	EUR 75,875.42
Group insurance[2]	-	EUR 68,339.13
Expat expenses	-	EUR 74,860.00
Other elements[3]	-	EUR 20,472.18
Total	EUR 385,125	EUR 1,608,711.45

Notes:

[1] The amounts reflect the proportion of the remuneration and compensation paid to the members of the executive management team for the period of the year during which they were part of the executive management team. The amounts include both (proportional) gross salaries (excluding employer social security contributions) and compensation paid to the self-employed members of the executive management team.

[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.

In 2016, 135,000 warrants were granted to and accepted by members of the executive management team under the 2015 Plan as follows: 10,000 warrants were granted to Mrs. Susy Spruyt, 62,500 warrants were granted to Mr. Reginald Vangenechten and 62,500 warrants were granted to Citros vof (permanently represented by Mrs. Hilde Eylenbosch). These warrants vest in 48 monthly instalments. In total, 5,000 warrants were exercised by members of the executive management team in 2016 (i.e. by Mr. Erwin Sablon). No stock options or warrants granted to the members of the executive management team expired or became null and void during 2016. The warrants are not considered as a variable remuneration as they are not linked to any performance criteria.

The table below provides an overview of the number of stock options and warrants held by the members of the executive management team as at 31 December 2016:

NAME	GRANTED	VESTED	EXERISED	TOTAL HELD	EXERCISE PRICE	PLAN
Rudi Pauwels[1]	-	-	-	-	-	-
Hilde Windels[2]	100,000	100,000	0	100,000	EUR 8.1309	2013 Plan
Hilde Eylenbosch[3]	62,500	1,302	0	62,500	EUR 8.4967	2015 Plan
Ewoud Welten	62,500	20,832	0	62,500	EUR 13.28	2015 Plan
Ulrik Cordes	62,500	52,082	0	62,500	EUR 8.1309	2013 Plan
Erwin Sablon	30,000	30,000	10,000	20,000	EUR 8.1309	2013 Plan
Susy Spruyt	10,000	3,120	0	10,000	EUR 12.77	2015 Plan
Erik Vossenaar	12,000	12,000	0	12,000	CHF 4.14	2008 Plan
	18,000	18,000	0	18,000	EUR 8.1309	2013 Plan
Reginald Van Genechten	62,500	11,718	0	62,500	EUR 11.52	2015 Plan

Notes:

[1] Permanently representing Valetusan Ltd / [2] Permanently representing Hilde Windels BVBA. / [3] Permanently representing Citros vof.

For an overview of the features of the stock options and warrants, see also 'Characteristics of the Stock Options'.

6.4.3.

Contractual provisions regarding compensation for severance for the members of executive management

The CEO, Deputy CEO and chief commercial officer are self-employed. Their contracts contain customary provisions regarding remuneration, non-competition and confidentiality.

The service 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 twelve months. In certain cases, the contract can be terminated by Biocartis with immediate effect.

The service contract of the Deputy CEO was entered into for an indefinite period of time and can be terminated by either the Deputy 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 indemnity equal to the pro rata fee for that period). In certain cases, the contract can be terminated by Biocartis with immediate effect or subject to a prior notice of three months.

The service contract of the chief commercial officer was entered into for an indefinite period of time and can be terminated by either the chief commercial officer 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 chief commercial officer with immediate effect.

The other members of the executive management team 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. One of the members of the executive management team will benefit of a relocation fee in case of termination in certain circumstances.

6.4.4.

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.

6.4.5.

Severance payments for departing members of the executive management

In 2016, only one member of the executive management team left Biocartis (i.e. Mr. Patrick Hofkens, General Counsel). No severance payment was made to Mr. Hofkens.

6.5.

Characteristics of the stock option plans

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

6.5.1.

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 Mr. Rudi Pauwels, Mr. Ferdinand Verdonck and Mr. 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 the stock option is equal to CHF 4.14 (rounded), and (v) the stock options vest in 48 monthly instalments.

On 31 December 2016, a total number of 42,101 stock options are still outstanding under the 2008 Plan, entitling the holders to acquire 42,101 shares of the Company. All stock options are vested.

6.5.2.

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 stock options. The key features of the stock options under the 2013 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 unless the grant stipulates otherwise, (iii) the stock options have a term of ten years when they were created but this term is contractually reduced to seven years upon grant of the stock options, (iv) the exercise price of the stock options is determined at the time of the grant of the stock options, and (v) in principle the stock options vest in 48 monthly instalments, subject to acceleration in case of a change of control event. 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 stock options have been granted under the 2013 Plan, having an exercise price of EUR 8.1308. The exercise price of the stock options 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 2016, a total of 750,340 stock options have been granted of which 589,291 are outstanding (i.e. stock options under the 2013 Plan which have been granted to and accepted by selected participants and which have not yet been exercised or became null and void for any reason). A total number of 249,660 stock options can still be granted under the 2013 Plan.

6.5.3.

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. The key features of the stock options under the 2015 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 ten years when they were created, but this term will be contractually reduced to seven years, (iv) the exercise price of the stock option is determined at the time of the grant of the stock options, and (v) in principle the stock options vest in 48 monthly instalments, subject to acceleration in case of a change of control event. The exercise price of the stock options 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 2016, a total of 232,500 stock options have been granted, all of which were outstanding at such date (i.e. none of the stock options under the 2015 Plan which have been granted to and accepted by selected participants have been exercised, nor have they become null and void for any reason). A total number of 30,434 stock options can still be granted under the 2015 Plan.

CHAPTER 7

Consolidated annual accounts

7.1.

Consolidated financial statements as of and for the years ended 31 December 2016 and 2015

7.1.1.

Consolidated income statement

In EUR000	Notes	Years ended 31 December, 2016	2015
Revenue			
Collaboration revenue	7.2.4	5,278	9,686
Product sales revenue	7.2.4	6,767	3,593
Service revenue	7.2.4	53	54
		12,098	13,334
Other operating income			
Grants and other income	7.2.5	1,674	1,617
Total operating income		13,772	14,951
Operating expenses			
Cost of goods sold	7.2.6	-5,701	-2,642
Research & Development expenses	7.2.7	-42,091	-36,554
Marketing & Distribution expenses	7.2.8	-10,324	-8,747
General & Administrative expenses	7.2.9	-5,827	-6,662
		-63,943	-54,606
Operating loss for the year		-50,171	-39,655
Financial income	7.2.11	86	107
Financial expense	7.2.11	-674	-819
Foreign exchange gains/(losses), net	7.2.11	2	-78
Financial result, net		-586	-790
Loss for the year before taxes from continuing operations		-50,757	-40,445
Income taxes	7.2.28	980	648
Loss for the year after taxes from continuing operations		-49,777	-39,797
Loss for the year		-49,777	-39,797
Attributable to owners of the Company		-49,777	-39,797
Attributable to non-controlling interest			
Earnings per share			
Basic and diluted loss per share from continuing and discontinued operations	7.2.12	-1.21	-1.07
Basic and diluted loss per share from continuing operations	7.2.12	-1.21	-1.07

7.1.2.

Consolidated statement of other comprehensive income

In EUR000	Notes	Years ended 31 December, 2016	2015
Loss for the year		**-49,777**	**-39,797**
Actuarial gain (loss) on defined benefit plan	7.2.23	19	0
Tax impact actuarial gain (loss)		-6	0
Total comprehensive loss for the year		**-49,764**	**-39,797**
Attributable to owners of the Company		-49,764	-39,797
Attributable to non-controlling interest		0	0

7.1.3.

Consolidated balance sheet

In EUR000	Notes	As of 31 December, 2016	2015
Assets			
Non-current assets			
Intangible assets	7.2.13	9,921	8,987
Property plant and equipment	7.2.14	23,088	14245
Participating interests	7.2.15	5,052	5,052
Other long term receivables		11	11
Deferred tax assets	7.2.16	3,090	1,986
		41,162	30,281
Current assets			
Inventory	7.2.17	9,829	5,837
Trade receivables	7.2.18	2,935	5,852
Other receivables	7.2.18	2,201	1,063
Other current assets	7.2.19	1,932	1,258
Cash and cash equivalents	7.2.20	83,246	104,087
		100,143	118,097
Total assets		**141,305**	**148,378**
Equity and liabilities			
Capital and reserves			
Legal share capital	7.2.21	446	405
Historical share capital adjustment	7.2.21	-221,232	-221,232
Share premium	7.2.21	554,065	522,708
Share based payment reserve	7.2.22	1,716	1,345
Accumulated deficit	7.2.21	-238,088	-188,310
Other comprehensive income	7.2.21	-19	0
Total equity attributable to owners of the Company		96,889	114,916
Non-current liabilities			
Provisions	7.2.23	47	0
Financial debt	7.2.24	27,709	2,662
Deferred income	7.2.26	142	1,342
Accrued charges	7.2.27	1,610	1,580
		29,508	5,585
Current liabilities			
Financial debt	7.2.24	3,698	8,152
Trade payables	7.2.25	6,293	13,927
Deferred income	7.2.26	1,963	3,812
Other current liabilities	7.2.25	2,954	1,986
		14,908	27,877
Total equity and liabilities		**141,305**	**148,378**

7.1.4.

Consolidated cash flow statement

in EUR000	Notes	Years ended 31 December, 2016	2015**
Operating activities			
Loss for the year		-49,777	-39,797
Adjustments for			
Depreciation and amortization	7.2.13	4,848	5,021
Loss on disposal of fixed assets	7.2.14	207	73
Tax income in profit and loss	7.2.28	-980	-648
Financial result, net	7.2.11	813	688
Net movement in retirement benefit obligation	7.2.23	47	0
Share based payment expense	7.2.22	371	179
Other comprehensive income		-28	0
Changes in working capital			
Net movement in inventories	7.2.17	-3,991	-2,254
Net movement in trade and other receivables and other current assets	7.2.18	1,105	10,574
Net movement in trade payables & other current liabilities	7.2.19 7.2.25	-2,659	4,003
Net movement in deferred income	7.2.26	-3,049	-4,479
Interests paid		-105	-304
		-53,198	-26,944
Taxes paid	7.2.28	-114	-391
Cash flow used in operating activities		-53,312	-27,335
Investing activities			
Interest received		79	106
Purchases of property, plant & equipment	7.2.14	-9,123	-5,263
Purchases of intangible assets	7.2.14	-1,927	-371
Proceeds from sale and lease back of property, plant and equipment	7.2.14	1,629	18
Proceeds from the sale of fixed assets	7.2.14	0	74
Cash flow from / (used in) investing activities		-9,342	-5,436
Financing activities			
Proceeds from borrowings	7.2.24	15,000	600
Proceeds from the lease financing of property, plant and equipment	7.2.24	3,978	1,217
Proceeds from issue of preference shares F	7.2.21	0	21,513
Proceeds from the issue of common shares, net of transaction costs	7.2.21	31,398	107,688
Repayment of borrowings	7.2.24	-8,539	-5,057
Bank charges		-33	-18
Cash flow from financing activities		41,804	125,943
Net increase / (decrease) in cash and cash equivalents		-20,850	93,172
Cash and cash equivalents at the beginning of the year		104,087	10,919
Effects of exchange rate changes on the balance of cash held in foreign currencies		10	-4
Cash and cash equivalents at the end of the year*		83,247	104,087
Supplementary cash flow disclosures			
New finance leases		8,494	1,216

* Including EUR 1.2 million restricted cash related to KBC lease financing / ** Restatement cash flow statement 2015, for the details refer to 7.2.2.3

7.1.5.

Consolidated statement of changes in equity

In EUR000	Notes	Attributable to owners of the Company							
		Legal share capital	Historical share capital adjustment	Share premium	Share based payment reserve	Gains and losses on defined contribution plans	Accumulated deficit	Total equity attributable to the owners of the Company	Total equity
Balance as at 31 December 2014		**222,268**	**-221,232**	**166,592**	**1,166**	**0**	**-148,513**	**20,280**	**20,280**
Loss for the year							-39,797	-39,797	-39,797
Share issue - tranche 2 of round F on 15 January 2015	7.2.21	20,488		1,025				21,513	21,513
Share issue - contribution in kind of the participation in MyCartis on 15 January 2015	7.2.21	4,812		241				5,052	5,052
Capital increase by incorporation of share premium on 15 January 2015	7.2.21	8		-8				-	-
Capital decrease by conversion into share premium on 13 April 2015	7.2.21	-247,272		247,272				-	-
Share issue -Initial Public Offering on 28 April 2015	7.2.21	87		99,913				100,000	100,000
Share issue - exercise of over-allotment warrant on 19 May 2015	7.2.21	13		14,987				15,000	15,000
Cost related to Initial Public Offering	7.2.21			-8,124				-8,124	-8,124
Share issue - exercise of stock options on 3 June 2015	7.2.21			171				171	171
Share issue - exercise of stock options on 6 October 2015	7.2.21			313				313	313
Share issue - exercise of stock options on 23 December 2015	7.2.21			295				295	295
Costs related to capital increase	7.2.21			33				33	33
Share-based payment expense	7.2.22				179			179	179
Balance as at 31 December 2015		**405**	**-221,232**	**522,707**	**1,345**	**0**	**-188,310**	**114,916**	**114,916**
Loss for the year	7.2.21						-49,777	-49,777	49,777
Other comprehensive income	7.2.21					-19		-19	-19
Total comprehensive income		0	0	0	0	-19	-49,777	-49,796	-49,796
Share issue - exercise of stock options on 7 April 2016	7.2.21			366				366	366
Share issue – private placement 21 November 2016	7.2.21			32,634				32,674	32,674
Cost related to private placement	7.2.21	41		-1,642				-1,642	-1,642
Share-based payment expense	7.2.22				371			371	371
Balance as at 31 December 2016		**446**	**-221,232**	**554,065**	**1,716**	**-19**	**-238,088**	**96,889**	**96,889**

7.2.

Notes to the consolidated financial statements

7.2.1.

General Information

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

The Company is using its CE-IVD marked Idylla™ platform to develop and market a broad set of high value clinical assays.

The Group's mission is to become a global, fully-integrated provider of novel molecular diagnostics solutions with industry-leading, high clinical value tests. The Company has subsidiaries in Mechelen (Belgium), Eindhoven (The Netherlands) and Lausanne (Switzerland).

The Group has so far been funded by a combination of private and public equity, upfront licensing fees, milestone payments and contract R&D income from collaborations. Several grants have been awarded to the Group to support its R&D activities.

The consolidated financial statements have been authorized for issue on 23 February 2017 by the board of directors of the Company (the 'board of directors').

7.2.2.

Summary of significant accounting policies

The principal accounting policies for preparing these consolidated financial statements are explained below.

7.2.2.1

Statement of compliance

The consolidated financial statements of the Group for the year ended 31 December 2016 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.

7.2.2.2

Change in reporting entity

Biocartis Group NV was created in November 2014 by the shareholders of Biocartis SA, by means of a contribution in kind (in two consecutive stages, on 24 November 2014 and 25 November 2014, respectively) of all shares in Biocartis SA on a share-for-share basis for a total amount of EUR 222m. This contribution

in kind is considered in the IFRS consolidated financial statements of Biocartis Group NV to be a transaction between entities under common control and consequently does not fall within the scope of IFRS 3 'Business combinations'. The Group has applied the guidance as referred to in the US Accounting Standard Codification 805-50 with regard to the 'Pooling-of-Interest method'. In this context, the continuity of the book values method is applied.

The consolidated financial statements for the year ended 31 December 2016 include Biocartis Group NV and its subsidiaries. Prior to the incorporation of Biocartis Group NV the consolidation was performed at the level of Biocartis SA.

7.2.2.3

Basis of preparation

The consolidated financial statements have been prepared on the historical cost basis except for available for sale financial assets and non-cash distribution 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 and IFRIC that are relevant to its operations and effective for accounting periods beginning on 1 January 2016:

- Improvements to IFRS (2010-2012) (applicable for annual periods beginning on or after 1 February 2015)
- Improvements to IFRS (2012-2014) (applicable for annual periods beginning on or after 1 January 2016)

- Amendments to IFRS 10, IFRS 12 and IAS 28 Investment Entities: Applying the Consolidation Exception (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IAS 1 Presentation of Financial Statements – Disclosure Initiative (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IAS 16 and IAS 38 Property, Plant and Equipment and Intangible Assets – Clarification of Acceptable Methods of Depreciation and Amortization (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IAS 19 Employee Benefits – Employee Contributions (applicable for annual periods beginning on or after 1 February 2015)

The above application of new standards did not have a significant impact on the financial position and the results of the Group. Standards and interpretations published, but not yet applicable for the annual period beginning on 1 January 2016, are listed in note 7.2.35.

Reclassifications in the consolidated cash flow statement of the year ended 31 December 2015

The presentation of the consolidated cash flow statement of the year ended 31 December 2015 has changed compared to what has been published in the annual report of 2015, predominantly related to activities for cartridge manufacturing expansion. The implemented changes were all qualified as reclassifications and are listed and explained below.

The first reclassification relates to income taxes. Per 31 December 2015 EUR 0.4m income taxes were paid to the income tax authorities, therefore these should be presented on a separate line and not as a non-cash adjustment. Corresponding adjustments in the line 'tax income in profit and loss' and 'income tax paid" have been made in the consolidated financial statement of the year ended 31 December 2015.

	Years ended 31 December,		
in EUR000	2015 new	2015 reported	Difference
Tax income in profit and loss	-648	-1,039	391
Income tax paid	-391		-391
Total	**-1,039**	**-1,039**	**0**

The second reclassification relates to investments for cartridge manufacturing expansion. Per 31 December 2015 trade payables included prepayment invoices related to these investments for an amount of EUR 4m, which were paid early 2016. Whereas the Company initially included these prepayment invoices as a positive cash flow under 'net movement in trade payables & other current liabilities' and as negative cash flow under 'purchases of property, plant and equipment', these movements have now been excluded as there was no actual cash flow recorded. The Company consequently has decided to deduct the respective amounts from 'the net movement in trade payables & other current liabilities' and from 'the purchases of property, plant and equipment'.

	Years ended 31 December,		
in EUR000	2015 new	2015 reported	Difference
Net movement in trade payables & other current liabilities	4,003	7,981	-3,978
Purchases of property, plant & equipment	-5,263	-9,241	3,978
Total	**-1,260**	**-1,260**	**0**

The third reclassification relates to two new financing facilities Biocartis NV has obtained in 2015. The first facility is an investment credit for an amount of EUR 0.6m, provided by a bank, the second one is a leasing facility for EUR 4.4m, provided by a lease company of which EUR 1.2m was drawn per 31 December 2015. Whereas the proceeds from both facilities were initially presented under 'proceeds from borrowings', the Company has now decided to show the EUR 1.2m proceeds from the leasing facility under 'proceeds from the lease financing of property, plant and equipment' since the EUR 1.2m relates to payments first made by Biocartis NV and where afterwards reimbursed by the lease company, this results in a more accurate presentation.

	Years ended 31 December,		
in EUR000	2015 new	2015 reported	Difference
Proceeds from borrowings	600	1,817	-1,217
Proceeds from the lease financing of property, plant and equipment	1,217	0	1,217
Total	**1,817**	**1,817**	**0**

7.2.2.4

Consolidation principles

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries as at 31 December 2016. 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 Company has 100% of the shares in its subsidiaries at the end of the reporting date.

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 resultant 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.

7.2.2.5

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 balance sheet 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.

7.2.2.6

Intangible assets

Research and development costs

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

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

Due to uncertainties inherent to the development and registration with health care authorities of the Group's Idylla™ solution and the Company's other clinical diagnostics platforms such as Idylla™-Enrich or Idylla™-Retrieve, and its tests, the Group considers that the conditions for capitalization are not met until the regulatory procedures required by health care authorities have been completed. Development costs incurred after the recognition criteria are met have not been 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.

Purchased intangible assets

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

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

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

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

7.2.2.7

Property, plant and equipment

Property, plant and equipment are initially recorded 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, 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 property, plant and equipment is depreciated depends on the estimated useful life of each asset category, as per the table below.

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

The Company records as manufacturing and other equipment under construction all the physical equipment, including custom-designed equipment and generic pieces of equipment, and related costs, such as 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 disposal proceeds 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.

7.2.2.8

Impairment of tangible and intangible assets, other than goodwill

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

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

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

A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset 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.

7.2.2.9

Inventory

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

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

7.2.2.10

Financial instruments

Financial assets and financial liabilities are recognized when a Group entity becomes a party to the contractual provisions of the instruments.

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

Financial assets

The Company has financial assets classified in the following categories: 'available for sale' (AFS) financial assets and 'loans and receivables'. The classification depends on the nature and the purpose of the financial assets and is determined at the time of initial recognition.

Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Loans and receivables include trade receivables, loans, cash and cash equivalents, and other receivables which are measured at amortized cost using the effective interest method, less any impairment.

Interest income is recognized by applying the effective interest rate, except for short-term receivables when the effect of discounting is immaterial.

Available for sale financial assets

AFS financial assets are non-derivatives that are either designated as AFS or are not classified as loans or receivable, held to maturity or financial assets at fair value through profit or loss. The Company accounts for its participation in MyCartis as an AFS financial asset as of 31 December 2015.

After initial measurement, AFS financial assets are subsequently measured at fair value with unrealized gains or losses recognized in other comprehensive income and credited in the AFS reserve until the investment is derecognized, at which time the cumulative gain or loss is recognized in other operating income, or the investment is determined to be impaired, when the cumulative loss is reclassified from the AFS reserve to the statement of profit or loss in finance costs.

Interest earned whilst holding AFS financial assets is reported as interest income using the effective interest rate method.

Regular Way trades

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

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, at each reporting date, whether there is objective evidence that a financial asset or a group of financial assets is impaired. An impairment exists if one or more events that has occurred since the initial recognition of the asset (an incurred 'loss event'), has a negative impact on the estimated future cash flows of the financial asset or the group of financial assets that can be reliably estimated.

The carrying amount of the asset is reduced through the use of an allowance account and the loss is recognized in the statement of profit or loss.

Financial liabilities

The Group only has financial liabilities classified as "other 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.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest rate method. Gains and losses are recognized in profit or loss when the liabilities are derecognized as well as through the effective interest rate amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortization is included as finance costs in the consolidated income statement.

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 issued by the Company are recorded at the fair value of the proceeds received, net of transactions costs.

7.2.2.11

Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks, other short-term bank deposits with a maturity of or less than 3 months, and which are subject to an insignificant risk of changes in value.

7.2.2.12

Income taxes

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

Current income tax

Current income 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 income 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 profit 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 profit 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 Government Grants 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 Income Taxes. 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".

7.2.2.13

Employee benefits

Short-term employee benefits

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

Post-employment benefits

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

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

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 compensation

The Group operates equity-settled share-based compensation 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 balance sheet 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.

7.2.2.14

Provisions

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

7.2.2.15

Revenue recognition

The Group recognizes revenue from the sale of the Idylla™ platform and related cartridges as well as from license fees, milestones and contingent payments earned on research and collaboration arrangements.

These transactions may involve multiple elements. The Group evaluates whether the elements under these arrangements have value to its customers or collaboration partners on a stand-alone basis.

If the Group determines that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition.

Licensing, contracting and collaboration revenues

Upfront fees received by the Group in license and collaboration arrangements that include future obligations are recognized 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.

A contingent consideration received upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which is consistent with the substance of the Group's performance under the Group's various license and collaboration agreements. 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, relates solely to the Group's past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement.

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 achieved and collection is reasonably assured. Contingency and milestones payments, when recognized as revenue, are classified as contract revenues in the Group's Consolidated Income Statement.

Revenues and expenses from collaborations are recorded as contract revenues or research and development expenses in the period incurred.

Product sales, reagent rental contracts and rental contracts

Product sales

Revenues from the sale of goods are recognized when the Group has transferred to the buyer the significant risks and rewards of ownership of the goods, when the amount of revenues can be measured reliably, when it is probable that the economic benefits associated with the transaction will flow to the Group and when the costs incurred or to be incurred in respect of the transaction can be measured reliably.

Revenue from the sale of goods is measured at the fair value of the consideration received or receivable, net of returns and allowances, trade discounts and volume discounts.

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.

The Group makes a distinction between financial lease and operational lease reagent rental agreements:

Financial lease reagent rental agreements:
These agreements include a binding cartridge volume commitment from the customer that will result in a full payment of the Idylla™ systems price over the term of the agreement providing all contractual commitments are fulfilled. When the minimum required consumption of cartridges is not met, evaluated at each calendar year, the Group has the right to increase the sales prices and/or the volume commitments for the cartridges, or can require the customer to pay an indemnity (to fully recover the remaining price of the Idylla™ systems) when the reagent rental agreement is terminated early by the Group (for reasons caused by the customer) or by the customer.

If the Group determines that the significant risks and rewards for the Idylla™ systems are transferred already upon delivery to the customer, the revenue for those Idylla™ systems is recognized at that time. Revenue for those Idylla™ systems is spread linearly over the term of the contract if the Group determines that the risks and rewards are not transferred upon delivery to the customer or if it is still uncertain the customer will be in a position to meet the contractual obligations. The revenue of the cartridge tests (excluding mark-up premium) is recognized when the cartridges are delivered to the customer.

Operational lease reagent rental agreements:
There is no binding cartridge volume commitment from the customer that will result in a full payment of the Idylla™ systems price over the term of the agreement. However, there is a minimum yearly 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 yearly consumption of cartridges is evaluated at each calendar year. 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 yearly 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 yearly 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.

7.2.2.16

Grants

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

R&D grants

On certain specific research and development projects, the costs incurred are partially reimbursed by IWT (Institute for the Promotion of Innovation by Science and Technology in Flanders), Hermes (a fund from the Agency for Entrepreneurship 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 Hermes fund and 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 depreciation expense.

7.2.2.17

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 obligation. Lease payments are apportioned between financial charges and reduction of the lease obligation so as to achieve a constant rate of interest on the remaining balance of the liability. Financial charges are charged directly against income. 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.

7.2.2.18

Borrowing costs

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

7.2.3.

Critical accounting estimates, assumptions and judgments

7.2.3.1

Critical accounting estimates, assumptions and judgments

When preparing the consolidated financial statements, judgments, estimates and assumptions are made that affect the carrying value 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 arrangement, 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 2016, 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.

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 2018.

Critical accounting estimates and assumptions

Estimations of post-employment benefit obligations

The Belgian defined contribution plans classify as defined benefit plans in view of 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.

With the change in the law in December 2015, there was no longer a reason not to apply the PUC method. However, because of the late law change in and impact of applying the PUC method was estimated to be immaterial, the Company decided to only apply the PUC method in 2016.

The related obligations 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 7.2.25.

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 7.2.23.

Revenue recognition

For revenue recognition, the significant estimates relate to allocation of value to the separate elements in multiple-element arrangements. With respect to the allocation of value to the separate elements, 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. 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.

Upfront fees under collaboration or licensing agreements are recognized over the expected duration of the collaboration. Management estimates this period at the start of the collaboration and validates the remaining estimated collaboration term at each closing date.

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. 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 operational 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 7.2.2.6.

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 net book value.

7.2.3.2

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 per 31 December 2016.

7.2.4.

Revenue

The Group's revenues are summarized in the table below:

	Years ended 31 December,	
In EUR000	2016	2015
Collaboration revenue		
R&D services	255	662
Upfront license revenues	4,691	5,025
Milestone revenues	332	4,000
	5,278	**9,686**
Product sales revenue		
Idylla™ system sales	2,752	2,299
Cartridge sales	4,015	1,294
	6,767	**3,593**
Service revenue		
Service revenue	53	54
	53	**54**
Total	**12,098**	**13,334**

7.2.4.1

Collaboration revenues

Upfront license fees and milestone payments were earned under the Group's collaboration and development agreements as outlined below.

Janssen Pharmaceutical

The Group's main collaboration agreement is a license and development agreement with Janssen Pharmaceutical NV (JPNV), an entity linked to a shareholder of the Group. Under this agreement, the Group commits to further develop its Idylla™ platform and parties agree upon various test development collaborations. In return, the Group is entitled to non-refundable upfront payments, performance milestones and royalties on certain future test sales.

Certain upfront payments under this collaboration were recognized in collaboration revenues in 2016.

Abbott Molecular

Biocartis NV, a subsidiary of the Company, and Abbott Molecular signed a collaboration to develop and commercialize companion diagnostics tests. Under the agreement, the parties will leverage Biocartis' molecular diagnostics system, Idylla™, and Abbott's regulatory, scientific and commercialization expertise. The agreement is a framework agreement which can be supplemented with specific project agreements in the future including the determination of the collaboration fees.

No revenue was recognized under this agreement in the year presented.

Amgen collaboration

On 3 February 2016, Biocartis NV, a subsidiary of the Company, and Amgen entered into a collaboration to evaluate Idylla™ RAS testing as a tool for rapid decentralized testing in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain, and Turkey. 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 sales as it relates to the placement of Idylla™ systems and cartridges.

Merck KGaA (Merck)

Biocartis NV, a subsidiary of the Company, signed a collaboration agreement with Merck KGaA (Merck) for the development and commercialization of a new liquid biopsy RAS biomarker test for patients with metastatic colorectal cancer (mCRC). The test will be developed on Idylla™. The new test aims to support clinical practice in performing integrated liquid biopsy RAS biomarker tests, independently of the laboratories' volume of testing or level of expertise. Certain upfront and milestone revenue was recognized under this agreement in the year presented. Product revenue recognized under this agreement is shown under product sales as it relates to the placement of Idylla™ systems and cartridges.

Potential upfront and milestone revenues

In aggregate the potential upfront and milestone revenues that can be earned by the Group over the remaining term of these collaboration agreements amounts to EUR 3.1m (2015: EUR 5m).

7.2.4.2

Product sales

The product sales relate to Idylla™ system sales (instruments and consoles) and test sales (cartridges) to customers and collaboration partners. The total product sales can be categorized in commercial sales and research and development sales.

	As of 31 December,	
In EUR000	2016	2015
Commercial revenue	5,691	2,550
Research & Development revenue	1,076	1,044
Total	**6,767**	**3,593**

7.2.4.3

Revenues by region and major customers

	Years ended 31 December,	
In EUR000	2016	2015
Country of domicile	**1,196**	**731**
Belgium	1,196	731
Total all foreign countries, of which	**10,902**	**12,603**
United states of America	3,933	9,890
Germany	2,365	243
Rest of the world	4,615	2,470
Total	**12,098**	**13,334**

Revenues in the above table are assigned according to the location of parent company of the customer. The Group has recognized revenues from one customer representing at least 10% of the total revenues. This customer accounts for EUR 4.3 million of the revenues in 2016 (2015: EUR 9.9 million).

7.2.5.

Other operating income

	Years ended 31 December,	
In EUR000	2016	2015
R&D project support (IWT grants)	1,592	1,614
Other project grants	20	0
Other income	62	3
Total	**1,674**	**1,617**

7.2.6.

Cost of sales

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

	Years ended 31 December,	
In EUR000	2016	2015
Staff costs	-1,115	-916
Material, lab consumables & small equipment	-3,123	-1,104
Depreciation and amortization	-532	-499
Royalty expense	-499	-80
Provision for doubtful debt	-382	0
Other	-50	-43
Total	**-5,701**	**-2,642**

7.2.7.

Research & Development expenses

In EUR000	Years ended 31 December, 2016	2015
Staff costs	-20,667	-16,826
Subcontracting	-4,589	-6,205
Laboratory expenses	-2,226	-2,197
Platform and cartridge prototype costs	-4,631	-2,050
Consultancy	-1,479	-1,409
Quality and regulatory	-67	-16
Intellectual property	-763	-923
Facilities, office & other	-2,735	-2,073
ICT	-1,502	-903
Travel, training & conferences	-615	-759
Depreciation and amortization	-4,155	-4,443
Capitalized systems for internal use	1,341	1,250
Total	**-42,091**	**-36,554**

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.

Platform and cartridge prototype costs relate to the development of diagnostic platform prototypes not taken into inventory for sale or into fixed assets for internal use. These include both the raw materials and (sub) assembly costs.

Capitalized systems for internal use are Idylla™ Consoles and Idylla™ Instruments used for amongst other assay development and quality purposes. Capitalized systems for rent are Idylla™ Consoles and Idylla™ Instruments that are leased by clients.

The remaining expenses relate to quality, regulatory, patenting, building facilities, ICT, office, maintenance of equipment, logistics, travel, training and conferences.

7.2.8.

Marketing & Distribution expenses

In EUR000	Years ended 31 December, 2016	2015
Staff costs	-5,576	-3,566
Subcontracting	-876	-2,344
Sales and promotional expenses	-1,215	-918
Business development	-155	-276
Consultancy	-289	-228
Facilities, office & other	-409	-263
Travel, training & conferences	-1,634	-1,079
Depreciation and amortization	-170	-73
Total	**-10,324**	**-8,747**

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

7.2.9.

General & Administrative expenses

In EUR000	Years ended 31 December, 2016	2015
Staff costs	-3,498	-2,809
External advice	-654	-1,330
Facilities, office & other	-746	-1,287
Human resources	-670	-965
Travel, training & conferences	-270	-266
Depreciation and amortization expenses	11	-6
Total	**-5,827**	**-6,662**

External advice expenses include fees, service and consulting expenses related to legal, human resources, investor relations, accounting, audit and tax services. Other expenses include office, insurance and other miscellaneous expenses used in general and administrative activities.

7.2.10.

Personnel expenses

	Years ended 31 December,	
In EUR000	2016	2015
Short term employee benefits	-29,779	-23,687
Post-employee defined benefit expense	0	0
Post-employee defined contribution expense	-619	-111
Termination benefits	-87	-139
Share based compensation	-371	-143
	-30,856	-24,117

The headcount can be presented as follows:

	As of 31 December,	
	2016	2015
Operations staff	115	89
Research and development staff	128	123
Marketing and distribution staff	48	32
General and administrative staff	26	34
Total headcount	**317**	**278**
Average full time equivalents	**308**	**270**

7.2.11.

Financial income and expense

	Years ended 31 December,	
In EUR000	2016	2015
Interest income	79	107
Other financial income	7	0
Total	**86**	**107**
Interest expense	-447	-775
Other financial expense	-226	-44
Total	**-674**	**-819**
Foreign exchange gains/(losses), net	2	-78
Total	**2**	**-78**
Financial result, net	**-586**	**-790**

7.2.12.

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	
	2016	2015
Loss for the year attributable to the owners of the Company (in EUR000)	-49,777	-39,797
Weighted average number of ordinary shares for basic loss per share (in number of shares)	41,022,042	37,061,213
Basic loss per share (EUR)	**-1.21**	**-1.07**

7.2.13.

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 EUR000	Patents and licenses	ICT software	Total
Year ended 31 December 2015			
Opening net carrying value	9,223	429	9,652
Additions	184	187	371
Disposals	0	0	0
Disposal depreciations	0	0	0
Amortization expense	-745	-291	-1,036
Closing net carrying value	**8,662**	**326**	**8,987**
As at 31 December 2015			
Cost	12,209	1,309	13,517
Accumulated amortization	-3,547	-983	-4,530
Net carrying value	**8,662**	**326**	**8,987**
Year ended 31 December 2016			
Opening net carrying value	8,662	326	8,987
Additions	1,825	103	1,927
Disposals	0	0	0
Disposal depreciations	0	0	0
Amortization expense	-769	-224	-993
Closing net carrying value	**9,717**	**204**	**9,921**
As at 31 December 2016			
Cost	14,034	1,411	15,444
Accumulated amortization	-4,316	-1,201	-5,523
Net carrying value	**9,717**	**204**	**9,921**

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 2016 is EUR 6.5m (2015: EUR 7.0m). The remaining useful life is 12 years. In 2011, the Group acquired a license from the same partner for access to the 'Idylla™-Enrich' technology for EUR 0.5m. The technology scope of the licenses from Philips consists of intellectual property rights, invention disclosures, technical and biological data, drawings and know-how. Simultaneously with this agreement, Philips and the Group have entered into asset transfer agreements, for the purpose of transferring the assets relating to the 'Idylla™' and 'Idylla™-Enrich' technologies to the Group. In 2016, the group recognized a variable consideration liability, based on contractual obligations with a corresponding increase of the licenses from Philips related to the 'Idylla™-Enrich' technology for EUR 1.8m.

Amortization expense on intangible assets is shown in the income statement under research and development expenses. The Group has not recorded any impairment related to its intangible assets.

7.2.14.

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 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 net carrying value	**477**	**623**	**1,307**	**1,640**	**277**	**570**	**2**	**20**	**4,239**		**9,154**
Additions	194	311	4,807	1,323	126	896	0	80	1,216	285	9,240
Disposals	0	0	-18	-205	0	0	0	0	0	0	-223
Disposal depreciation	0	0	0	58	0	0	0	0	0	0	58
Depreciation charge of the period	-204	-302	-1,158	-502	-52	-310	-1	0	-1,456	0	-3,984
Transfers gross book value	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 net carrying value	**467**	**632**	**4,939**	**2,315**	**351**	**1,156**	**1**	**100**	**3,998**	**285**	**14,245**
As at 31 December 2015											
Cost	1,231	1,437	9,606	3,037	545	2,083	10	100	8,334	285	26,669
Accumulated depreciation	-764	-805	-4,666	-723	-194	-928	-9	0	-4,335	0	-12,424
Net carrying value	**467**	**632**	**4,939**	**2,315**	**351**	**1,156**	**1**	**100**	**3,998**	**285**	**14,245**
Opening net carrying value	**467**	**632**	**4,939**	**2,315**	**351**	**1,156**	**1**	**100**	**3,998**	**285**	**14,245**
Additions	387	465	1,001	839	135	1,982	284	8,494	0	949	14,535
Disposals	-26	0	0	-116	0	-1,629	-51	-72	0	-11	-1,905
Disposal depreciation	25	0	0	44	0	0	0	0	0	0	69
Depreciation charge of the period	-215	-314	-649	-685	-59	-387	-4	0	-1,459	-83	-3,855
Transfers gross book value	0	0	-3,978	0	0	0	0	5,176	-1,198	0	0
Transfers depreciations	0	0	0	0	0	0	0	0	0	0	0
Closing net carrying value	**639**	**783**	**1,313**	**2,396**	**426**	**1,121**	**230**	**13,698**	**1,342**	**1,140**	**23,089**
As at 31 December 2016											
Cost	1,592	1,902	6,628	3,760	680	2,436	243	13,698	7,136	1,223	39,299
Accumulated depreciation	-953	-1,119	-5,315	-1,364	-254	-1,315	-13	0	-5,794	-83	-16,210
Net carrying value	**639**	**783**	**1,313**	**2,396**	**426**	**1,121**	**230**	**13,698**	**1,342**	**1,140**	**23,089**

Assets held under lease relate to the Idylla™ semi-automated cartridge manufacturing line which was refinanced on 8 March 2013 via a EUR 7.9m sale and lease back. The net carrying value is EUR 1.3m as per 31 December 2016 (2015: EUR 2.8m). In 2015, the purchase option at the end of the lease period was decreased from EUR 0.2m to EUR 0.1m and the leasing period was extended (note 5.2.24).

The transfers from manufacturing equipment and assets held under lease to equipment under construction are all related to the cartridge production expansion. The upgrade of the current cartridge production line has a net carrying value of EUR 3.4m as per 31 December 2016 of which EUR 2.2m was invested in 2016. The total financial lease line granted is EUR 4.4m, of which EUR 3.4m was drawn per 31 December 2016. The purchase option amounts 1% of the invested amount. The second IdyllaTM cartridge production line that is built in Mechelen (Belgium) has a net carrying value of EUR 10.3m as per 31 December 2016 of which EUR 6.3m was invested in 2016. The total financial lease line granted is EUR 15m, of which EUR 11.2m was drawn per 31 December 2016.

Leasehold improvements relate to the cleanroom of the second cartridge manufacturing line which was refinanced via a EUR 2m sale and lease back.

7.2.15.

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 8.40% per 31 December 2016 because the Group did not participate in the additional capital increase of March 2016 in MyCartis NV. No impairment has been made per 31 December 2016.

	As of 31 December,	
In EUR000	2016	2015
Initial recognition amount	5,052	5,052
Total	**5,052**	**5,052**

7.2.16.

Deferred tax assets

Deferred taxes relate to the investment tax credit on research and development and amount to EUR 3.1m per 31 December 2016 (2015: EUR 2.0m).

	As of 31 December,	
In EUR000	2016	2015
Tax credit research and development	3,074	1,986
Other	16	0
Total	**3,090**	**1,986**

7.2.17.

Inventory

The inventory can be analyzed as follows:

	As of 31 December,	
In EUR000	2016	2015
Inventory		
Raw materials	4,881	2,379
Semi-finished products	1,151	190
Finished products	3,796	3,268
Total	**9,829**	**5,837**
Amount recognized as an expense	**-5,319**	**-2,642**

The inventory increase with approximately EUR 4 million is mainly driven by higher levels of raw materials and semi-finished products in view of the increased commercial cartridge volumes. Finished products include cartridges and systems held for expected commercialization, including systems placed under trial at customers under the Company's early adaptor program.

7.2.18.

Trade and other receivables

Trade and other receivables can be analyzed as follows:

	As of 31 December,	
In EUR000	**2016**	**2015**
Trade receivables	2,935	5,852
Allowance for doubtful receivables	0	0
Total	**2,935**	**5,852**

	As of 31 December,	
	2016	**2015**
VAT receivables	1,304	1,050
Other receivables	897	13
Total	**2,201**	**1,063**

Trade receivables have decreased from EUR 5.9 million per 31 December 2015 to EUR 2.9 million per 31 December 2016. The decrease of EUR 3 million results from large payments in 2016 from strategic collaboration partners such as JPNV and Amgen, and from the contract manufacturer organization related to the remaining Idylla™ systems inventory transfer in 2015.

At the reporting dates, the Group has approximately EUR 0.5 million trade and other receivables that were past due but were not impaired. In 2016 EUR 0.4 million of trade receivables were impaired, in 2015 no trade receivables were impaired.

The trade receivables from Merck account for 20% of the total trade receivable balance. The credit concentration risk is limited in view of the creditworthiness of these partners. Reference is made to note 7.2.29.3 for further detail.

The other receivables show an increase by EUR 0.3 million compared to 31 December 2015, which is explained by higher VAT receivables. In 2016, the Group was granted a new capital grant by IWT and STS which explains the increase in other receivables of EUR 0.9m.

7.2.19.

Other current assets

Other current assets can be analyzed as follows:

	As of 31 December,	
In EUR000	2016	2015
Accrued grant income	769	570
Other accrued income	6	80
Deferred charges	1,157	609
Total	**1,932**	**1,258**

Other current assets include accrued income mainly related to Flemish government grants from IWT for R&D projects totaling EUR 0.8 m (2015: 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.

7.2.20.

Cash and cash equivalents

The cash and cash equivalents can be analyzed as follows:

	As of 31 December,	
In EUR000	2016	2015
Cash and cash equivalents		
Cash at bank and on hand	82,046	102,587
Total cash and cash equivalents	82,046	102,587
Total restricted cash	1,200	1,500
Total cash and cash equivalents for cash flow purposes	**83,246**	**104,087**

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

7.2.21.

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 2015 and 31 December 2016 and of Biocartis SA as at 31 December 2013. The shares are fully paid up shares.

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

	Biocartis SA				Biocartis Group NV		
	Number of common shares issued and outstanding	Number of preferred F shares issued and outstanding	Share capital in '000 CHF	Share capital in'000 EUR	Number of common shares issued and outstanding	Number of preferred F shares issued and outstanding	Share capital in '000EUR
At 31 December 2013	**24,690,864**		**1,235**	**926**			
Capital increase by conversion reserves			37,036	30,487			
Capital decrease on 26 August 2014, in effect on 6 November 2014			-37,036	-30,487			
Share issue - Round F.1 at 29 August 2014		2,645,868	132	109			
Change in reporting entity							
Incorporation Biocartis Group NV at 24 November 2014 by contribution in kind	-18,812				16,992	1,820	153
Contribution in kind at 25 November	-24,672,052	-2,645,868			24,673,872	2,644,048	222,115
At 31 December 2014	**0**	**0**	**1,367**	**1,035**	**24,690,864**	**2,645,868**	**222,268**
Share issue - tranche 2 of round F on 15 January 2015						2,519,855	20,488
Share issue - contribution in kind of the participation in MyCartis on 15 January 2015					591,774		4,812
Capital increase by incorporation of share premium on 15 January 2015							8
Capital decrease by conversion into share premium on 13 April 2015							-247,272
Conversion preferred F shares into common shares on 28 April 2015					5,165,723	-5,165,723	
Share issue -Initial Public Offering on 28 April 2015					8,695,652		87
Share issue - exercise of over-allotment warrant on 19 May 2015					1,304,347		13
Share issue - exercise of stock options on 3 June 2015					21,000		0
Share issue - exercise of stock options on 6 October 2015					38,500		0
Share issue - exercise of stock options on 23 December 2015					36,328		0
At 31 December 2015	**0**	**0**	**1,367**	**1,035**	**40,544,188**	**0**	**405**
Share issue – exercise of stock options on 7 April 2016					45,000		
Capital increase – private placement 21 November 2016					4,058,917		41
At 31 December 2016	**0**	**0**	**1,367**	**1,035**	**44,648,105**	**0**	**446**

The following capital transactions took place at the Company from 1 January 2016 until 31 December 2016:

- On 7 April 2016, the Company raised EUR 0.4m following the exercise of 45,000 stock options. The amount is fully paid by an increase in share capital of EUR 0.00045m and an increase in share premium of EUR 0.4m.
- On 21 November 2016, the Company raised EUR 32.7m following a private placement, fully paid by an increase in share capital of EUR 0.041m and an increase in share premium of EUR 32,6m.

Capital increase expenses

The Group has incurred EUR 1.6m expenses in connection with the capital increase of 21 November 2016, consisting of underwriting fees, legal costs and share registration and other regulatory costs. These costs are fully attributable to the issuance of the new shares and were entirely deducted from the funds raised.

Option to acquire shares in the Company

On 15 August 2011, at the occasion of the IdyllaTM-Enrich technology acquisition, Philips, a shareholder of the Company, has been granted two conversion options, of which one remains outstanding per 31 December 2016. This option foresees that the Company can, at its sole discretion, grant Philips the right to convert all or part of the future payments that Biocartis is required to make under this agreement (including milestone, royalties and other revenue sharing payments) into common shares of the Company. This right is limited to a maximum of 10% of the then outstanding capital of the Company on a fully diluted post-money basis. This option ends on 31 December 2018. However, the Company is also contractually able to replace future royalty and revenue sharing payments by a lump sum payment to Philips, reducing the above conversion option.

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.

7.2.22.

Share based compensation

The table below provides an overview of the movement in stock options since 1 January 2015:

		SOP 2008	SOP 2013	SOP 2015	SOP WHC	Total
Total outstanding at 31 December 2014		**94,362**	**720,340**			**814,702**
Options granted	+		30,000	72,500	100,000	202,500
Options exercised	-	26,660	95,828			122,488
Options forfeited	-				33,000	33,000
Options cancelled	-					
Total outstanding at 31 December 2015		**67,702**	**654,512**	**72,500**	**67,000**	**861,714**
Options granted	+			160,000		160,000
Options exercised	-	25,601	45,000			70,601
Options forfeited	-		20,221		67,000	87,221
Options cancelled	-					
Total outstanding at 31 December 2016		**42,101**	**589,291**	**232,500**	**0**	**863,892**

ESOP 2008

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 25,601 options were exercised in 2016 at CHF 4.14 exercise price (rounded) and a weighted average share price of EUR 11.53 at the moment of the exercise of the options. A total of 42,101 options are still outstanding per 31 December 2016. The weighted average remaining contractual life is 2.8 years.

The key terms of the SOP 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.

ESOP 2013

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 750,340 options were granted per 31 December 2016.

In total 45,000 options were exercised in 2016 at an exercise price of EUR 8.1309 with a weighted average share price of EUR 10.90 at the moment of the exercise of the options. In 2016 20,221 options were forfeited.

A total of 589,291 options are still outstanding per 31 December 2016 of which 559,291 options have an exercise price of EUR 8.1309 and 30,000 options have an exercise price of EUR 13.28. The weighted average remaining contractual life is 3.8 years.

The key terms of the SOP 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
Number of warrants granted	680,340	20,000	20,000	30,000
Number of warrants not vested at 31/12/2015	27,935	7,514	10,848	18,976
Exercise price	EUR 8.13	EUR 8.13	EUR 8.13	EUR 13.28
Expected dividend yield	0	0	0	0
Expected stock price volatility	25%	30%	30%	31%
Risk-free interest rate	0.7%	0.2%	0.1%	0.1%
Expected duration	3.5 years	2.8 years	2.6 years	2.3 years
Forfeiture rate	0%	0%	0%	0%
Fair value	EUR 1.78	EUR 1.87	EUR 1.56	EUR 2.70

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).

ESOP 2015

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 160,000 options were granted in 2016 at weighted average exercise price of EUR 9.98. No options were exercised and 232,500 options are outstanding per 31 December 2016. The weighted average remaining contractual life is 6.2 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
Number of warrants granted	72,500	10,000	62,500	15,000	10,000	62,500
Number of warrants not vested at 31/12/2016	47,092	6,880	50,782	0	9,168	61,198
Exercise price	€ 13.28	€ 12.77	€ 11.52	€ 9.72	€ 7.25	€ 8.50
Expected dividend yield	0	0	0	0	0	0
Expected stock price volatility	31%	34%	36%	36%	38%	38%
Risk-free interest rate	0.5%	0.8%	0.4%	0.4%	0.7%	0.9%
Expected duration	3.4 years	4.6 years	4.6 years	4.5 years	4.4 years	4.2 years
Forfeiture rate	0%	0%	0%	0%	0%	0%
Fair value	€ 3.29	€ 3.85	€ 4.13	€ 2.08	€ 2.52	€ 2.74

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).

WHC Warrants

In execution of a decision of the board of directors of Biocartis SA of 24 April 2014, 100,000 options on shares of the Company were granted by the Company to Whitemarsh Capital LLC, a commercial partner of the Company that assists in brokering agreements for the Company with US governmental institutions for the payment of its products. On 25 November 2014, the option grant was rolled up in order to relate to the Company and the Company's shares instead of shares in Biocartis SA. The options, called "WHC Warrants", were formally granted by an award letter on 14 April 2015. In the first half of 2015, 33,000 options were forfeited. The remaining 67,000 options were forfeited in 2016. No share-based compensation was recorded as per 31 December 2016.

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 EUR000	2016	2015
share based compensation	371	179
Total	**371**	**179**

7.2.23.

Defined Benefit Plans

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.

With the change in the law in December 2015, there was no longer a reason not to apply the PUC method. However, because of the late law change in and impact of applying the PUC method was estimated to be immaterial, the Company decided to only apply the PUC method in 2016.

	As of 31 December	
In EUR000	2016	2015
Provisions for pensions and similar obligations	47	0
Total	**47**	**0**

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 2015	**0**
Service cost	612
Pension expense/income	-4
Company contributions	-590
Benefits paid/ Transfer	0
Actuarial gains/losses	28
As per 31 December 2016	**47**

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

	2016
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:

	2016
Discount rate + 0.5%	40
Discount rate - 0.5%	-4

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

The weighted average duration of the plan until retirement age is 21.5 years.

The pension plan contains 219 active and 101 passive affiliates.

7.2.24.

Financial Debt

The financial debt can be analyzed as follows:

	As of 31 December,	
In EUR000	2016	2015
PMV & FPIM	15,263	0
Lease company	12,022	2,120
Bank	425	542
Total non-current	**27,709**	**2,662**
PMV & FPIM	0	7,176
Lease company	3,581	918
Bank	118	58
Total current	**3,698**	**8,152**

In 2010, The Group was granted a loan facility for a total amount of EUR 5.0m by PMV (Participatie Maatschappij Vlaanderen), a shareholder of the Company, bearing an interest rate of 7%. The interest on the loan was capitalized until the maturity date. The loan was fully repaid end of 2016.

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, of which EUR 3.4m was drawn per 31 December 2016. The interest applicable for this leasing facility equals currently 1.69% and will be fixed when the entire investment package is drawn. The leasing includes a purchase option of 1% of the financed amount.

In 2016, Biocartis NV and the Company obtained a new lease financing facility for the development of a second cartridge production line in Mechelen, for EUR 15 million, provided by a lease company, of which EUR 11.2 million was drawn per 31 December 2016. The interest applicable for this leasing facility equals 1.77% and the leasing includes a purchase option of 1% of the financed amount. As a security, the existing debt service reserve account of EUR 1.2m is also applicable.

In 2016, Biocartis NV and the Company also obtained a new 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 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 year-end. The agreement contains a set of business covenants which require, to obtain the lenders' approval for certain major transactions outside the ordinary course of business.

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

Loan	Year	Nominal amount (in EUR000)	Secured (s) Non secured (ns)	Interest rate	Maturity date
PMV	2010	5,000	Ns	7.00%	31/12/2016
KBC Lease	2013	7,910	S	3.35%	31/05/2021
KBC Lease	2015	3,372	S	1.69%	1/12/2021
KBC Bank	2015	600	S	1.93%	1/06/2021
KBC Lease	2016	11,212	S	1.77%	1/12/2021
PMV	2016	7,500	S	7.00%	30/09/2021
FPIM	2016	7,500	S	7.00%	30/09/2021

In July 2016, the Group also obtained a EUR 25 million credit line facility from a bank to strengthen the Company's financial position and to continue the execution of the strategic plan. The credit line facility consists of a EUR 10 million working capital credit line and of a EUR 15 million roll over credit line. These facilities are 50% guaranteed by the Flemish Guarantee Fund Gigarant. As per 31 December 2016, no withdrawals have been made by the Company on this facility.

In addition, the Group also has access to a bank guarantee line of EUR 0.5 million of which EUR 0.5 million has been taken up for rental guarantees as per 31 December 2016, and an credit line with a bank of EUR 0.6 million for currency hedging, of which EUR 0 million has been taken up as per 31 December 2016.

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 EUR000	2016		2015	
	Minimum lease payments	Present value of minimum lease payments	Minimum lease payments	Present value of minimum lease payments
Financial lease				
< 1 year	3,829	3,581	975	918
>1 and < 5 years	12,450	12,022	1,972	1,893
> 5 years	0	0	229	227
Total	**16,279**	**15,603**	**3,177**	**3,038**
less interests	-676		-138	
Present value	**15,603**	**15,603**	**3,038**	**3,038**

The net carrying value of the related leased assets amounts to EUR 13.7m at 31 December 2016 (2015: EUR 4.0m).

7.2.25.

Trade payables and other current liabilities

Trade payables have decreased from EUR 13.9 million per 31 December 2015 to EUR 6.3 million per 31 December 2016. This is mainly explained by the payment of advance payment invoices related to the second cartridge production line.

	As of 31 December	
In EUR000	2016	2015
Trade payables	6,293	13,927
Total trade payables	**6,293**	**13,927**

The other current liabilities show an increase by EUR 0.7 million compared to 31 December 2015, which is explained by a higher provision for vacation pay, due to a higher number of average FTE's and a higher provision for bonuses.

	As of 31 December,	
In EUR000	2016	2015
Provision vacation pay	2,357	1,884
Other social debt	563	15
VAT payable	4	0
Other	30	88
Total other current liabilities	**2,954**	**1,986**

7.2.26.

Deferred income

	As of 31 December,	
In EUR000	2016	2015
Grants	268	47
Partner income	1,837	5,107
Total	**2,106**	**5,154**
current	1,963	3,812
non-current	142	1,342

Deferred partner income includes upfront payments from Amgen Inc. and upfront payments received from JPNV in relation to the strategic licensing, development and commercialization collaborations. Most of these upfront payments were recognized in 2016, which explains the decrease in deferred partner income with EUR 3.2m. The remaining amount will be recognized as collaboration revenue in the following year.

	Deferred partner income
As per 31 December 2014	**9,559**
Invoiced	574
recognized in profit or loss	-5,025
As per 31 December 2015	**5,107**
Invoiced	1,668
recognized in profit or loss	-4,939
As per 31 December 2016	**1,837**

7.2.27.

Accrued Expenses

Accrued expenses primarily include accruals for rental charges.

7.2.28.

Taxes

7.2.28.1

Composition of tax expense

	Years ended 31 December,	
In EUR000	2016	2015
Current tax	114	391
Deferred tax	-1,094	-1,039
Income tax expense (profit)	**-980**	**-648**

7.2.28.2

Tax reconciliation

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

	Years ended 31 December,	
In EUR000	2016	2015
Loss before taxes	**-50,757**	**-40,445**
Income tax credit calculated at 33,99%	-17,253	-13,747
Effect of different tax rates	3	24
Effect of income that is exempt from taxation	-4,331	-6,684
Effect of expenses that are non-deductible in determining tax profit	428	284
Effect of unused tax losses and tax offsets not recognized as deferred tax assets	21,152	20,124
Effect of tax credit for research and development	-1,088	-1,039
Effect of capital tax in Biocartis SA	114	104
Other	-6	0
	-980	-935
Adjustments recognized in the current year in relation to the current tax of prior years	0	287
Income tax expense (profit) recognized in loss for the period	**-980**	**-648**

7.2.28.3

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 194,8m (2015: EUR 133.8m). The tax losses related to Biocartis SA amount to EUR 39.1m in 2016 (2015: EUR 39.2m) with the following expiration years. Each annual tax loss expires seven years after the fiscal period it has been realized.

The tax losses of Biocartis NV for EUR 146.4m per 31 December 2016 (2015: EUR 84.7m) in Belgium will not expire as they can be carried forward indefinitely.

in EUR000	Tax losses	Expiry year
	7,751	2019
	30,574	2020
	753	2022
	39,078	

7.2.28.4

Recognized deferred tax assets

The Group has R&D tax credit carry-forwards in Belgium for a total amount of EUR 3.1m (2015: EUR 2.0m) for which a deferred tax asset of EUR 3.1m (2015: EUR 2.0m) has been recognized as the recognition criteria have been met as from 2014.

7.2.29. Financial risk management

7.2.29.1

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.

7.2.29.2

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.

7.2.29.3

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 2016 and 2015.

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

In EUR000	As of 31 December 2016	2015
Liabilities		
CHF – Switzerland	7	248
USD - United States	112	193
GBP - Great Britain	5	117
Assets		
CHF - Switzerland	50	88
USD - United States	262	624
GBP - Great Britain	57	58

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 2016:

In EUR000	As of 31 December 2016	2015
Carrying value		
Merck	648	60
VAT receivable	1,300	1,050
Capital grant	897	0
Other trade and other receivables	2,290	5,804
	5,135	6,914

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 balance sheet 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 two credit lines with one financial institution of EUR 1.1m (2015: EUR 1.1m) mainly being used for investments and bank guarantees. As per 31 December 2016, the credit lines were used for EUR 0.5m (2015: EUR 1.1m). In July 2016 the Group also obtained a EUR 15 million roll over credit line, which is part of the EUR 25 million credit line facility as mentioned in note 1.2.24.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 maturities of financial liabilities at 31 December is as follows (amounts in EUR000):

	As of 31 December,					
	2016			2015		
In EUR000	Trade payables	financial debt	other current liabilities and accrued expense	Trade payables	financial debt	other current liabilities and accrued expense
Less than 1 month	6,293	305	2,954	13,927	99	1,986
1-3 months		612			126	
3 months to 1 year		2,781			7,927	
1-5 years		27,709	715		2,377	632
5+ years		0	894		285	948
Total	**6,293**	**31,407**	**4,563**	**13,927**	**10,815**	**3,566**

7.2.30.

Fair value

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

- The carrying value 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 value on 31 December 2016 and 2015.
- The fair value of the participation in MyCartis is not significantly different than its carrying value on 31 December 2016 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 value of current liabilities approximates their fair value due to the short term character of these instruments;
- Loans and borrowings are evaluated based on their interest rates and maturity date. Most interest bearing debts have fixed interest rates and its 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 2016 and 2015.

	Carrying value		Fair value	
In EUR000	2016	2015	2016	2015
Available for sale financial assets				
Participating interest	5,052	5,052	5,052	5,052
Total available for sale financial assets	**5,052**	**5,052**	**5,052**	**5,052**
Loans and receivables measured at amortized cost				
Trade and other receivables (current)	5,518	6,914	5,518	6,914
Other long term receivables	11	11	11	11
Other current assets	1,932	1,258	1,932	1,258
Total loans and other receivables	**7,461**	**8,183**	**7,461**	**8,183**
Cash & cash equivalents				
cash & cash equivalents	83,246	104,087	83,246	104,087
Total cash & cash equivalents	**83,246**	**104,087**	**83,246**	**104,087**
Financial liabilities measured at amortized cost				
Loans & Borrowings	31,407	10,815	34,979	11,171
Trade payables	6,293	13,927	6,293	13,927
Other liabilities and accrued charges	4,563	3,566	4,563	3,566
Total financial liabilities measured at amortized cost	**42,264**	**28,308**	**45,835**	**28,664**

7.2.31.

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.

Phillips option

Under contractual conditions, payments (milestone payment, royalties and other revenue sharing payments) may arise in the future to Philips, a shareholder of the Company. These payments may – at the sole discretion of the Group - be converted into common shares of the Company following the conversion option granted to Philips.

7.2.32.

Commitments

7.2.32.1

Capital commitments

Commitments related to capital expenditures at the balance sheet date are as follows:

	As of 31 December,	
In EUR000	2016	2015
ICT software	37	31
ICT equipment	3	14
Laboratory equipment	434	443
Manufacturing equipment	59	11,866
Furniture and fixtures	16	40
Leasehold improvements	106	106
Equipment under construction	6,307	0
Assets held under Lease	0	3,184
Total	**6,962**	**15,684**

Capital commitments relate to the upgrade of the current cartridge production line and the investment in the second cartridge production line. Both are located in Mechelen (Belgium) for which the Group is engaged in several contractual arrangements with specified suppliers. The Group had no other material commitments to capital expenditures on 31 December 2016.

7.2.32.2

Operating commitments

The Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 2.5m. It is expected that the majority of the commitments will be fulfilled in 2017.

7.2.32.3

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 employee cars for which the average lease term is 48 months.

The breakdown of the Group's committed future payments as per 31 December 2016 under its leasing contracts per nature and maturity is summarized in the table below.

In line with the rental/lease agreements, a total amount of EUR 0.5m (2015: EUR 0.5m) in bank guarantees has been provided.

In EUR000	As of 31 December			
	2016		2015	
	Rent/Lease facilities	Car Lease	Rent/Lease facilities	Car Lease
not later than 1 year	1,588	1,066	1,297	921
more than 1 year and less than 5 years	5,226	1,712	5,811	1,716
more than 5 years	5,539	0	3,770	0
Total	**12,353**	**2,778**	**10,878**	**2,636**

In EUR000	As of 31 December	
	2016	2015
Payments recognized as an expense		
minimum lease payments	1,528	2,112
Total	**1,528**	**2,112**

7.2.33.

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.

7.2.33.1

Remuneration of key management

Remuneration of key management consists of the directors and the members of the executive management team.

	Years ended 31 December	
In EUR000	2016	2015
Short-term employee benefits (salaries, social security bonuses and fringe benefits)	2,447	1,834
Post -employment benefits (Group insurance)	68	17
Share based payment	278	122
Total	**2,793**	**1,973**

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 2016 and 2015 under the ESOP 2013 and 2015 plan, the roll forward of the options granted to key management is included in the remuneration report.

7.2.33.2

Subsidiaries

Details of the Company's subsidiaries at 31 December 2016 are as follows:

Name of subsidiary	Principal activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2016	2015
Biocartis SA	Intermediate holding company	Scientific Parc EPFL, PSE-C 1015 Lausanne, Switzerland	100%	100%
Biocartis NV	Develop and market diagnostic platforms	Generaal De Wittelaan 11 B - 2800 Mechelen, Belgium	99.99%*	99.99%*
Biocartis BV	Develop and market diagnostic platforms	High Tech Campus 9 PO Box 775 NL - 5600 AT Eindhoven, The Netherlands	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 IdyllaTM cartridge manufacturing line. This debt service reserve account has a carrying value of EUR 1.2m and is reflected under cash and cash equivalents.

7.2.34.

Events after the balance sheet date

Four important events were announced after the reporting date.

- **Companion diagnostics (CDx)** – In January 2017, Biocartis signed a first companion diagnostics partnership with an undisclosed pharmaceutical company (ranked amongst the global top 10 pharmaceutical companies by sales) for the joint development of an Idylla™ CDx test for an undisclosed phase II oncology compound.
- **Launch of the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Test** – On 2 March 2017, Biocartis launched the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (RUO[67]), an important milestone in the partnership with Merck[68] as well as the Company's third liquid biopsy test for oncology.
- **Change CEO position** – On 2 March 2017, Biocartis announced a change in the CEO position of the Company.
- **Grant for the development of MSI Test** – On 15 March 2017, Biocartis announced to have received an approximately EUR 750k grant from VLAIO, the Flanders organization for Innovation & Entrepreneurship, for the development of a fully automated MSI test on the Idylla™ platform.

There were no further important events between 31 December 2016 and the approval date of this annual report.

[67] Research Use Only.

[68] Merck KGaA, Darmstadt, Germany.

7.2.35.

Standards and interpretations published, but not yet applicable for the annual period beginning on 1 January 2016

- IFRS 9 Financial Instruments and subsequent amendments (applicable for annual periods beginning on or after 1 January 2018)
- IFRS 14 Regulatory Deferral Accounts (applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- IFRS 15 Revenue from Contracts with Customers (applicable for annual periods beginning on or after 1 January 2018)
- IFRS 16 Leases (applicable for annual periods beginning on or after 1 January 2019, but not yet endorsed in EU)
- Improvement to IFRS (2014-2016) (applicable for annual periods beginning on or after 1 January 2017 or 2018, but not yet endorsed in the EU)
- Amendments to IFRS 2 Classification and Measurement of Share-based Payment Transactions (applicable for annual periods beginning on or after 1 January 2018, but not yet endorsed in EU)
- 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, but not yet endorsed in the EU)
- Amendments to IFRS 10 and IAS 28 Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (the effective date has been deferred indefinitely, and therefore the endorsement in EU has been postponed)
- Amendments to IAS 7 Statement of Cash Flows – Disclosure Initiative (applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed in EU)
- Amendments to IAS 12 Income Taxes – Recognition of Deferred Tax Assets for Unrealized Losses (applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed in EU)
- Amendments to IAS 40 Transfers of Investment Property (applicable for annual periods beginning on or after 1 January 2018, but not yet endorsed in the EU)
- IFRIC 22 Foreign Currency Transactions and Advance Consideration (applicable for annual periods beginning on or after 1 January 2018, but not yet endorsed in the EU)

The impact of the initial application of IFRS 16 is that generally all operating leases will have to be reflected in the statement of financial position.

IFRS 15 Revenue from Contracts with Customers

IFRS 15 specifies how and when a company will recognize revenue as well as requiring such 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

IFRS 15 was issued in May 2014 and 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. IFRS 15 is applicable for annual period beginning on or after 1 January 2018 and is subject to endorsement by the European Union.

The management of the Group has investigated the impact of the initial application of IFRS 15 and concluded that the application will not have a significant impact on the timing or value of the Group's revenue.

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 to be potentially impacted:

Product related income:

Under its reagent rental contracts, the Group bundles the following multiple elements together: the use of the Idylla™ system (including servicing) and the consumption of Idylla™ cartridges. 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. As explained in 7.2.2.15 Revenue Recognition, the total Idylla™ cartridge price includes a cost for the use of the Idylla™ system by the customer. The revenue for the Group for the use of the Idylla™ system is considered a distinct performance obligation and is individualized based on a fair market price allocation towards the different parts of the Idylla™ system, which are the Idylla™ instrument, the Idylla™ console and the servicing of the IdyllaTM system. Customers are invoiced based on received sales orders for Idylla™ cartridges. Revenue for each distinct element will only be recognized when both the Idylla™ system is delivered to the customer, as control is passed, and in accordance with the actual Idylla™ cartridge delivery, when the variable revenue is earned. As such, no variable consideration is recognized upon delivery of the Idylla™ system taking into account the constraining estimates of variable consideration. The fair market price allocation is based on the Group's internal pricing calculation used by the Group's sales organization to prepare quotations so that each element is adequately priced in line with stand-alone selling prices. The Group currently does not apply variable considerations such as retro-active volume discounts which could result in a refund and consequently a revenue reversal. Contractual price modifications are only adopted prospectively. The Group only applies fixed price discounts as from the start of the contract, individualized for each distinct element taking into account the following observable evidence: customer segmentation such as customer size and country specific market dynamics such as government reimbursement policies.

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.

Collaboration revenue:

Under its research and development collaboration contracts, the Group may also bundle multiple elements together: upfront license fees, contingent milestone payments and research and development services. As explained in 7.2.2.14 Revenue Recognition, the revenue for the Group for each distinct element is individualized based on a fair market price allocation towards the distinct performance obligations. Revenue is recognized when the performance obligations are me

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 will have no significant impact on the Group's financial reporting since the fair market allocation principles have already being applied since the commercial launch of Idylla™ in September 2014.

The Group will effectively apply IFRS 15 as of 1 January 2018. Any possible impact from further analysis will be accounted for by the cumulative catch-up transition method.

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.

CHAPTER 8

Statutory Annual Accounts

8.1.

Abbreviated statutory annual accounts

The Annual Accounts of Biocartis Group NV are presented in an abbreviated form. The annual report, the full annual accounts and the opinion of the statutory auditor are deposited at the National Bank of Belgium. On request a copy of these documents can be obtained. There is also an electronic version of the full Statutory Annual Report which can be obtained via the internet from the Biocartis website (www.biocartis.com).

The statutory financial statements as filed with the Belgian National Bank are based upon Belgian GAAP.

8.2.

Activity Biocartis Group NV

Biocartis Group NV was incorporated on 24 November 2014 and became – after the contribution in kind of Biocartis SA and her subsidiaries - on 25 November 2014 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.

8.3.

Income statement and balance sheet Biocartis Group NV

Income Statement

	Years ended 31 December,	
In EUR000	2016	2015
Revenues	3,348	1,709
Other operating income	70	20
Total operating income	**3,418**	**1,729**
Services and other goods	-1,319	-2,600
Salaries, social security contributions and pensions	-1,981	-988
Other operating expenses	-3	
Operating expenses	**-3,304**	**-3,588**
Financial income	1,037	450
Financial expenses	-2,023	-7,750
Result from continuing operations	**-871**	**-9,159**
Income taxes	-17	-18
Net result	**-889**	**-9,175**

Balance Sheet

In EUR000	As of 31 December 2016	2015
Financial fixed assets	227,320	227,320
Non-current assets	**227,320**	**227,320**
Trade receivables	21	-
Other receivables	107,592	54,746
Cash and cash equivalents	68,627	80,904
Transitory accounts	49	66
Current assets	**176,289**	**135,716**
Total assets	**403,609**	**363,036**
Legal share capital	446	405
Share premium	397,205	364,206
Accumulated deficit	-10,064	-9,175
Total equity	**387,588**	**355,436**
Financial debt	15,263	-
Non-current liabilities	**15,263**	-
Financial debt	-	7,176
Trade payables	348	320
Provision taxes	258	-
Salaries, social security contributions and pensions	153	104
Current liabilities	**759**	**7,600**
Total equity and liabilities	**403,609**	**363,036**

8.4.

Discussion of statutory accounts

Income statement

Total operating income in 2016 amounted to EUR 3.4m (2015: EUR 1.7m) and consists mainly of expense recharges to the Biocartis Group NV subsidiaries. Operating expenses recorded in the period under review amounted to EUR 3.3m (2015 EUR 3.6m) and consist of salaries, social security contributions and pensions expenses for EUR 2.0m (2015: EUR 1.0m) and of expenses for services and other goods of EUR 1.3m (2015: EUR 2.6m). Services and other goods mainly consist of recurring general and administrative expenses.

Financial income amounted to EUR 1m (2015: EUR 0.5m) 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 2.0m (2015: EUR 7.8m) and relate to the non-recurring expenses made in relation of the capital increases of Biocartis NV in November 2016 for EUR 1.6m (April 2015: EUR 7.3m) and interest charges on the PMV loan.

The net result after taxes for the period ended 31 December 2016 amounts to EUR 0.9m (2015: EUR 9.2m)

Balance sheet

Assets

The financial fixed assets consist of shares in the Biocartis Group NV subsidiaries for EUR 222.3m and a financial participation in a third party company MyCartis NV for EUR 5.1m.

Other receivables amounted to EUR 107.6m (2015: EUR 54.7m) and mainly relate to receivables on the Biocartis Group NV subsidiaries, mainly related to financial advances. Cash and equivalents amounted to EUR 68.6m per 31 December 2016 (2015: EUR 80.9m). Deferred charges relate to prepaid expenses.

Equity

Total equity per 31 December 2016 amounted to EUR 387.6m (2015: EUR 355.4m) and the legal share capital and share premium amount to respectively EUR 0.4m (2015: EUR 0.4m) and EUR 397.2m (2015: EUR 364.2m)

Following movements in equity were recorded during the reporting period:

- Capital increase following the execution of stock options of 7 April 2016 for an amount of EUR 450. The share premium account was increased with EUR 365,441.
- Capital increase on 21 November 2016 for an amount of EUR 40,589. The share premium account was increased with EUR 32,633,693

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.

As per 31 December 2015, financial debt comprised of a loan from Participatie Maatschappij Vlaanderen (PMV) of EUR 7.2m consisting of EUR 5m nominal amount and EUR 2.2m accrued interests. The loan was fully repaid by the end of 2016.

Other liabilities

As per 31 December 2016, trade payables amounted to EUR 0.3m (2015: EUR 0.3m), provision for taxes to EUR 0.3m (2015: EUR 0m) and payables for salaries, social security contributions and pensions to EUR 0.2m (2015: EUR 0.1m).

Total assets and liabilities

Total assets and on the other hand total liabilities amounted per 31 December 2016 to EUR 403.6m (2015: EUR 363.0m).

8.5.

Appropriation of results

The statutory accounts of the Company reported a net loss of EUR -0.9m for the year 2016. The Board of Directors proposes to carry forward the statutory net loss of EUR -0.9m of 2016 to the following financial year.

8.6.

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 April 2016, Biocartis Group NV raised EUR 0.4 m and furthermore the Company raised EUR 33 m in the context of a private placement in November 2016, both through the issuance of new shares. Taken into account the strong cash position of the Company at the end of 2016 as well as the expectations for 2017, 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 2018, and thus that the application of the valuation rules going concern is justified.

CHAPTER 9

Auditor's Report

Statutory auditor's report to the shareholders' meeting on the consolidated financial statements for the year ended 31 December 2016

The original text of this report is in Dutch

As required by law, we report to you in the context of our appointment as the company's statutory auditor. This report includes our report on the consolidated financial statements together with our report on other legal and regulatory requirements. These consolidated financial statements comprise the consolidated balance sheet at 31 December 2016, 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.

Report on the consolidated financial statements – Unqualified opinion

We have audited the consolidated financial statements of Biocartis Group NV ("the company") and its subsidiaries (jointly "the group"), prepared in accordance with International Financial Reporting Standards as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium. The consolidated balance sheet shows total assets of 141,305 (000) EUR and the consolidated income statement shows a consolidated loss (group share) for the year then ended of 49,777 (000) EUR.

Board of directors' responsibility for the preparation of the consolidated financial statements

The board of directors is responsible for the preparation and fair presentation of 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.

Statutory auditor's responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing (ISA). Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the statutory auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the statutory auditor considers internal control relevant to the group's preparation

and fair presentation of consolidated financial statements 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. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the board of directors, as well as evaluating the overall presentation of the consolidated financial statements. We have obtained from the group's officials and the board of directors the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Unqualified opinion

In our opinion, the consolidated financial statements of Biocartis Group NV give a true and fair view of the group's net equity and financial position as of 31 December 2016, and of its results and its cash flows for the year then ended, in accordance with International Financial Reporting Standards as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

Report on other legal and regulatory requirements

The board of directors is responsible for the preparation and the content of the directors' report on the consolidated financial statements.

As part of our mandate and in accordance with the Belgian standard complementary to the International Standards on Auditing applicable in Belgium, our responsibility is to verify, in all material respects, compliance with certain legal and regulatory requirements. On this basis, we make the following additional statement, which does not modify the scope of our opinion on the consolidated financial statements:

The directors' report on the consolidated financial statements includes the information required by law, is consistent with the consolidated financial statements and is free from material inconsistencies with the information that we became aware of during the performance of our mandate.

Zaventem, 21 March 2017

The statutory auditor

DELOITTE Bedrijfsrevisoren / Reviseurs d'Entreprises

BV o.v.v.e. CVBA / SC s.f.d. SCRL

Represented by Gert Vanhees

CHAPTER 10

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.

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.

Biopsy (solid/liquid)

The Idylla™ platform is capable of processing both solid biopsies (FFPE tissue which is the standard tissue type for solid tumour 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.

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 favourably 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.

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.
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.
Sepsis	Severe overall inflammatory response of the body to an infection..


High precision diagnostics for personalized medicine
See how you can
guide the path
her cancer takes
Sample-to-result within 2 hours
idylla
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idylla

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