BIOCARTIS

2017

Annual report

Contents

CHAPTER 1

Biocartis Group

1.1 / At a glance

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, with a focus on oncology.

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

- Listed on Euronext Brussels, ticker BCART
- Headquartered in Belgium (Mechelen)
- US R&D center
- 318 employees
- Active in over 70 countries worldwide

1.2 / Message from the Chairman and CEO

Reflections on 2017 and looking ahead on 2018

"2017 was a year of transition for Biocartis, building further momentum in our commercialization efforts with the aim to support the global roll-out and adoption of the Idylla™ platform. Most important in that respect was the strategic decision in March 2017 to focus our own resources on oncology, driven by a strong traction in that market, and to seek accelerated Idylla™ test menu expansion through partnerships with pharma companies, co-development partners and third-party diagnostic test providers. The collaborations that we signed in 2017 as part of this strategy, generated substantial income on top of a strong product revenue growth. Another key event was the successful preparation for and launch of the Idylla™ platform in the US. Gaining commercial traction in that market will be an important revenue driver for our company going forward and will make Biocartis an even more attractive partner for pharmaceutical companies and diagnostic test content providers. As we continue to enjoy extremely positive feedback from our customers and partners on the quality and performance of the Idylla™ platform, I look forward to working with the team on executing our plans for 2018 which is poised to be another thrilling year for Biocartis!"

Herman Verrelst, CEO Biocartis

Executing on strategy with a focus on oncology

Oncology MDx represents approx. 19% of the global USD 6.5bn[1] MDx market and is the fastest growing segment with an expected annual growth rate of 26% per annum (doubling of market) to 2020[2]. It is the unique positioning of the Idylla™ technology in combination with the fast-growing nature of the market that led the company to decide to focus its own resources on the oncology market and to further accelerate menu expansion through partnerships. Those partnerships are aimed at joining forces with pharmaceutical companies and third party diagnostic test providers that need rapid and reproducible diagnostic solutions allowing for a global roll-out of their products, but also on R&D partners that want to innovate within the MDx market, using Idylla™'s unique features. Biocartis made important steps on this front in 2017 with the expansion of our activities with Merck KGaA (Darmstadt, Germany) and Amgen, as well as the entering of the breast cancer domain with three test development partnerships, with A*STAR, LifeArc and Genomic Health Inc. Partnerships are an essential part of our menu expansion strategy and we are on a continuous basis seeking to add strong partners to our platform that will support its further roll-out.

Initiating development of a breast cancer test menu

Breast cancer is the most common cancer among women worldwide and the largest segment of the cancer diagnostics market, expected to equal to USD 13.1bn by 2020[3]. Today, an increasing number of targeted and hormone therapies is driving the demand for tests that guide therapy selection. Biocartis was excited to initiate the development of its test menu for this promising market by renewing its partnership with ETPL[4] and by signing new collaborations with LifeArc (formerly known as MRC Technology) and Genomic Health Inc. Under these partnerships, parts of the development work are executed by and financed through our partners. This allows Biocartis to further scale its R&D organization. Additionally, taking the example of the Genomic Health partnership, enabling premium tests such as the Oncotype DX Breast Recurrence Score®, the only test proven to predict chemotherapy benefit and included in all major cancer guidelines worldwide, further increases the overall attractiveness of the Idylla™ platform. We see our approach within breast cancer as an operational blueprint that we will roll-out in other oncology areas.

Continued expansion in colorectal cancer and lung cancer test menus

In 2017, Biocartis further grew its oncology menu. In colorectal cancer, by year-end of 2017 Biocartis offered three CE-marked solid biopsy tests (together detecting 44 mutations directly from a slice of FFPE tumor tissue each) and two liquid biopsy tests (together targeting 44 mutations and each working directly on 1 ml of blood plasma with less than one minute hands-on time), now allowing to further improve the health outcome of mCRC patients. In lung cancer, the Idylla™ EGFR Mutation Test launch as a CE-marked IVD test in June 2017 was another important landmark. This test allows the detection of 51 EGFR mutations directly from only one slice of FFPE tissue, in contrast with traditional EGFR testing methods that often require up to six or more tumor slices, and delivers results in approx. 2.5 hours with less than two minutes hands-on time.

US commercialization launched

In the second half of 2017, we commercially launched the Idylla™ platform on the US market. Our distribution agreement with Thermo Fisher Scientific Inc. as well as own sales efforts led to first sales in the US in H2 2017. Additionally, we made first strides to develop a Key Opinion Leader network in the US. This lead to the presentation of first excellent Idylla™ performance data during the Biocartis workshop at the annual Association for Molecular Pathology (AMP) meeting in November 2017. Dr. Gregory Tsongalis from the Dartmouth Hitchcock Medical Center, which Biocartis is proud to count among one of its first US customers, presented results from an internal study, demonstrating excellent performance of the Idylla™ KRAS, NRAS and BRAF tests in terms sensitivity, specificity and predictive value compared to the internal Standard of Care methods at the Dartmouth Hitchcock Medical Center, in this case a Next-Generation Sequencing (NGS) technology. The confirmation that the Idylla™ platform and its assays are attractive to any US lab looking for rapid, easy and accurate molecular testing, puts us in higher gear to realized our full potential in this exciting new market.

[1] MarketsandMarkets: Molecular Diagnostics Market, Global Forecast to 2021 (November 2015).
[2] Berenberg research
[3] Source: GrandView Research, "Cancer Diagnostics Market Analysis By Type (Laboratory Tests, Genetic Tests, Imaging, Endoscopy), By Application (Breast, Lung, Liver, Cervical, Colorectal, Skin), By Region, And Segment Forecasts, 2014 – 2025", http://www.grandviewresearch.com/industry-analysis/cancer-diagnostics-market, last consulted on 15 May 2017
[4] The commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research

Strong cash position secured

We successfully raised EUR 80 million by means of a private placement in the second year-half of 2017. The significant amount raised was an important milestone for us in securing funds for the further execution our plans. Consequently, we managed to close 2017 with a cash position of around EUR 113m on top of which the company has significant credit lines available including the recently announced financing facility of the European Investment Bank.

We would like to thank all of our dedicated employees for their unremitting hard work, our customers and business partners for their commitment to our joint programs, our suppliers, shareholders and other stakeholders for their continued support and engagement to revolutionize MDx together.

Yours sincerely,

Herman Verrelst, CEO

Rudi Mariën, Chairman of the Board of Directors

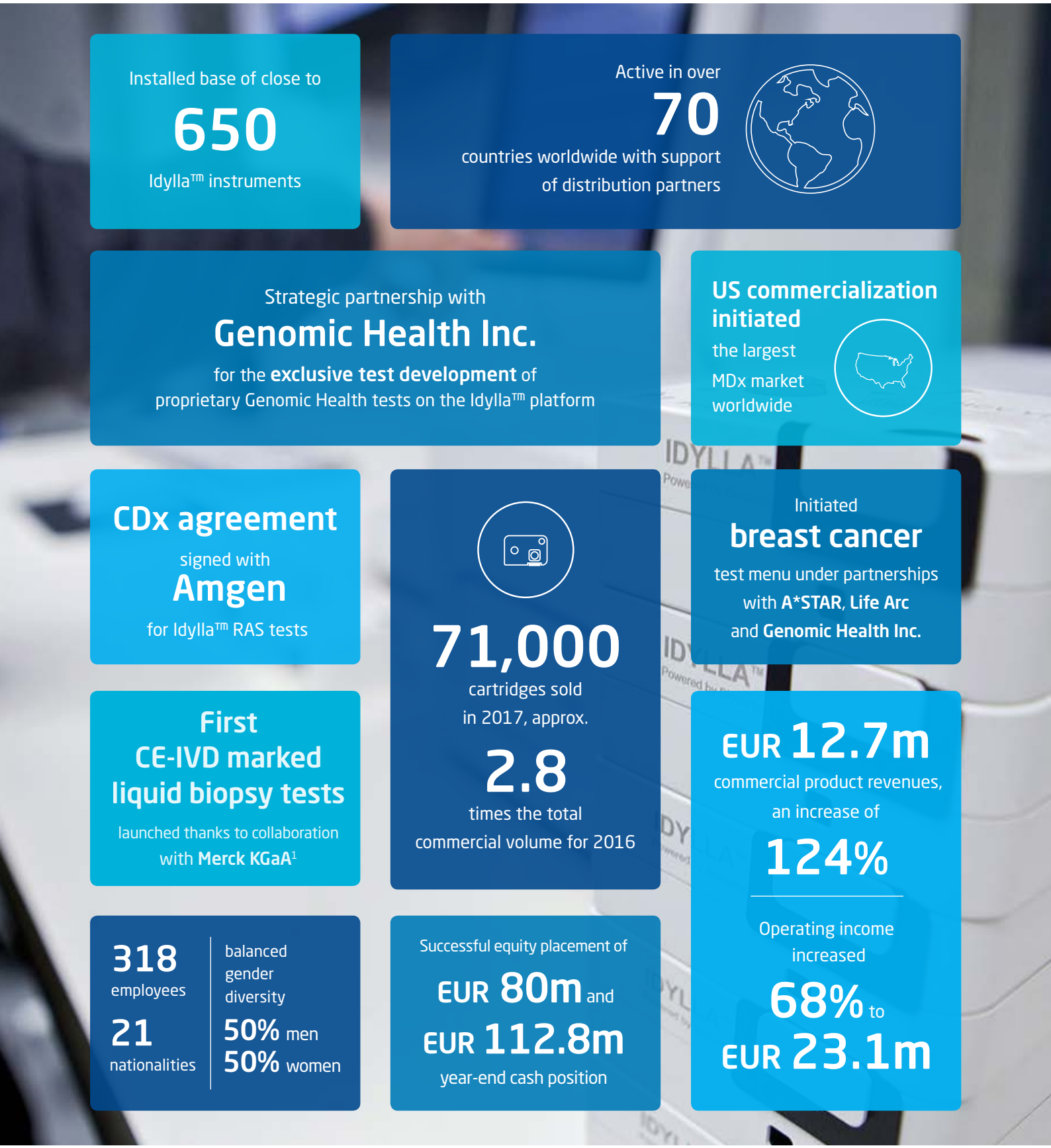
1.3 / Reponsibility statement

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

Herman Verrelst, CEO

Rudi Mariën, Chairman of the Board of Directors

1.4 / 2017 highlights and business review



Installed base of close to
650
Idylla™ instruments

Active in over
70
countries worldwide with support of distribution partners

Strategic partnership with
Genomic Health Inc.
for the **exclusive test development** of proprietary Genomic Health tests on the Idylla™ platform

US commercialization initiated
the largest MDx market worldwide

CDx agreement
signed with
Amgen
for Idylla™ RAS tests

71,000
cartridges sold in 2017, approx.
2.8
times the total commercial volume for 2016

Initiated
breast cancer
test menu under partnerships with **A*STAR**, **Life Arc** and **Genomic Health Inc.**

First CE-IVD marked liquid biopsy tests
launched thanks to collaboration with **Merck KGaA**[1]

EUR 12.7m
commercial product revenues, an increase of
124%

Operating income increased
68% to
EUR 23.1m

318 employees
21 nationalities
balanced gender diversity
50% men
50% women

Successful equity placement of
EUR 80m and
EUR 112.8m
year-end cash position

[5] Merck KGaA, Darmstadt, Germany.

1.4.1 / Commercial and regulatory highlights

Cartridge consumption – Driven by continued test menu expansion and installed base growth, commercial cartridge consumption showed a strong increase in 2017 and grew to over 71k Idylla™ cartridges. This represents a year-over-year volume growth of about 2.8 times. Whereas we have seen a strong performance in our European direct markets, overall volume was slightly below expectations driven by a slower take-up in RoW distribution markets as mentioned in the Company's Q3 business update and as further outlined below.

Installed base – The installed base of Idylla™ instruments amounted close to 650 as per year-end driven by 258 new installations in 2017. Both Europe and RoW[6] distribution markets showed strong new placements and contributed to the majority of the overall installed base growth that was complemented by initial placements in the US market during H2 2017.

US commercialization – Following the establishment of Biocartis US and the hiring of a core US team in H1 2017, Biocartis and its distribution partner Fisher Healthcare[7] initiated the US commercialization of the Idylla™ platform in Q3 2017, and successfully installed the first Idylla™ instruments with US customers.

Distribution markets RoW – Biocartis expanded its commercial footprint with additional new distribution agreements for Latin American, Middle East and Asian markets in 2017. As mentioned in the Company's Q3 2017 business update, cartridge volume growth in RoW markets has been lower than expected in 2017 driven by several factors including delays in obtaining local market authorization.

CDx – Biocartis launched its companion diagnostics (CDx) business early 2017 with the signing of a first undisclosed CDx deal. A second CDx deal was signed early December 2017 with Amgen, a leading biotechnology company (NASDAQ: AMGN), for the Idylla™ RAS biomarker tests and aims at the registration of these tests with the US Food and Drug Administration (FDA) as a companion diagnostic test for Amgen's drug Vectibix® (panitumumab). The CDx agreement with Amgen further builds on collaborations[8] between both companies which are focused on accelerating results of RAS biomarker testing from up to one month to, in principle, same-day results for mCRC patients, using Biocartis' Idylla™ platform and Idylla™ RAS biomarker tests.

Regulatory - In July 2017, the US FDA published a final list of devices that it has exempted from 510(k) premarket notification requirements. The product codes applicable to the Biocartis Idylla™ Instrument and Idylla™ Console are included on this list. Consequently, Biocartis' Idylla™ Instrument and Idylla™ Console are no longer subject to 510(k) notification requirements prior to being placed on the US market for in vitro diagnostic use with FDA approved or cleared assays.

[6] RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan.
[7] Fisher HealthCare is part of Thermo Fisher Scientific Inc.
[8] Biocartis and Amgen announced a first collaboration on 3 February 2016, aimed at accelerating access to RAS biomarker information for metastatic colorectal cancer (mCRC) patients in a number of selected countries worldwide (Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey) and expanded their collaboration on 22 December 2016 to additional selected hospitals in up to 10 European countries.

1.4.2 / Idylla™ test menu highlights

Breast cancer menu – In 2017, Biocartis initiated its test menu for breast cancer, the most common cancer among women worldwide[9], with the development initiation of three tests, all in collaboration with renowned partners:

Partnership LifeArc[10]: In June 2017, Biocartis announced a partnership with LifeArc to develop selected molecular diagnostic tests for use on Biocartis' fully automated Idylla™ platform. The first test to be developed under the partnership is a liquid biopsy test aimed at monitoring of metastatic breast cancer patients for resistance to hormone therapy. For each selected test, LifeArc will act as a development contractor, whereas Biocartis will be responsible for the commercialization of the tests under its own label.

Partnership A*STAR[11]: In July 2017, Biocartis announced an extended partnership with A*STAR focused on the development of IVD tests for the Idylla™ platform. The first assay selected for development under the partnership is a fully automated solid biopsy assay, aimed at supporting optimal therapy selection decisions for breast cancer patients. Under the terms of the agreement, parties will co-invest in the development of jointly selected tests. For each selected test, Biocartis will be responsible for the commercialization of the tests under its own label, while A*STAR will act as a development partner through Singapore's Diagnostics Development Hub.

Collaboration Genomic Health: On 13 September 2017, Biocartis and Genomic Health, Inc. (NASDAQ: GHDX), the world's leading provider of genomic-based diagnostic tests, announced an exclusive agreement to develop an IVD version of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform that can be performed locally by laboratory partners and in hospitals around the world. The Oncotype DX Breast Recurrence Score® test, the only test proven to predict chemotherapy benefit, is included in all major cancer guidelines worldwide and is currently considered a standard test for early-stage breast cancer. The collaboration will provide Genomic Health with exclusive worldwide rights to develop and commercialize its Oncotype DX Breast Recurrence Score® test on the Idylla™ platform, with the option to expand the collaboration to include additional tests in oncology and urology. The development timeline of the Oncotype DX® IVD test aims at providing initial access to patients in Europe, beginning with France and Germany, in 2019. As part of the agreement, Genomic Health has made a payment of approximately USD 3.3m to Biocartis. Additional payments to Biocartis will be made as certain developmental and commercial milestones will be achieved in the future. Upon commercialization, Genomic Health will make royalty payments to Biocartis based on net sales.

Colorectal cancer menu – During 2017, Biocartis expanded its CRC menu with the launch of two new tests and CE-marking of three tests as well as further advanced the development of the Idylla™ MSI (microsatellite instability[12]) Assay:

NRAS only testing: In May 2017, Biocartis CE-marked the Idylla™ NRAS Mutation Test which, alongside the Idylla™ NRAS-BRAF Mutation Test, will allow for more flexibility in geographies where BRAF testing for metastatic colorectal cancer (mCRC) patients is not reimbursed.

Liquid biopsy RAS testing: In November 2017, Biocartis CE-marked the liquid biopsy tests, the Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test (launched as RUO in March 2017), that were developed under a collaboration with the leading science and technology company Merck KGaA[13] (Darmstadt, Germany, ETR: MRK). This collaboration is aimed at improving access to easy, rapid and low invasive blood-based molecular diagnostic testing for patients with mCRC. Both companies now collaborate to make the tests commercially available to medical centers[14].

MSI testing: Biocartis advanced the development of the Idylla™ MSI Assay during 2017, which is set for launch in 2018. Two studies on the performance of the exclusively licensed novel set of MSI biomarkers that are to be included in the Idylla™ MSI Assay (the 'MSI Biomarkers') were presented at the renowned European Society for Medical Oncology (ESMO) congress in September 2017. Both studies, of which one was performed in collaboration with Merck KGaA (Darmstadt, Germany), show strong performance of Biocartis' MSI Biomarkers for the detection of

[9] One in eight women is diagnosed with breast cancer in her lifetime. Source: World Health Organization, www.breastcancer.org, last consulted on November 2017.
[10] LifeArc is an independent UK based life science medical research charity and aims to move promising medical research forward into patient treatments and diagnostics and has been involved in helping deliver a number of therapies including Keytruda® (pembrolizumab, marketed by MSD) which is an important immunotherapy treatment for various cancers.
[11] Partnership is signed with ETPL, the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research.
[12] Microsatellite instability is the result of errors in the body's so-called DNA mismatch repair (MMR) system. Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, resulting potentially in tumor growth.
[13] Merck KGaA, Darmstadt, Germany.
[14] The collaboration does not include the US, China and Japan.

MSI status in gastric and colorectal cancer samples. The Idylla™ MSI Assay is another important addition to the CRC test menu as all major guidelines now recommend universal testing of all patients with CRC, and could also become of relevance within the immuno-oncology field as MSI is believed to be a key factor in predicting a patient's response to certain immunotherapies[15].

Lung cancer menu – In June 2017, Biocartis CE-marked its solid biopsy Idylla™ EGFR Mutation Test, which is the only on-market fully automated CE-IVD test detecting all relevant EGFR mutations according to international guidelines and able to produce results faster and easier[16], based on only one slice of tumor tissue. Furthermore, Biocartis advanced the development of the Idylla™ ctEGFR Mutation Assay, a liquid biopsy version of the solid biopsy Idylla™ EGFR Mutation Test that is set for launch in 2018. This test is an important addition to Biocartis' lung cancer menu as liquid biopsy EGFR testing is included in guidelines for the situations where no tumor tissue is available for testing.

Infectious diseases – On 5 September 2017, the US FDA granted 510(k) clearance[17] for the Idylla™ Respiratory (IFV-RSV) Panel, developed by Biocartis' strategic partner Janssen Diagnostics, LLC ('Janssen'). The Idylla™ Respiratory (IFV-RSV) Panel is intended for the detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV). This is the first US FDA cleared test on the Idylla™ platform, marking another important milestone and adding yet another layer of validation to the quality of Biocartis' product offering.

1.4.3 / Organizational highlights

New CEO – On 1 September 2017, Herman Verrelst started as new CEO of Biocartis. Herman is a seasoned executive with a proven international commercial track-record in molecular diagnostics. Prior to joining Biocartis, he held the position of Vice President and General Manager of the Genomics and Clinical Applications Division of Agilent Technologies Inc. (NYSE: A).

Expansion team – In April 2017, Biocartis appointed Vishal Sikri as its US General Manager. Before joining Biocartis, Vishal was Managing Director and VP Commercial Operations responsible for all global commercial operations of Sysmex Inostics, the molecular diagnostics' division of Sysmex Corporation (TYO: 6869). Furthermore, in December 2017, Benoit Devogelaere was appointed as Biocartis' Chief Technology Officer. Prior to joining Biocartis, Benoit held the position of Product Marketing Expert within the Genomics and Clinical Applications Division of Agilent Technologies Inc. and R&D Manager of Cartagenia NV, a diagnostic software company that was acquired by Agilent Technologies Inc. in 2016.

Cartridge manufacturing – Strong progress was made during 2017 in the construction of a second cartridge manufacturing line that should provide for an additional annual cartridge capacity of 1 million Idylla™ cartridges. Validation of this manufacturing line has been initiated with the aim to start commercial production end of 2018.

[15] Recent data have shown that advanced CRC patients with an MSI-high status respond particularly well to certain immunotherapies (Xiao Y et al. (2015) The microsatellite instable subset of colorectal cancer is a particularly good candidate for checkpoint blockade immunotherapy. Cancer Discov. 5, 16-18; and, Le et al. (2015) PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. N Engl J Med 372, 2509-2520).

[16] Based on a comparison between the Biocartis' Idylla™ platform for the detection of EGFR mutations in archived formalin-fixed paraffin-embedded (FFPE) tumor samples with the results obtained by the TherascreenEGFR Pyro assay (Qiagen)-ISO 15189 accredited laboratory method.

[17] 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 amounted to EUR 12.9m in 2017 (EUR 6.8m in 2016), representing a year-over-year growth of 91% driven by both higher Idylla™ system sales (EUR 4.6m in 2017 versus EUR 2.8m in 2016) and Idylla™ cartridge sales (EUR 8.3m in 2017 versus EUR 4.0m in 2016). Commercial product sales increased year-over-year with 124% to EUR 12.7m in 2017 from EUR 5.7m in 2016 as the result of amongst others higher commercial cartridge consumption at customers.

Total operating income – Driven by increased product sales revenues, collaboration revenues (EUR 7.7m in 2017) and grant income, total operating income amounted to EUR 23.1m in 2017 versus 13.8m in 2016, an increase of 68%.

Equity raise – In November 2017, Biocartis successfully raised an amount of EUR 80m in gross proceeds by means of a private placement via an accelerated bookbuild offering of 6.4m new shares (being approximately 14.33% of the Company's outstanding shares).

Debt funding – End of Q3 2017, Biocartis reached agreement with KBC and BNP Paribas Fortis to replace the Company's EUR 25m multiple purpose credit facility (partially guaranteed by the Flemish Government) with a new multiple purpose credit facility of EUR 27.5m[18] (not covered by a government guarantee). As per 31 December 2017, no drawdowns were made on this credit facility.

EUR 12.7m
commercial product revenues, an increase of
124%

Operating income increased
68% to
EUR 23.1m

Cash flow - Biocartis' cash flow from operational and investment activities amounted to EUR -45.7m in 2017, compared to EUR –62.7m in 2016, mainly driven by an improved operational result, lower investments in working capital and less capital expenditures. Given a cash flow from financing activities in 2017 of EUR 75.3m, the total net cash flow of 2017 amounted to EUR 29.5m.

Cash position - Biocartis' cash position as per 31 December 2017 amounted to EUR 112.8m compared to EUR 83.2m as per 31 December 2016.

Additional details – see 'Financial review 2017' below for more details.

1.4.5 / Update test menu

In order to efficiently execute the announced partnerships as well as new partnerships that the Company expects to add in the near future, Biocartis re-organized its assay development organization, decided to expand its assay development capabilities [(including amongst others the establishment of an US R&D center)] and re-prioritized resources across the portfolio of development projects. This has resulted in a shift of launch dates of some internal assay development projects in order to accommodate external commitments.

Based on Key Opinion Leaders (KOLs) feedback and extended market analysis, Biocartis evaluated the commercial potential of the Company's Next-Generation Sequencing (NGS) FFPE[19] sample preparation and target enrichment capabilities on Idylla™ (the 'Idylla™ NGS Prep Panels') to complement its menu of Idylla™ qPCR[20] tests. Priority was given to develop a cancer hotspot NGS Prep Panel to complete the Idylla™ lung cancer menu, as the clinical utility of multi-gene panels for this cancer type are now gradually becoming accepted in the international clinical guidelines. Non-small-cell lung cancer is a highly prevalent and deadly cancer type, which is of high interest for pharmaceutical companies who are developing various types of therapies for this cancer type, many of which will require a CDx test. Easy-to-use and cost-efficient Idylla™ NGS Prep Panels will facilitate getting more of these therapies to the patient, which will expand the attractiveness of the Idylla™ platform for end-users in the lab, as well as create opportunities for additional collaborations with pharmaceutical companies. An updated Idylla™ test menu roadmap is included in the Company's corporate presentation that can be found **here**.

[18] Of which EUR 3m for guarantees.
[19] Formalin fixed, paraffin embedded.
[20] Quantitative Polymerase Chain Reaction or real-time PCR.

1.4.6 / Financial review 2017

The tables below show an overview of the key figures and a breakdown of operating income for 2017. A consolidated income statement, balance sheet, cash flow statement and statement of changes in equity of Biocartis Group NV can be found in chapter 6 under 'Consolidated Annual Accounts'.

Key figures (EUR 1,000)	2017	2016	% Change
Total operating income	23,110	13,772	68%
Cost of sales	-8,673	-5,701	52%
Research and development expenses	-39,594	-42,091	-6%
Marketing and distribution expenses	-11,600	-10,324	12%
General and administrative expenses	-6,832	-5,827	17%
Operating expenses	-66,699	-63,943	4%
Operational result	-43,589	-50,171	-13%
Net financial result	-1,736	-586	196%
Income tax	3,365	980	243%
Net result	-41,960	-49,777	-16%
Cash flow from operating activities	-41,405	-53,312	-22%
Cash flow from investing activities	-4,320	-9,342	-54%
Cash flow from financing activities	75,256	41,804	80%
Net cash flow	29,531	-20,850	-242%
Cash and cash equivalents[1]	112,765	83,247	35%
Financial debt	35,388	31,407	13%

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

Operating income (EUR 1,000)	2017	2016	% Change
Collaboration revenue	7,739	5,278	47%
Idylla™ System sales	4,620	2,752	68%
Idylla™ Cartridge sales	8,316	4,015	107%
Product sales revenue	12,936	6,767	91%
Service revenue	282	53	432%
Total revenue	20,957	12,098	73%
Grants and other income	2,153	1,674	29%
Total operating income	23,110	13,772	68%

Product sales revenue by type (EUR 1,000)	2017	2016	% Change
Commercial revenue	12,748	5,691	124%
Research & Development revenue	187	1,076	-83%
Total product sales revenue	12,936	6,767	91%

Income statement

Operating income

Collaboration revenue increased year-over-year with 47% to EUR 7.7m in 2017 driven by a higher amount of received milestone payments (total amount of EUR 2.5m in 2017) and increased proceeds from R&D services (EUR 0.3m in 2017) combined with upfront license revenues that remained more or less at the same level of 2016 (EUR 4.6m in 2017). Product sales revenue equaled EUR 12.9m in 2017 versus EUR 6.8m in 2016 as a consequence of both higher cartridge and system sales.

Recognized grants and other income amounted to EUR 2.2m in 2017 which represents a year-over-year increase of 29% mainly because of recognition of higher R&D project support grants and training subsidies related to the establishment of a second cartridge manufacturing line. Furthermore, in March 2017 Biocartis received a EUR 750k grant from VLAIO[21] to support Biocartis' ongoing microsatellite instability (MSI) and mutational load research program in collaboration with Prof. Diether Lambrechts (VIB – KU Leuven Center for Cancer Biology, Belgium).

Driven by the above Biocartis' total operating income in 2017 amounted to EUR 23.1m versus EUR 13.8m in 2016, representing an increase of 68%.

EUR 7.7m collaboration revenues, an increase of **47%** compared to 2016

EUR -43.6m operational result compared to **EUR -50.2m** in 2016

EUR -42m net result compared to **-49.8m** in 2016

Product sales revenue **EUR 12.9m** in 2017 versus **EUR 6.8m** in 2016

Operating expenses

Total operating expenses in 2017 amounted to EUR 66.7m versus EUR 63.9m in 2016, an increase of 4%. This included cost of sales of EUR 8.7m in 2017 compared to EUR 5.7m in 2016 as the consequence of an overall increase in commercial product volumes. Operating expenses excluding cost of sales amounted to 58.0m in 2017 versus EUR 58.2m in 2016 as the result of a decrease in research and development ('R&D') expenses that was offset by higher expenses for marketing and distribution and general and administrative expenses ('G&A').

R&D expenses amounted to EUR 39.6m in 2017 versus EUR 42.1m in 2016. This represents a year-over-year decrease of approx. 6% driven by amongst others lower expenses for staffing and subcontracting as well as depreciation costs that were partially offset by higher Idylla™ platform and cartridge prototype costs and increased expenses for facilities and consultants. Marketing and distribution expenses amounted to EUR 11.6m in 2017 compared to EUR 10.3m in 2016, a year-over year increase of approx. 12%. This increase is a consequence of additional operational expenses incurred in relation to the US commercialization of the Idylla™ platform that were partially offset by lower sales & promotional and consultancy expenses. G&A expenses amounted to EUR 6.8m in 2017 compared to EUR 5.8m in 2016 being a year-over-year increase of approx. 17% as a result of higher costs for staffing (including share based payment expenses) and external advice.

Operating result

The above resulted in an operational result for the period of EUR -43.6m compared to EUR -50.2m in 2016, a year-over-year improvement of approx. 13%.

Net financial result and income taxes

Net financial expenses amounted to EUR 1.7m in 2017 compared to EUR 0.6m in 2016. This increase is driven by amongst others higher financial expenses for debt facilities that were obtained mid-2016 and which are now expensed for on a full-year basis. As the Company had no taxable income in 2017, income tax expense consists of recognized research and development tax credits in Belgium. These increased to EUR 3.4m in 2017 versus EUR 1.0m in 2016 as the consequence of amongst others an adjusted fiscal treatment of certain historical IP investments.

Net result

As a result of the foregoing the net result for the year 2017 amounted to EUR -42.0m compared to EUR -49.8m in 2016.

[21] The Flanders organization for Innovation & Entrepreneurship.

Balance sheet

Non-current assets

Intangible assets predominantly consist of patents and licenses on third-party intellectual property and increased from EUR 9.9m in 2016 to EUR 10.3m in 2017 driven by additions of EUR 1.2m and amortization expenses of EUR 0.8m. 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 cartridge manufacturing expansion), Idylla™ systems placed at clients (under operational lease contracts or rental contracts) or held for internal use as well as laboratory & ICT equipment. In 2017, property plant & equipment increased with EUR 3.1m to EUR 26.2m driven by additions of EUR 7.4m and depreciation charges for the period of EUR 4.3m. Additions predominantly consisted of new manufacturing equipment for cartridge manufacturing as well as capitalization of instrumentation placed at clients under leasing or rental contracts as well as instrumentation held for internal needs.

Per 31 December 2017, a financial participation of EUR 5.1m was included on the balance sheet, which relates to 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 7.1% participation in MyCartis NV.

Deferred tax assets per 31 December 2017 amounted to EUR 6.6m (versus EUR 3.1m in 2016) and relate to tax credits for research and development in Belgium. Recognized research and development tax credits in Belgium increased with EUR 3.4m in 2017 from EUR 1.0m in 2016 as a consequence of an adjusted fiscal treatment for certain historical IP investments.

Current assets

Inventory amounted to EUR 9.1m as per end 2017 compared to EUR 9.8m as per end 2016. This decrease year-over-year was driven by lower inventory levels of raw materials and semi-finished products, partially offset by a higher inventory level of finished products. Trade receivables increased to EUR 6.9m as per year-end 2017 (EUR 2.9m end of 2016) as a consequence of amongst others invoicing to strategic partners in Q4 in light of new collaboration as well as higher overall commercial volumes.

Other receivables were related to VAT receivables and capital grants and amounted EUR 2.9m as per end of 2017 versus EUR 2.2m end of 2016. Other current assets include accrued grant income and deferred charges and decreased in 2017 to EUR 1.5m compared to EUR 1.9m in 2016.

The Company's cash and cash equivalents end of 2017 amounted to EUR 112.8m compared to EUR 83.2m end of 2016.

Equity

Biocartis' total equity end of 2017 amounted to EUR 132.2m compared to EUR 96.9m end of 2016. This increase was driven by the net proceeds from the shares issued in the private placement of November 2017 that was partially offset by the loss for the period.

Financial debt

Total financial debt amounted to EUR 35.4m as per end of 2017 versus EUR 31.4m as per end of 2016, representing an increase of EUR 4.0m. This increase was predominantly driven by increased uptakes on lease financing facilities to finance the ongoing cartridge manufacturing expansion as well as the addition of capitalized interest to the Company's subordinated loan.

Other liabilities

Trade payables end of 2017 amounted to EUR 5.6m, representing a decrease of EUR –0.7m compared to the EUR 6.3m that was outstanding end of 2016. Deferred income increased in 2017 to EUR 2.8m (EUR 2.1m end of 2016) as a consequence of payments received in relation to new collaborations signed in 2017 as well as the addition of grants. Accrued charges as of 31 December 2017 increased slightly to EUR 1.8m and predominantly consisted of accruals for rental charges. Other current liabilities increased to EUR 3.4m as per end of 2017 (EUR 3.0m end of 2016) and consist predominantly of provisions for vacation pay.

Cash flow statement

Cash flow from operating activities

The cash flow from operating activities amounted to EUR -41.4m in 2017 compared to EUR -53.3m in 2016 driven by an improved operational result for the period in combination with lower investments in working capital in 2017 compared to 2016.

Cash flow from investing activities

The cash flow from investing activities in 2017 amounted to EUR –4.3m compared to EUR -9.3m in 2016 and included predominantly capitalization of Idylla™ instrumentation 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 2017 amounted to EUR 75.3m compared to EUR 41.8m in 2016 and predominantly consists of the net proceeds from the capital raise of November 2017 that was partially offset by some repayment on borrowings.

Total net cash flow

Driven by the aforementioned, the total net cash flow in 2017 amounted to EUR 29.5m compared to EUR -20.9m in 2016.

1.4.7 / Important events after the reporting date

Four important events were announced after the reporting date.

Second CDx partnership Amgen – On 9 January 2018, Biocartis announced a new companion diagnostic (CDx) development agreement with Amgen, a leading biotechnology company (NASDAQ: AMGN), aimed at the development of Idylla™ CDx biomarker tests for a novel oncology compound to be used in the treatment of certain solid tumors.

Collaboration Immunexpress – On 24 January 2018, Biocartis and Immunexpress Pty Ltd ('Immunexpress'), a host response molecular diagnostic company, announced a partnership agreement aimed at the development and commercialization of Immunexpress' SeptiCyte™ test for use on the Idylla™ platform. The SeptiCyte™ LAB test recently received 510(k) clearance from the US FDA for use on a manual PCR instrument, aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS[22]) systemic inflammation in critically ill patients on their first day of their admission in the ICU (intensive care unit). Under the partnership, parties will co-develop the SeptiCyte™ Idylla™ test, whereas Immunexpress will take the lead in the commercialization, with an initial focus on the US and the European markets.

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

EIB financing facility – On 1 March 2018, Biocartis announced to have obtained a EUR 24m debt financing facility from the European Investment Bank. The financing facility is supported by InnovFin – EU Finance for Innovators' Infectious Diseases Finance Facility, with the financial backing of the European Union under its research and innovation programme Horizon 2020. It can be used to part-finance up to 50% of further investments in infectious diseases diagnostics solutions.

There were no further important events between 31 December 2017 and the approval date of this annual report.

1.4.8 / Outlook 2018

Installed base – Maintain installed base growth at 250-275 new instrument placements, bringing the total installed base to around 900-925 Idylla™ instruments by year end 2018.

Menu expansion:

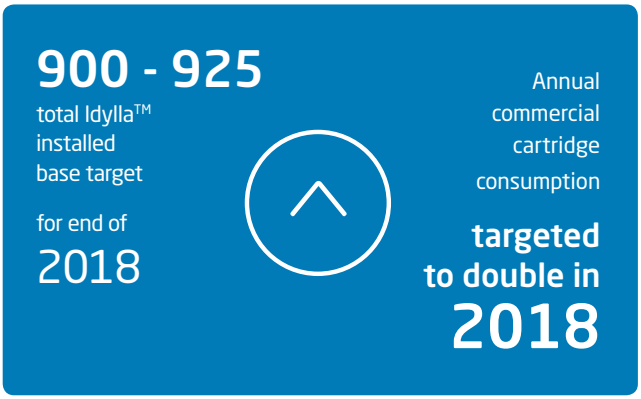
Colorectal cancer: Launch of the Idylla™ MSI Assay (RUO[23]), aimed at the identification of MSI in all colorectal cancer patients as per recently updated guidelines in H2 2018 and submission of the Idylla™ RAS PMA (Pre-Market Approval) documentation with the US FDA around year-end, subject to feedback from US FDA interactions;

Lung cancer: Launch of the Idylla™ ctEGFR Assay (RUO), a liquid biopsy version of the Idylla™ EGFR Mutation Test, and CE-marking of the solid biopsy Idylla™ BRAF Mutation Test, that will be validated for therapy selection in BRAF positive non-small cell lung cancer patients, both in H2 2018; and

Breast cancer: Launch of the Idylla™ ctESR1 (RUO) Assay, a liquid biopsy test aimed at monitoring of metastatic breast cancer patients for resistance to hormone therapy, which is developed in collaboration with LifeArc in H2 2018.

Commercial cartridge consumption - Annual commercial cartridge consumption in 2018 is targeted to double compared to the 2017 volume.

Cash position – Targeted cash position in the range of EUR 50m – EUR 60m by 2018 year end, excluding drawdowns on the Company's multiple purpose credit facility.



[22] Systematic inflammatory response syndrome.
[23] RUO = Research Use Only.

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 a rapid and continuous drive for technological innovation, evolving market standards, changes in customer needs, emerging competition and new product launches. Biocartis may need to develop or in-license new technologies and solutions to remain competitive, which could come with significant investments. Current or future competitors may succeed, or may have already succeeded, in developing solutions or services that are more effective or affordable which could render Biocartis' present or future solutions obsolete or uneconomical. Biocartis faces intense competition from a number of companies that offer solutions and technologies in its target markets. The Idylla™ platform is a sample-to-result platform, and several other companies have brought such platforms to the market or aim to do so. Some competitors have substantially greater financial resources and larger, more established marketing, sales and service organizations than those of Biocartis.

The commercial success of Biocartis will depend on commercial market acceptance of the Idylla™ platform and its menu of tests.

Biocartis launched its Idylla™ platform and its first test, the Idylla™ BRAF Mutation Test, for commercial sale in countries recognizing CE-marked in vitro diagnostic ('IVD') devices at the end of 2014. Since that date, Biocartis and/or its partners have launched several additional tests, but so far Biocartis has only generated limited revenue. There can be no assurance that these products or any further products launched by Biocartis will gain acceptance by the market as many factors, of which many outside the control of Biocartis, can influence market acceptance.

Biocartis faces uncertainties over the reimbursement for its products by third parties and may be subject to strict price controls.

The commercial success of Biocartis' Idylla™ platform and menu of tests depends, in part, on the degree to which they are reimbursed by public health administrations, private health insurers, managed care organizations and other organizations in the countries in which Biocartis operates. Although Biocartis' first wave of tests predominantly involve biomarkers for which reimbursement is already established, reimbursement procedures in most countries where Biocartis is or will be active are highly complex and third-party payer health plans are fragmented, which makes systematic reimbursement arrangements for new products that do not yet have an existing reimbursement difficult to establish. As a result, Biocartis will need to continue to expend significant effort and expense to establish, and may never succeed in establishing, widespread or systematic reimbursement arrangements for its products. Furthermore, reimbursement levels are set by parties outside the control of Biocartis and they may change over time. A reduction in reimbursement levels may affect the price that Biocartis is able to obtain for the Idylla™ platform and tests.

Operational risks

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

To date, the Idylla™ platform has been commercialized on the basis of a limited number of tests for clinical use. The availability of a broad and clinically relevant menu of tests that are approved for clinical use is an important decision factor to acquire and use a diagnostic platform, and management believes that offering a broader menu of such tests in combination with making such tests globally available will be a key driver of demand for the Idylla™ platform. The continued development and commercialization of additional tests and geographical expansion are therefore a key part of Biocartis' strategy. In addition, Biocartis intends to seek regulatory approval for the Idylla™ platform and its menu of tests in a broad range of jurisdictions, which could come with significant investments. Furthermore, Biocartis may experience unexpected delays or difficulties in the development and commercialization of tests (both on a standalone basis and together with partners), which may jeopardize and/or delay market acceptance of the Idylla™ platform, could jeopardize Biocartis' ability to enter into additional partnerships for the development and commercialization of tests and could consequently affect future revenue growth. Such delays may occur due to a variety of factors, of which many outside the control of Biocartis.

Biocartis has only limited experience in commercializing MDx platforms and tests and therefore may not be successful in further growing its commercialization infrastructure.

Biocartis has limited experience in deploying a commercialization infrastructure in diagnostics markets and may not succeed in hiring additional and/or retaining key personnel, or making appropriate arrangements with distributors and other parties, to execute the commercial deployment of the Idylla™ platform and tests. In addition, part of Biocartis' commercial strategy is placing its diagnostic platform with clients under, among others, operational lease contracts. Under such contracts, the customers are entitled to return the platform to Biocartis under certain conditions, which could have an impact on the Company's installed base and could result in a loss in revenues. Furthermore, Biocartis will need to continue to build a maintenance and service organization in order to ensure adequate installation and servicing of its installed base.

Biocartis may not be able to manufacture or outsource manufacturing of its products in sufficient quantities, in a timely manner or at a cost that is economically attractive.

Biocartis' revenues and other operating results going forward will depend, in large part, on its ability to manufacture and deliver its Idylla™ platform in sufficient quantities and quality, in a timely manner, and at a cost that is economically attractive. The Idylla™ platform comprises three components: the instrument, the console and the cartridge. The manufacturing or assembly of the instrument and the console has been outsourced to a contract manufacturing partner (CMO). The manufacturing or assembly of the cartridge is currently performed in-house at Biocartis' facilities in Mechelen (Belgium). In order to meet future expected demand, Biocartis has started construction of a more automated and higher volume production line for Idylla™ cartridges. 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.

Biocartis relies on multiple suppliers to produce the individual components required for its Idylla™ platform and Idylla™ tests, some of whom are single source suppliers.

The nature of Biocartis' products requires customized components that are currently available from a limited number of sources. For a few components Biocartis is exposed to single source risk. There can be no assurance that Biocartis' suppliers will at all times be able to continue to provide the components Biocartis needs, at suitable prices or in sufficient quantity or quality. This could affect Biocartis' ability to continue supply to its customers which could result in potential financial and reputational damages. If Biocartis needs alternative sources for key components, for any reason, these alternative component parts may not be available on short notice, on acceptable terms, or at all. Furthermore, alternative components may require Biocartis to modify its products which is likely to result in important re-design and approval costs and delays in supply.

Biocartis faces an inherent risk of product liability claims.

Biocartis is exposed to potential product liability claims that are inherent in clinical testing and MDx. Biocartis faces the risk of liability for damages if there are deficiencies with any of its products, affecting among others product performance, due to component failures, manufacturing errors, design or labelling defects or other deficiencies and issues. Biocartis cannot be certain that it will be able to successfully defend any product liability lawsuit brought against it. Regardless of merit or eventual outcome, product liability claims may result in decreased demand, reputational damage, litigation costs and potential monetary awards. Biocartis has entered into product liability insurance with an overall cover that it believes to be market conform.

Biocartis cannot provide assurance that patients, hospitals, surgeons or other parties will not try to hold it responsible for all, or part, of the medical decisions underlying the treatment of patients.

Biocartis' MDx products are designed solely to detect the levels of certain specified biomarkers and are not designed to specify the treatment necessary for each patient, which remains the responsibility of relevant medical personnel. Although Biocartis makes this very clear when it markets its products and on its labelling (which indicates, among other things, the relevant test's accuracy rate), Biocartis cannot provide assurance that patients, hospitals, surgeons or other parties will not try to hold Biocartis responsible for all or a part of the medical decisions underlying the treatment of patients, exposing Biocartis to potential litigation or civil or criminal liability.

If Biocartis fails to obtain patent protection for the products it develops or otherwise fails to maintain and adequately protect its intellectual property rights, Biocartis' business could suffer.

Biocartis' intellectual property rights form the basis of its products and technologies. Biocartis invests in different forms of intellectual property right development and has set up an internal IP department that overlooks the different IP related activities. The patent portfolio of Biocartis consists of various proprietary families comprising issued and pending patents worldwide. The portfolio further includes multiple in-licensed patent families. In addition to patents, Biocartis also relies on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements and other contractual provisions and technical measures. Protecting the intellectual property rights may be critical to Biocartis' success, but will depend on a number of complex legal and factual questions.

Biocartis is dependent on (sub)licenses for key technologies from third parties and may require additional licenses.

Biocartis relies on key technologies from third parties and has entered into (sub)license agreements with a number of (sub)licensors. Various license agreements impose on Biocartis various development obligations, payment of royalties and fees obligations, as well as other obligations. If Biocartis fails to comply with any of its obligations under these agreements, the (sub)licensor may have the right to terminate the (sub)license. In addition, if the sublicensor fails to comply with its license or the licensor fails to enforce its intellectual property, the (sub)licensed rights may not be adequately maintained. The termination of any (sub)license agreements, or the failure to adequately protect the intellectual property rights which are the subject matter of such (sub)license agreements, could prevent Biocartis from commercializing products covered by the (sub)licensed intellectual property or have another negative impact on such commercialization. In addition, Biocartis may require access to additional third-party technologies for which an additional (sub)license, or (sub) licenses, needs to be obtained in order to be able to sell certain of its products. If Biocartis is unable to sustain or enter into adequate (sub)licensing agreements to access these technologies, either on acceptable terms or at all, it may be unable to sell all, or certain of, its products, or access some geographic or industry markets. Finally, certain technologies and patents have been developed with collaboration partners, and Biocartis may be limited by restrictions on this jointly developed intellectual property.

Intellectual property infringement claims from third parties could be time-consuming and costly to defend and may result in liability for damages, or prevent Biocartis from commercializing its products.

The MDx industry is characterized by a large number of patents, claims of which appear to come close to one another or overlap in certain cases. Furthermore, certain proprietary rights of third parties may be unknown to Biocartis up until the point of enforcement. As a result, there is a degree of uncertainty regarding the extent of patent protection and infringement. Biocartis may thus have unknowingly infringed in the past, and may still be infringing, the proprietary rights of third parties. In addition, third parties may have pending patent applications, which are typically confidential for the first eighteen months following filing, and which may cover technologies Biocartis and/or its partners incorporate in their MDx platforms and tests. In the event that third parties accuse Biocartis of infringing their patents, Biocartis could incur substantial costs and consume substantial resources in defending against these claims. If such claims prove to be valid, this could lead to significant damages, royalty payments or an injunction preventing the sale of certain of Biocartis' products.

If Biocartis fails to attract or retain key personnel, its ability to conduct and expand its business would be negatively affected.

Competition for skilled personnel is intense and may limit Biocartis' ability to hire and retain highly qualified personnel on acceptable terms or at all. Many of the competitors have greater financial and other resources, different risk profiles and a longer history than Biocartis. Attracting, retaining and training personnel with the requisite skills is therefore challenging. If, at any point, Biocartis is unable to hire, train and retain a sufficient number of qualified employees to match its growth, this could have a material adverse effect on its ability to implement its business strategy.

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

Like all software products and computer systems, Biocartis' software products and computer systems are vulnerable to cyber-attacks. The impact of cyber-attacks could disrupt the proper functioning of Biocartis' software products and computer systems (including Idylla™ Connect and Idylla™ Explore), cause errors in the output of Biocartis' systems, allow unauthorized access to sensitive, proprietary or confidential information of Biocartis, its customers or the patients that Biocartis and Biocartis' customers serve.

Potential liability related to the privacy and security of personal information Biocartis collects.

Biocartis may inadvertently gain access, or be determined to have access to personal information that is subject to a number of US federal and state laws, EU laws and other applicable foreign laws protecting the confidentiality of certain patient health or other private information, including patient records, and restricting the use and disclosure of that protected information. If Biocartis would be alleged to have breached any such laws, it may be subject to substantial sanctions and irreparable harm to its reputation.

Regulatory risks

Failure to comply with regulations of the MDx market.

Regulatory agencies (such as the US Food and Drug Administration ('FDA')) strictly regulate the promotional claims that may be made about medical devices or related products placed on their market. If Biocartis is found to have made false or misleading claims about its products, or otherwise have violated promotion or advertising restrictions, Biocartis may become subject to significant fines and/or other liabilities, including being prohibited from importing into these markets.

If Biocartis' products are defective, or otherwise pose safety risks, the relevant governmental authorities could require their recall, or Biocartis may initiate a recall of Biocartis' products voluntarily.

The relevant governmental authorities may require the recall of commercialized products in the event of material deficiencies, or defects in design or manufacture, or in the event that a product poses an unacceptable risk to health. Manufacturers, on their own initiative, may recall a product if any material deficiency in a device is found. A government mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labelling defects or other deficiencies and issues. Recalls of any of Biocartis' products would divert managerial and financial resources and have a material adverse effect on Biocartis' business, financial condition and results of operations. In addition, any product recall may result in irreparable harm to Biocartis' reputation.

Biocartis' business could be significantly and negatively affected by substantial changes in government regulations, particularly in 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.

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.

Financial risks

Biocartis has incurred operating losses, negative operating cash flow and an accumulated deficit since inception and may never become profitable.

Biocartis has incurred operating losses and negative operating cash flow in each period since it was founded in 2007. There can be no assurance that Biocartis will achieve profitability, which could impair its ability to sustain operations or obtain any required additional funding. If Biocartis does achieve profitability in the future, it may not be able to sustain profitability in subsequent periods, and it may suffer net losses and/or negative operating cash flows in subsequent periods.

Biocartis might require substantial additional funding to respond to business challenges or take advantage of new business opportunities, which may not be available on acceptable terms, or at all.

Biocartis intends to continue to make appropriate investments to support the execution of its business plan. Existing sources of financing and any funds generated from operations may not provide Biocartis with sufficient capital. Biocartis may require additional equity or debt funding from time to time to meet funding needs, respond to business challenges, or to take advantage of new business opportunities. Equity and debt financing, however, might not be available when needed or, if available, might not be available on acceptable terms. In addition, to the extent that additional capital is raised through the issuance of equity or convertible debt securities, the issuance of these securities could result in the dilution of the interests of Biocartis' existing shareholders. In addition, these securities may be sold at a discount from the market price of Biocartis' common stock. If Biocartis is unable to obtain adequate financing, its ability to continue to support its business growth and to respond to business challenges could be significantly limited. Existing sources of cash and any funds generated from operations may not provide Biocartis with sufficient capital and may result in delays in its operations that could affect its operational and financial performance.

Biocartis' operating results could be materially adversely affected by unanticipated changes in tax laws and regulations, adjustments to its tax provisions, exposure to additional tax liabilities, or forfeiture of its tax assets.

The determination of Biocartis' provision for income taxes and other tax liabilities requires significant judgment, including the adoption of certain accounting policies and Biocartis' determination of whether its deferred tax assets are, and will remain, tax effective. Although management believes its estimates and judgment are reasonable, they remain subject to review by the relevant tax authorities. Biocartis cannot guarantee that its interpretation will not be questioned by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof by the relevant tax authorities, will not be subject to change. Biocartis is subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing and tax regulations for the compensation of personnel and third parties. Biocartis' tax structure involves a number of transfers and transfer price determinations between 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. When disposing of assets, Biocartis may not be able to complete the disposal at terms deemed acceptable, may be required to give guarantees, and may expose itself to claims from purchasers, as well as creditors of the transferred business.

Biocartis has no fixed dividend policy.

Biocartis has not declared or paid dividends on its shares to date, and it is not expected that Biocartis will declare or pay dividends in the near future. In the future, Biocartis' dividend policy will be determined and may change from time to time by proposal of Biocartis' board of directors. Any declaration of dividends will be based upon Biocartis' earnings, financial condition, capital requirements and other factors considered important by the board of directors. Belgian law and the Company's articles of association do not require Biocartis to declare dividends.

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

1.6 / 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 shall prevail. An electronic version of the annual report 2017 is available on 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 2017 and 31 December 2017.

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, except if specifically required to do so by law or regulation Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this report or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this report.

About Biocartis

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

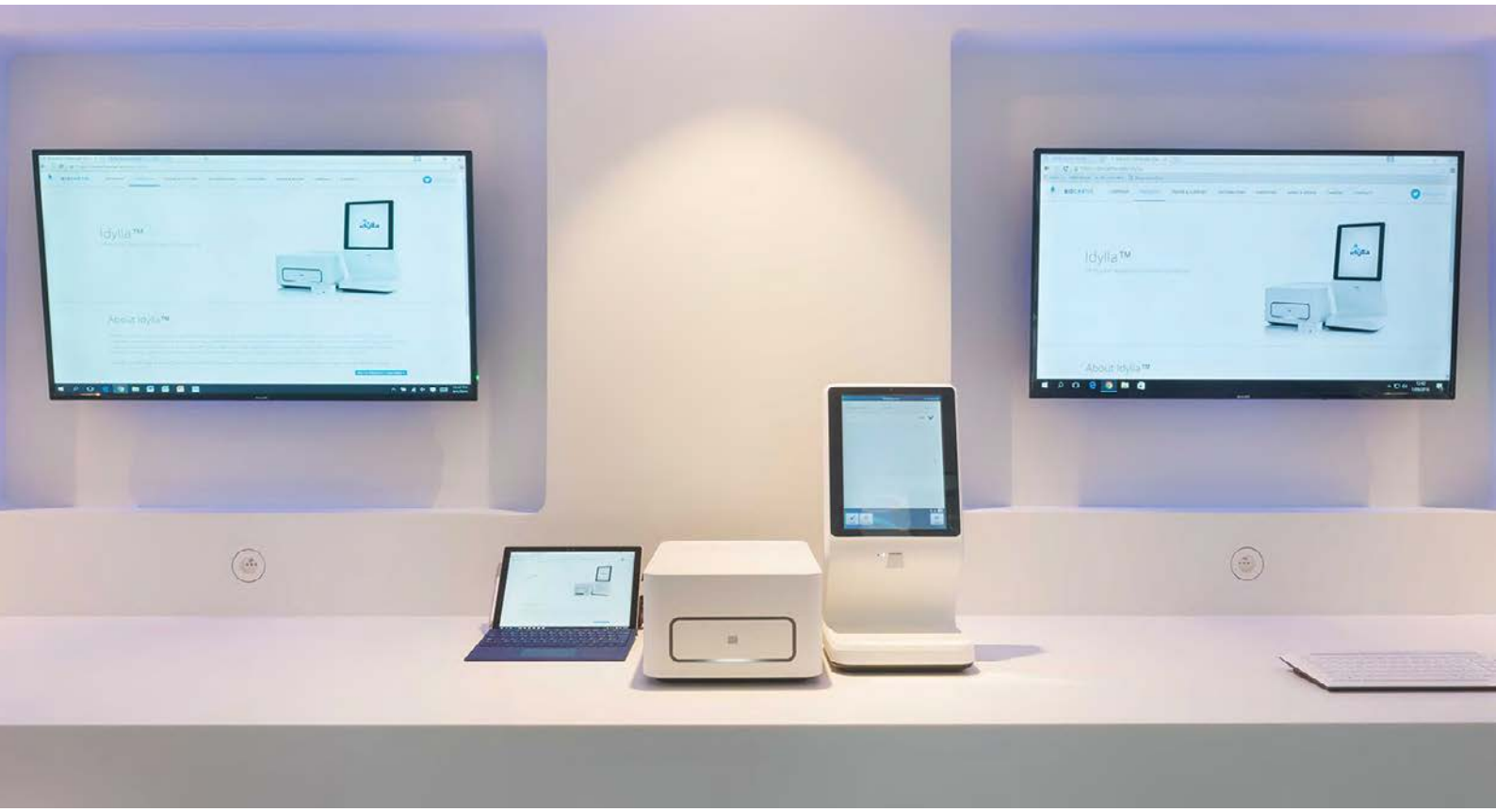
Use of the Idylla™ trademark, logo and CE-marking

Biocartis and Idylla™ are registered trademarks in Europe, the United States and other countries. Biocartis trademark and logo and Idylla™ trademark and logo are used trademarks belonging to Biocartis.
This press release is not for distribution, directly or indirectly, in any jurisdiction where to do so would be unlawful. Any persons reading this press release should inform themselves of and observe any such restrictions. Biocartis takes no responsibility for any violation of any such restrictions by any person. Please refer to the product labeling for applicable intended uses for each individual Biocartis product. This press release does not constitute an offer or invitation for the sale or purchase of securities in any jurisdiction. No securities of Biocartis may be offered or sold in the United States of America absent registration with the United States Securities and Exchange Commission or an exemption from registration under the U.S. Securities Act of 1933, as amended.

CHAPTER 2

Biocartis in the molecular diagnostics market

2.1 / Mission and vision



Since the unravelling of the human genome in the 2000's, the study of human health and diseases has led to the discovery of macromolecules, called biomarkers, associated with specific diseases or treatment response. These biomarkers can be detected in patient samples such as blood, urine, sputum, saliva or tissue such as tumor tissue. MDx enables personalized medicine. This is the new generation of treatments that are tailored to the genetic profile of a patient, making these much more effective, with better outcomes and as such also leading to reduced healthcare costs. Detailed MDx information for example helps a doctor determine what the preferred treatment is for a melanoma patient whose tumor is driven by a specific genetic mutation. Molecular diagnostics (MDx) is the primary tool used to identify such biomarkers.

Today, access to molecular information is difficult. Many hospitals do not perform molecular tests in-house, but send the test samples out to specialized labs, sometimes even to other countries. Samples are often processed in batches based on workflows that require multiple complex instruments that can only be operated by highly trained personnel. All of this is time-consuming and labor-intensive: it can take up to several weeks before molecular results are available. This delays treatment decisions, which are often crucial to save patients' lives. As an example, in the US, nearly 80% of cancer patients do not have genetic mutation results available at initial oncology consultation and up to 25% of patients begin treatment before receiving their results[24].

Biocartis: High Precision Diagnostics for Personalized Medicine

Biocartis aims to make personalized medicine an everyday reality, by providing direct access to MDx information close to the clinical decision-making point. Establishing a new gold standard in diagnostic testing, Biocartis delivers innovative and vital solutions to the pharmaceutical and healthcare market. Providing highly automated instruments in combination with novel and broadly applicable MDx assays, Biocartis enables personalized molecular testing in a wide variety of medical settings.

[24] JMD, May 2017; 5 Scott et al. (2014) Asia Pac J Clin Oncol. 10(3):261-5.

2.2 / History

2016

Commercial collaboration agreements signed with two renowned pharmaceutical companies Merck KGaA (Darmstadt, Germany) and Amgen aimed at accelerating access to the RAS mutational status for patients with metastatic colorectal cancer. Distribution partnership signed with Thermo Fisher Scientific Inc. for the US market. Launch of three new oncology tests: the Idylla™ EGFR Mutation Assay, the Idylla™ ctKRAS Mutation Assay (both as RUO or Research Use Only) and the Idylla™ NRAS-BRAF Mutation Test. Successful equity placement of EUR 32.7m and EUR 55m of non-dilutive financing secured.

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), the first liquid biopsy test, the Idylla™ ctBRAF Mutation Assay (RUO) and the first infectious disease test, the Idylla™ Respiratory (IFV-RSV) Panel Test, developed by Janssen Diagnostics (a division of Janssen Pharmaceutica NV). Signing of five new collaborations for test development and/or commercialization, with Microbiome, Fast-track diagnostics, A*STAR, Merck KGaA (Darmstadt, Germany) and Amgen. Outsourcing of the Idylla™ Instrument and Idylla™ Console to a renowned Contract Manufacturing Organization (CMO) to enable scaling of production. Start of the construction of a new manufacturing line in Mechelen (Belgium).

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.

2013

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

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.

2011

R&D activities moved to Mechelen (Belgium), where a first pilot cartridge manufacturing production line was established. Biocartis received the prestigious 2012 Technology Pioneer Award by the World Economic Forum.

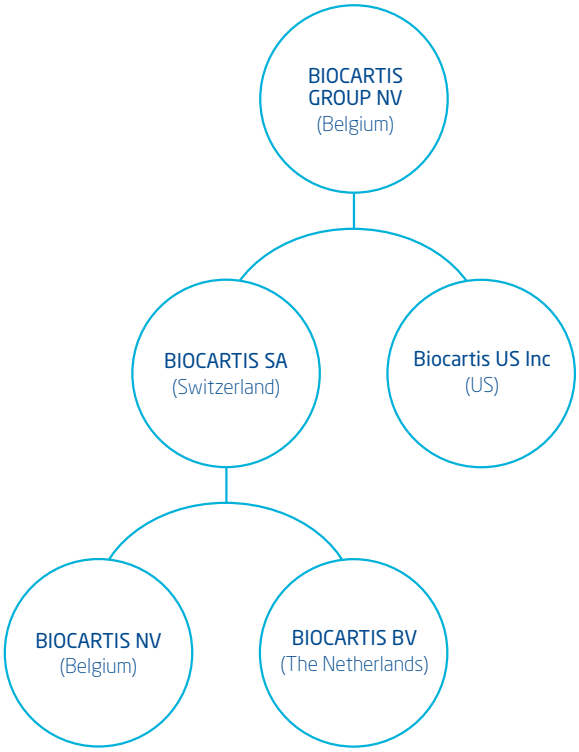
2010

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

2007

Biocartis was founded in Switzerland

Today, 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 2017:



Biocartis' headquarters are located in Mechelen, Belgium, incorporated on 24 November 2014, registered in Belgium under enterprise number 0505.640.808 (register of legal entities Antwerp, division Mechelen). In general, the majority of operational activities are centralized in Mechelen (Belgium) on several premises with a total size of approx. 5,500 sq m (leased from Intervest). This with the exception of the manufacturing of the Idylla™ Instrument and the Idylla™ Console that was outsourced to an external Contract Manufacturing Organization (CMO) in 2015 and certain operational activities of related to the US commercialization that is supported by Biocartis US Inc., including a US R&D center.

2.3 / The molecular diagnostics market

The global in vitro diagnostics (IVD) market had an estimated value of USD 60.22 billion in 2016. This market is expected to grow at a CAGR (Compound Annual Growth Rate) of 5.5% during the period 2016–2021 to reach USD 78.74 billion by 2021[25].

1) By application, the largest MDx segment in 2016 was infectious disease (43%), followed by oncology (19%). Oncology is expected to account for the highest growth rate, resulting in a CAGR of 17% in the period 2016-2021[25].

2) By technology, Polymerase Chain Reaction (PCR), which is the most established procedure conducted prior to the commencement of any MDx investigation and also the technology on which the Idylla™ tests are based, leads the way.

3) By geography, North America represents the largest MDx market, accounting for some 45% of the total, followed by Western Europe (25%)[26].

[25] MarketsandMarkets: Molecular Diagnostics Market, Global Forecast to 2021 (November 2015)
[26] https://www.mordorintelligence.com/industry-reports/molecular-diagnostics-market

2.4 / Strategy

Biocartis aims to become a global leader in molecular diagnostics solutions through a strategy based on three pillars:

1. Focus on oncology
2. Test menu for treatment selection, monitoring and screening
3. Acceleration of test menu expansion through partnerships

A companion diagnostic (CDx) test is an in vitro diagnostic device (IVD) used to identify whether a patient with a certain disease could be benefitted by a particular drug through the biomarker assessment. The first FDA-approved CDx test (Hercep-Test) was approved in 1998 for breast cancer treatment based on immunohistochemistry assay. The global CDx market is expected to reach USD 6.51 billion by 2022 from USD 2.61 billion in 2017, at a CAGR of 20.1% during the forecast period. The growth of the market can be attributed to the growing number of genetic testing, rising need for personalized medicines, and regulatory guidelines that support the CDx market. The pharmaceutical and biopharmaceutical companies – the key issuers of targeted oncology treatments - are expected to be the largest group of end users of CDx, also expected to grow at the highest CAGR during the forecast period 2017-2022[30].

1 Focus on oncology

As announced in March 2017, Biocartis will focus its own resources on MDx for oncology driven by the unique features that the Idylla™ platform has to offer for this market segment:

- Ability to combine advantages of **near-patient testing** with **performance of lab reference testing**, thereby enabling decentralization of MDx oncology testing in a much broader range of settings.

- **Reduction of time-to-result** from up to weeks to hours, driven by the fully automated nature of the Idylla™ platform in combination with testing close to the point of need.

- **Sample-to-result** (i.e. full automation) capabilities for all key clinical oncology samples: **solid biopsies** (e.g. FFPE-slices and tumor tissue) as well as **liquid biopsies** (e.g. blood, plasma and urine).

The oncology MDx market is forecasted to be the fastest growing segment of the MDx market[27], supported by three key drivers:

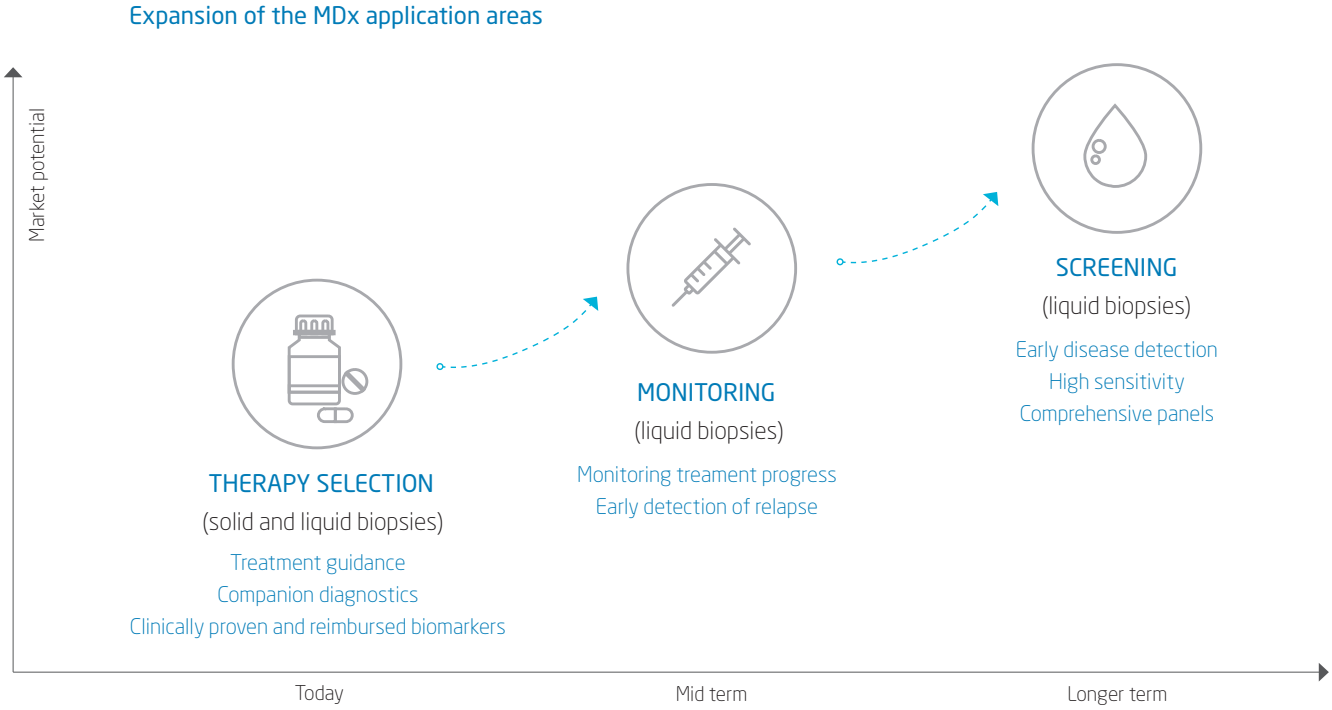
- **Increasing global prevalence of cancer:** According to the WHO, globally, nearly one in six deaths is due to cancer. Cancer was responsible for 8.8 million deaths in 2015 and the number of new cases is expected to rise by about 70% over the next two decades. According to Globocan (the WHO cancer research agency), colorectal and lung cancer are estimated to rise by 2.7% and 2.8%, respectively per annum.

- **Growth of MDx testing:** In 2015, over 800 cancer treatments were in development in the US[28] of which 73% have the potential to be personalized medicines[29] and as such will require MDx testing before treatments can be initiated, more and more done in a companion diagnostic setting. Furthermore, targeted therapies for oncology are increasingly adopted in the Western world supported by their integration in the clinical guidelines. In addition, patent expirations for the first wave of targeted therapies are expected to support a further roll-out of these drugs in developing countries.

- **Growth of decentralized MDx market:** Ongoing innovations and automation within the MDx market aim to reduce complexity of testing. Now, mid- and smaller sized labs and hospital settings, that used to send out testing to the specialized, larger labs, can conduct testing in-house, thereby increasing the overall potential customer base.

[27] MarketsandMarkets: Molecular Diagnostics Market, Global Forecast to 2021 (November 2015)
[28] PhRMA, "Medicines in Development for Cancer," September 2015, http://phrma.org/sites/default/files/pdf/oncology-report-2015.pdf; American Association for Cancer Research. "Jose Baselga, MD, PhD" http://cancerprogressreport.org/2015/Pages/baselga.aspx
[29] PhRMA, Oncology Report 2015
[30] MarketsandMarkets, Companion Diagnostics Market, Global Forecast to 2022 (2017)

2 Test menu for treatment selection, monitoring and screening



The ability of Idylla™ to offer both **solid biopsy testing** and **liquid biopsy testing** on the same platform allows Biocartis to be active in different application areas for oncology MDx. Today's focus is mainly on tests for **treatment selection**, with currently tests on the market assisting in therapy selection for melanoma, colorectal and lung cancer, and with tests for breast cancer under development. The panels of these tests are based on actionable mutations that are included in local and international clinical guidelines, followed by client-laboratories and hospitals. Consequently, in the majority of geographies these tests are reimbursed. Recently, Biocartis increased its focus on CDx with the aim to register, in partnership with pharmaceutical company partners, existing and new tests with the US FDA to further support and increase market adoption of the Idylla™ platform. Going forward, Biocartis aims to develop tests in other cancer domains, with an initial focus on immuno-oncology and urology.

Based on Idylla™'s unique features to run different sample types, Biocartis is developing tests based on both solid (operating directly on a slice of FFPE tissue) and liquid samples (operating directly on liquid biopsy samples such as blood plasma). The liquid biopsy market is expected to reach $3,805 million by 2023, at a CAGR of 28.9% from 2017 to 2023[31]. Thanks to the ease of use of Idylla™ in combination with the minimally invasive blood draw based sample, Idylla™ liquid biopsy testing has the potential to truly transform cancer care. 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.

With easy to perform liquid biopsy technology, such tests require high levels of sensitivity and are expected to consist of comprehensive panels including a large number of cancer-driving mutations. Although a single blood test to detect all cancers is often referred to as the 'holy grail' and today and a lot of clinical data has already been generated that supports the use of monitoring tests within oncology, there is still a lot of research to be done due to the complexity of (detecting) gene mutations in early stages, and before monitoring is more generally included in the clinical guidelines. Nevertheless, it is beyond doubt that liquid biopsies to enable novel strategies for early diagnosis represent huge impact on healthcare and outstanding growth potential with an expected market size of $3,805 million by 2023[31].

[31] Allied Market Research, Liquid Biopsy Market - Global Opportunity Analysis and Industry Forecast, 2017-2023

In the **mid-term**, Biocartis aims to add tests for **monitoring** purposes to its menu driven by the liquid biopsy capabilities of the platform. The majority of such tests will be used to monitor treatment progress and/or early detection of relapse. A first potential monitoring test is currently under development in the breast cancer field.

Finally, and on the longer term, Biocartis aims to expand the use of the Idylla™ technology and tests into screening applications that will amongst others focus on **early disease detection**, an essential factor in saving lives.

"Thanks to the ease of use of Idylla™ in combination with the minimally invasive blood draw based sample, Idylla™ liquid biopsy testing has the potential to truly transform cancer care."

3 Acceleration of test menu expansion through partnerships

Partnerships are a true cornerstone of Biocartis' commercialization strategy. In general, three types of partnerships are aimed for:

Partnerships with pharmaceutical and biotech companies: The focus here is on the (joint) development of CDx on the Idylla™ platform. This is expected to allow Biocartis to reach faster commercial adoption as well as high market shares. Biocartis' partners are expected to benefit from an increased number of eligible patients for their targeted therapies driven by the key benefits of the Idylla™ platform: fast turnaround times, thereby reducing competition with therapies not requiring a biomarker and high sensitivity, resulting in more patients that are detected with the relevant biomarkers. See chapter 'our stakeholders' to find out more.

Partnerships with diagnostic test content partners: The focus here is on the porting of proprietary biomarker panels of partners, in most cases already developed and clinically validated, to the Idylla™ platform. By doing so, Biocartis adds proprietary content to its menu that will further increase the attractiveness of the Idylla™ test menu. Driven by its unique features, partners are expected to benefit from an accelerated global roll-out of their content, cost efficiencies and faster customer adoption since no platform education is needed.

Partnerships with diagnostic test development partners: The focus here is on the development of Biocartis Idylla™ tests, predominantly in collaboration with research institutions. This will allow Biocartis to reduce initial test menu development costs while benefiting from the collective knowledge of its development partner. Through such collaborations, partners can further contribute to medical innovation as well as benefit from knowledge sharing and building.

[32] Allied Market Research, Liquid Biopsy Market - Global Opportunity Analysis and Industry Forecast, 2017-2023

2.5 / Go-to-market

Regulatory

Regulatory compliance is a key condition for market access in MDx. Depending on the type of product and the geography, various regulatory processes exist subject to which certain MDx devices need to be approved or cleared by regulators. Regulations affect, among other things, design and product standards, packaging, advertising and labelling requirements.

EU: A CE-marking is required for broad market access in the EU. Biocartis is compliant with the IVD Directive for manufacturers who place IVD devices on the EU market, allowing Biocartis to market CE-IVD products in the EU and in other countries accepting CE-marked IVD devices. An overview of the current CE-marked IVD products of Biocartis is available under 'Products'. On 5 April 2017, two new EU regulations on medical devices were adopted: the regulation on medical devices and the regulation on in vitro diagnostic medical devices, both entering into force on 25 May 2017 with a transition period of three years for the Regulation on medical devices (May 2020) and five years for the Regulation on in vitro diagnostic medical devices (May 2022). New requirements included in both regulations result in an increased level of necessary documentation during product development, a review by a Notified Body for a majority of IVD products prior to launch, as well as further on-market validation efforts to ensure devices continue to perform as expected. The new regulations aim for a consistent disclosure across medical devices on quality and performance. Its increased transparency as such allows for a better performance comparison of similar medical devices across the EU. Biocartis supports these new regulations and initiated the necessary preparations in 2017. The additional efforts now needed during development may affect the launch timing of future IVD products. However, as an international company already compliant with the more strict US regulations (see further) Biocartis expects an overall limited impact on its business of this new regulation.

United States: The US requires more rigorous product clearance efforts before market access is granted:

Idylla™ tests: Following the US FDA's different market entry requirements based on the risks class of the medical device, Idylla™ tests require more stringent Pre-Market Approvals (PMA) for most oncology products, when being used for decisions in therapy selection, whereas most infectious disease tests require a 510(k) clearance. On 5 September 2017, Biocartis announced that the US FDA granted 510(k) clearance for the Idylla™ Respiratory (IFV-RSV) Panel, developed by Janssen Diagnostics, LLC ('Janssen'). This was an important milestone, as it was the first US FDA cleared test on the Idylla™ platform. On 4 December 2017, Biocartis announced the signing of a CDx development agreement with Amgen (NASDAQ: AMGN), aimed at the registration of the Idylla™ RAS biomarker tests with the US FDA as a CDx test for Amgen's Vectibix® (panitumumab). Under the agreement, Biocartis will pursue a premarket approval (PMA) for the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test with the US FDA. Amgen will provide financial and operational support to Biocartis for the PMA process.

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

RoW markets: Although in many RoW markets CE-marking is accepted, various markets also have their own specific local authorization requirements, in which case additional product registration efforts are required. Consequently, every individual market needs to be assessed in terms of efforts needed to comply with these local market authorizations.

China and Japan: China (CFDA) and Japan (MHLW) have more extensive product clearance regulations and procedures, for which additional efforts are required in order for Biocartis to be able to enter these markets.

In addition to IVDs (i.e. products that received market access through compliance with regulations), Biocartis also offers products for Research Use Only (RUO), meaning they may be used only for research purposes, not for use in diagnostic procedures. An overview of all RUO-labelled products can be found under 'Products'. In most of the markets that Biocartis operates in, such RUO products may be offered for sale if similar IVD products are not yet approved for sale or distribution. Additionally, RUO products in general may be mainly used in research applications to evaluate or confirm the prevalence of certain mutations, or other research-oriented applications.

Reimbursement

The growing pressure on the healthcare budget, also driven by more expensive targeted cancer treatments, pushes healthcare policy makers, governments, insurers and other payers to favor early diagnosis, better screening and monitoring and cost-effective therapies. Diagnostic testing is therefore increasingly accepted as a critical tool to reduce healthcare costs.

Biocartis focuses mainly on tests with biomarkers that are already included in the clinical guidelines, as such most of the Biocartis oncology tests are already reimbursed by third-party payers. Additionally, in several geographies (including Spain), reimbursement of the test is included in the reimbursement of the targeted therapy.

Customer focus

Biocartis follows a phased customer approach in most of the geographies it is active in.

In a first phase, Biocartis targets the central molecular diagnostic testing labs and larger pathology laboratories that already perform oncology MDx testing today, and who are seeking faster turnaround alternatives to existing molecular diagnostic workflows. This segment represents a significant portion of the market in most countries and adoption of the Idylla™ platform here is driven by test performance and realization of cost and operational efficiencies.

In a second phase, Biocartis targets the mid and smaller sized pathology laboratories and hospitals that today do not yet perform MDx testing. The unique features and ease of use of the Idylla™ platform allows these customers to bring MDx testing in-house, to the benefit of patients thanks to faster turnaround times. Additionally, this segment benefits from MDx testing that used to be a cost, to MDx bringing profit as Idylla™ test prices are generally below reimbursement levels, as such leaving an interesting margin for the customer. Tapping into this customer segment will allow Biocartis to realize market growth through decentralization.

For the oncologist, being another important stakeholder as he/she is linking pin between the pathologist and the patient, fast turnaround times of test results and potential future monitoring of the efficiency of the treatment plan by means of liquid biopsy tests, are considered truly unique advantages in the oncology MDx testing market.

Sales channels

As per end 2017, Biocartis was active in over 70 countries through a combination of direct sales and (distribution) partners.

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

Hybrid sales strategy in the US: Here, Biocartis implements a hybrid model consisting of direct sales and sales through its distribution partner Fisher Healthcare (part of Thermo Fisher Scientific Inc.)[33], with who it launched commercial activities in H2 2017. Fisher Healthcare has exclusive distribution rights on the Biocartis Idylla™ tests and non-exclusive distribution rights on the Idylla™ instruments. A Biocartis specialized sales team, which has been established in the US, is supporting the Fisher Healthcare team, and is also selling directly in the US market.

Distributor sales strategy RoW: Outside of the key European countries and the US, Biocartis collaborates with a vast network of distributors in geographies that accept CE-marking. Over the course of 2017, Biocartis shifted its focus from expanding its distribution network towards a focused approach of assisting existing distribution partners in realizing commercial adoption of the Idylla™ platform in their respective geographies, especially in countries where pharmaceutical companies are requesting and supporting Idylla™ roll-out.

Pharmaceutical and (test) content partners: In addition to its own sales force and distribution partners, pharmaceutical and (test) content partners assist Biocartis in commercializing the Idylla™ platform. Current commercialization agreements exist for example with pharmaceutical partners Amgen and Merck KGaA (Darmstadt, Germany) to accelerate and broaden access to RAS bio marker testing for mCRC patients. These commercialization partnerships allows them to benefit from an increased number of eligible patients for their targeted therapies driven by the key benefits of the Idylla™ platform, such as fast turnaround times. Additionally, partnerships with diagnostic test development content partners who port their proprietary biomarker panels to the Idylla™ platform, benefit from an accelerated global roll-out of their test content, cost efficiencies and faster customer adoption since no platform education is needed. An example here is the partnerships with Genomic Health Inc., where the porting of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform allows a local roll-out using Genomic Health's own sales channels, i.e. laboratory partners and hospitals around the world.

[33] In November 2016, Biocartis announced a distribution agreement with Fisher Healthcare

Biocartis in the US

The US is the largest single market for oncology MDx testing in the world, with an expected market size of USD 1.45bn by 2020, representing over 45% of the global market[34]. With a significant number of mid and smaller sized labs and hospitals not performing MDx today, there is great potential for Idylla™ in the US. Here, access to molecular information is difficult, with nearly 80% of cancer patients that do not have genetic mutation results available at their initial oncology consultation, and up to 25% of patients that begin treatment before they receive their results[35].

The first go-to-market focus in the US is on the large laboratories performing oncology MDx today and mid-sized laboratories that are currently sending out samples for testing, and in a second wave on the smaller laboratories and hospitals that do not yet perform MDx testing. Today, the Biocartis US product offering consists of the Idylla™ platform and seven oncology RUO (Research Use Only) assays for melanoma, colorectal and lung cancer.

In order to obtain full regulatory approval, partnerships are an essential part of Biocartis' strategy. Most oncology products are subject to PMA (Pre-Market Approval) by the US FDA. A first CDx agreement for the US was announced with Amgen on 4 December 2017 to register the Idylla™ RAS biomarker tests with the US FDA as a CDx test for Amgen's drug Vectibix® (panitumumab). US FDA approval of the Idylla™ RAS biomarker tests could allow for a more widespread RAS clinical testing, regardless of the clinical practice size, available lab infrastructure or experience level, and could enable same-day turnaround times.

"Idylla™ delivers results within 2 hours instead of 2 days, with minimal hands-on time. This brings huge benefits, as it has the potential to enable faster and improved cancer treatment decisions."

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

[34] MarketsandMarkets, Molecular Diagnostics Market - Forecast to 2020, February 2017
[35] JMD, May 2017

2.6 / Products

The Idylla™ platform

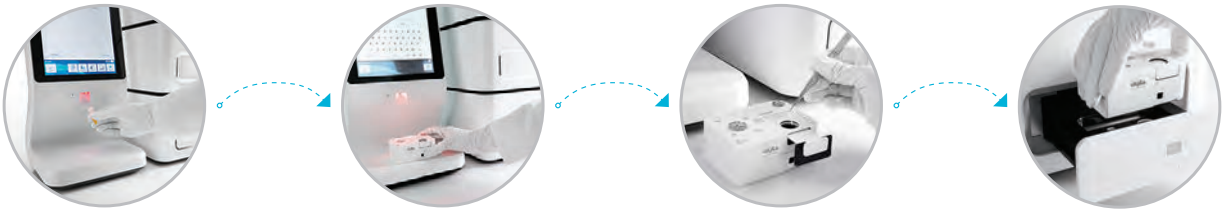
The Idylla™ platform, launched end of 2014 as a CE-marked product, is a fully automated, real-time PCR-based compact laboratory that integrates all the sample processing and analytical procedures required to provide high quality MDx results. The Idylla™ platform works on-demand in virtually any setting, allowing even smaller laboratories to rapidly report results since no complex lab infrastructure is required. The entire process from sample-to-result is covered in a timeframe between 35-150 minutes. 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, test results are displayed and if needed, communicated to the Idylla™ Connect central data center and/or the user's laborator yinformation 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 approx. 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 it suitable for use by non-expert personnel in a non-specialized laboratory environment, close to the patient[36]. 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, and its focus on clinically actionable mutations, enabling clinicians to make treatment decisions in a much shorter timeframe.

Menu of molecular diagnostic tests

Oncology

SOLID BIOPSY

Diagnostic products (CE IVD)	Research products (RUO)
Idylla™ BRAF Mutation Test	**Idylla™ BRAF** Mutation Assay
Idylla™ KRAS Mutation Test	**Idylla™ KRAS** Mutation Assay
Idylla™ NRAS-BRAF Mutation Test	**Idylla™ EGFR** Mutation Assay
Idylla™ NRAS Mutation Test	**Idylla™ NRAS-BRAF-EGFR S492R** Mutation Assay
Idylla™ EGFR Mutation Test	

LIQUID BIOPSY

Diagnostic products (CE IVD)	Research products (RUO)
Idylla™ ctKRAS Mutation Test	**Idylla™ ctBRAF** Mutation Assay
Idylla™ ctNRAS-BRAF Mutation Test	**Idylla™ ctKRAS** Mutation Assay
	Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay

Infectious disease

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)

[36] 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™ molecular oncology assays

As per end 2017, Biocartis had tests on the market for melanoma, colorectal and lung cancer.

Metastatic colorectal cancer (mCRC)

Colorectal cancer is the third most common cancer worldwide, with nearly 1.4 million new cases diagnosed in 2012[37]. About 46% of all metastatic colorectal tumors harbor KRAS gene mutations[38] and about 5% of all metastatic colorectal tumors harbor NRAS gene mutations[39]. According to the guidelines[40], (ESMO[41], NCCN[42], ASCO[43] and CAP/AMP/ ASCO), RAS mutation testing is 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]. 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). Using liquid biopsies for KRAS or NRAS-BRAF testing is minimally invasive, fast and easy to perform and can be used as an alternative or complement to tissue testing to determine the RAS mutation status at diagnosis.

The Idylla™ KRAS Mutation Test, Idylla™ NRAS-BRAF Mutation Test and Idylla™ NRAS Mutation test offer a complete testing for metastatic colorectal cancers (mCRC) for clinical use on Idylla™, as recommended by the most recent clinical guidelines of ASCO[45] and ESMO[46]. The ability of Biocartis' RAS test offering to enable same-day results can now open routes towards faster treatment selection for mCRC patients.

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

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

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

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

[37] World Cancer Research Fund International, http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/colorectal-cancer-statistics, last consulted on 26 January 2017
[38] 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
[39] 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
[40] http://www.amp.org/committees/clinical_practice/CRCOpenComment.cfm
[41] ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016
[42] NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016
[43] 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
[44] ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016
[45] 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.
[46] Van Cutsem et al, ESMO consensus guidelines for the management of patients with metastatic colorectal cancer, Annals of Oncology 2016, 8:1386-1422

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

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

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

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

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

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

Lung cancer

Lung cancer is the most common cancer worldwide, contributing for 13% of all cancer types. 85% of lung cancers are non-small cell lung cancers (NSCLC)[47]. EGFR mutations are mainly observed in lung cancer. EGFR mutation testing is recommended in all patients with advanced non-small cell lung cancer (NSCLC) of a non-squamous subtype. Activating mutations in the EGFR gene have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics[48].

Idylla™ EGFR Mutation Assay (CE IVD, diagnostic use)

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

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

Melanoma cancer

BRAF gene mutations occur in about 8% of all cancers[49], 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[50]. 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%[51].

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

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

[47] World Cancer Research Fund International, http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/colorectal-cancer-statistics, last consulted on 26 January 2017
[48] NCCN Clinical Practice Guidelines in Oncology – NSCLC – Version 6.2017; Novello S. et al. Metastatic non-small-cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 2016
[49] Mutations of the BRAF gene in human cancer. Helen Davies et al; Nature 2002, 417, 949-954
[45] Clinical Practice Guidelines - Cutaneous melanoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 26 (Supplement 5): v126–v132, 2015.
[51] ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016

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

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

Idylla™ molecular infectious disease assays

Biocartis aims to valorize the infectious disease capabilities of the Idylla™ platform through collaborations with partners that that can support amongst others test development and commercialization.

Currently, the menu of infectious disease tests on the Idylla™ platform is composed of:

The Idylla™ Respiratory (IFV-RSV) Panel (CE-IVD) has been developed by Janssen Diagnostics. It's a highly sensitive and standardized assay intended for the detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV). On 5 September 2017, Biocartis announced that the US FDA granted 510(k) clearance for the Idylla™ Respiratory (IFV-RSV) Panel, a process led by Biocartis' strategic partner Janssen Diagnostics. As such, this test was the first US FDA cleared test on the Idylla™ platform.

The Idylla™ Ebola Virus Triage Test (Emergency Use Authorization) was co-developed by Biocartis NV, Janssen Diagnostics and the Belgium Institute of Tropical Medicine. It received Emergency Use Authorization[52] by the US FDA on 1 June 2016. This assay delivers results within 100 minutes on a single cartridge. It is intended for the detection of the Ebola Zaire virus in patients with signs and symptoms of Ebola from the 2014 West Africa outbreak.

Quality

Biocartis has established, documented and implemented a quality management system ('QMS') compliant with the international standards and regulations. This quality system covers all of Biocartis' products and tests. All processes needed for the QMS and their application throughout the organization are defined in a QMS process. It describes the key processes to develop, manufacture and deliver high quality products to Biocartis' 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.

Biocartis 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)

[52] The Idylla™ Ebola Virus Triage Test is for use only under Emergency Use Authorization (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.

Main quality related achievements in 2017 included:

Organization related:

- Re-certification of the ISO 13485:2016 standard and obtaining a MDSAP certificate (Medical Device Single Audit Program) for Australia, Brazil, Canada and US, covering the design and development activities, manufacturing and testing activities and customer related processes in Mechelen (Belgium). The MDSAP allows medical device manufacturers to be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program's main mission is to "...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers." This will allow Biocartis to sell the Idylla™ platform and its oncology assays in the respective countries, once regulatory clearance is granted for the individual products.

- Implementation of the requirements of FDA QSR 21 CFR chapter 820 (Quality System Regulation) to comply with the FDA regulations governing IVD devices.

Product related:

- Obtaining regulatory exemption of the Idylla™ platform with the US FDA in July 2017.

- Obtaining 510(k) clearance for the Respiratory (IFV-RSV) Panel (CE-IVD) developed by Janssen Diagnostics.

Environment

One of the key aspects of Biocartis' environmental impact as a company manufacturing MDx materials is related to the 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[53]

Intellectual property (IP)

The protection of Biocartis' intellectual property rights, which form the basis of its products and technologies, is a critical factor for Biocartis' commercial success. Biocartis' intellectual property is predominantly held by Biocartis NV and is overlooked by Biocartis' IP department. Biocartis' current patent portfolio was built through acquisitions of third-party patents, patent applications and knowledge, as well as through internal creation and relates to various aspects of the Idylla™ platform.

Furthermore, Biocartis also has exclusively licensed specific third-party technologies. Currently, Biocartis' patent portfolio consists of 31 proprietary families comprising issued and pending patents worldwide. In 2017, the amount of granted patents in the patent portfolio was brought to over 70%. The portfolio further includes multiple in-licensed patent families.

Additionally, Biocartis relies 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 Biocartis maintain and develop its competitive IP position.

Based on amongst others the above-mentioned protections, competitors are not able to (re)produce tests or cartridges that operate on the Idylla™ platform.

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

CHAPTER 3

Stakeholders

3.1 / Society

In the history of medicine, the methods of testing and diagnosing a disease have evolved tremendously. With every improvement, humankind was able to look deeper into the human body. Today, molecular diagnostics – analyzing up to the molecular level in the body – can tell a clinician if the tumor of a patient is driven by a specific genetic mutation or not. This helps amongst others to decide on the preferred therapy for that patient.

Today, a whole new generation of so-called targeted therapies is available for many cancer types. These new, targeted therapies can block the growth and/or spread of cancer by interfering with specific molecules (called 'molecular targets' or 'biomarkers') that are involved in the growth, progression and spread of cancer. This in contrast to most standard chemotherapies that act on *all* rapidly dividing normal and cancerous cells. As such targeted therapies also block further tumor cell growth, versus standard chemotherapy that kills tumor cells[54] only. Rapid access to accurate data about relevant cancer driving mutations and treatment resistance is therefore vital to enable early disease interception[55] and/or to start rapidly with the best possible treatment, while reducing anxiety for patients who are waiting for results.

Current technologies in molecular oncology however are complex and require a lot of hands-on time, an expensive laboratory infrastructure and specialized staff. Furthermore, often sample batching is needed to optimize costs[56]. Consequently, most laboratories today do not perform molecular tests in-house, but send them out to specialized laboratories. This causes delay to the fast delivery of results, preventing rapid initiation of the best possible therapy.

Patient impact: faster treatment initiation with better health outcome

Fast initiation of targeted therapy as first-line treatment is crucial for cancer patients, as it increases overall survival rates[57]. Timely detection of biomarkers is therefore very important. Today, turnaround times of reference technologies are on average 18 days, with 14% of patients waiting longer than a month to be able to start treatment. 95% of the patients have to wait more than a week in order to receive biomarker results[58]. This means that precious time is lost whereas treatment could have been started and unnecessary use of chemotherapy with its side effects could have been avoided.

"Biocartis aims to democratize access to high quality molecular diagnostics, giving access to better treatments, for patients around the world." Rudi Pauwels, Founder Biocartis

[54] https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/targeted-therapies-fact-sheet#q1, last consulted on 29 January 2018.
[55] Bratzman SV et al. Expert Rev Mol Diagn. 2015; 15(6): 715—719. Siravegna G and Bardelli A. Genome Biol. 2014; 15(8): 449.
[56] 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.
[57] 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.
[58] Accès aux tests moléculaires EGFR, RAS et BRAF /Résultats d'une enquête dans 5 régions françaises, appui à la décision, INCa, janvier 2016.

Societal impact: a sustainable healthcare model with better health economics

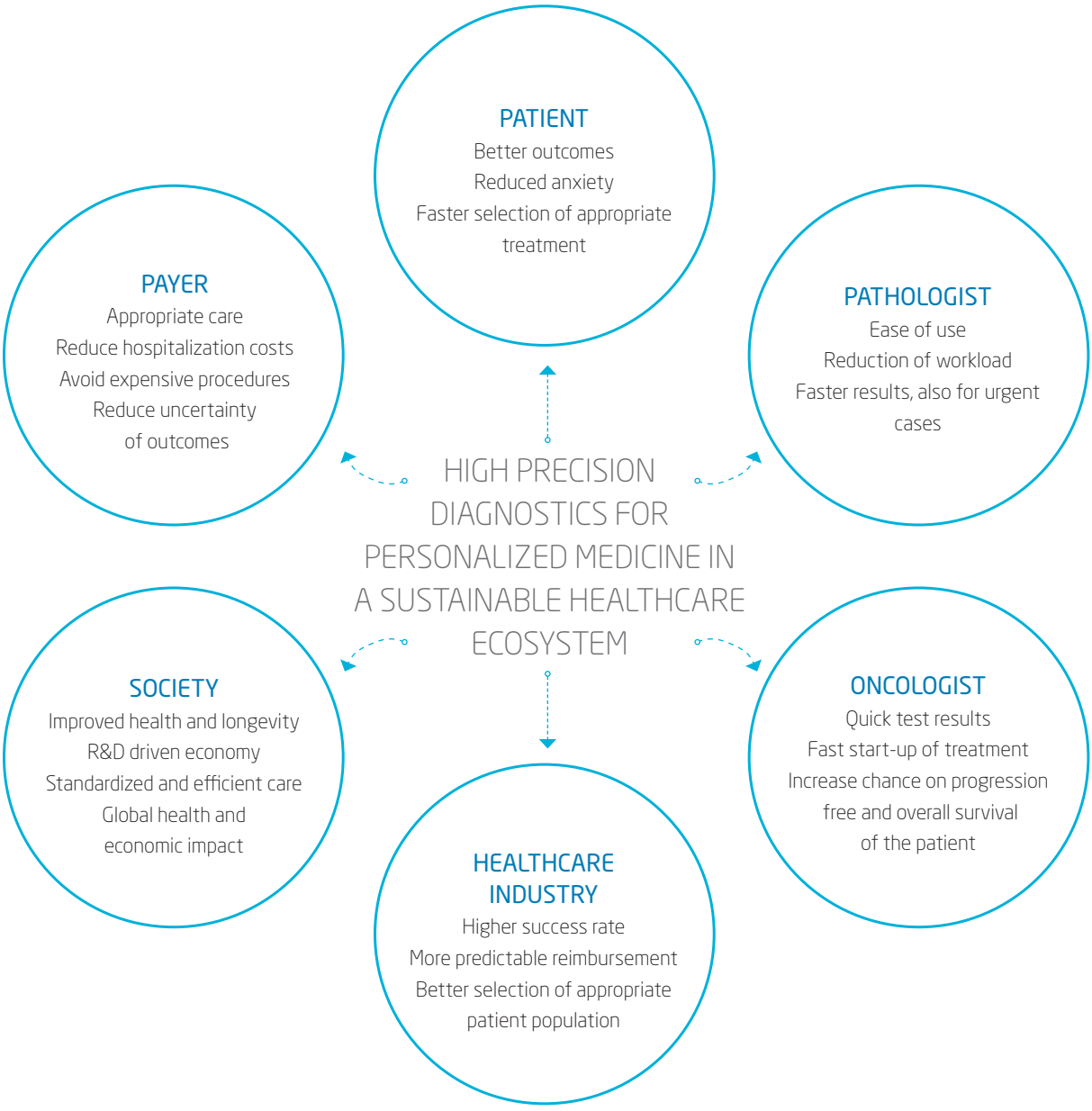
Biocartis creates value for society by contributing to sustainable healthcare costs worldwide as its products enable fast, early and highly accurate molecular information that enables faster and more efficient treatment decisions. This assists society to create a more sustainable healthcare model, where better informed treatment decisions lead to better health outcomes and more cost-efficient healthcare to the benefit of the patients, care providers, payers and the healthcare industry.

For the patient this could mean faster decision on therapy with the potential to better treatment outcomes

For the care provider such as the clinician or hospital, it could mean faster and cost effective access to accurate molecular information to better guide treatment selection with potentially less adverse effects. More information can be found under 'Customers' below.

For the payer, it could mean reduced healthcare costs, more predictable reimbursement costs and more certainty that the treatment will work efficiently for the patient, avoiding unnecessary costs

For the healthcare industry, it could mean a higher success rate and adoption of targeted treatments, an improved selection of the right patient population and a more predictable reimbursement related to more predictable healthcare outcomes.



3.2 / Partners

Partnerships aimed at enabling personalized medicine for patients across the globe through rapid, highly accurate and easy to use MDx solutions are a cornerstone of Biocartis' strategy in expanding its test menu and creating market adoption of its platform. Read more about Biocartis' partnership approach under 'Strategy'.

In 2017, Biocartis signed four new partnerships, incl. three partnerships (with A*STAR, LifeArc and Genomic Health Inc.) confirming its entry in the breast cancer domain, and a first CDx partnership with Amgen in the US. End of 2017, Biocartis had the following partnerships in place:

Johnson & Johnson – Janssen Pharmaceutica

Janssen Pharmaceutica NV (JPNV) signed a strategic partnership with Biocartis in December 2010 to co-develop assays for the Idylla™ platform and collaborate commercially. In November 2015, the Idylla™ Respiratory (IFV-RSV) Panel, 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), was launched as a CE-marked IVD test, and in September 2017 it received 510(k) clearance by the US FDA as the first US FDA cleared test on the Idylla™ platform. In June 2016, Biocartis received Emergency Use Authorization (EUA) by the US FDA for the Idylla™ Ebola Virus Triage Test for detection of the Ebola Zaire virus and which was co-developed by Biocartis NV, Janssen Diagnostics and the Belgian Institute of Tropical Medicine.

Merck KGaA, Darmstadt, Germany

Biocartis announced a partnership with Merck KGaA (Darmstadt, Germany) in January 2016 to improve access to easy, rapid and low invasive blood-based molecular diagnostic testing for patients with mCRC through liquid biopsy testing. After the launch of the RUO liquid biopsy assays (Idylla™ ctKRAS Mutation Assay in December 2016 and the Idylla™ ctN-RAS-BRAF-EGFR S492R Mutation Assay in March 2017), the Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test were launched as Biocartis' first CE marked liquid biopsy tests in November 2017 for in vitro diagnostic use to detect RAS and BRAF mutations in patients with metastatic colorectal cancer (mCRC). Both companies are now collaborating to make the tests commercially available to medical centers[59].

Amgen

In February 2016, Biocartis announced its collaboration with Amgen, a leading biotechnology company (NASDAQ: AMGN), to offer its new RAS biomarker tests to hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey. 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. One year later, in December 2017, Biocartis announced the signing of its CDx development agreement with Amgen, aimed at the registration of the Idylla™ RAS biomarker tests with the US FDA as a companion diagnostic test for Amgen's drug Vectibix® (panitumumab). This could allow for a more widespread RAS clinical testing, regardless of the clinical practice size, available lab infrastructure or experience level, and could enable same-day turnaround times. Post the reporting period, in January 2018, Biocartis announced the signing of a second CDx development agreement with Amgen, aimed at the development of Idylla™ CDx biomarker tests for a novel oncology compound to be used in the treatment of certain solid tumors.

Thermo Fisher Scientific

Biocartis announced in November 2016 to have granted rights in the US to 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 2017, the partnership was further developed through several activities including the establishment of Biocartis Inc. in the US (New Jersey area), the hiring of the US General Manager and core US support & sales team, the training of the Thermo Fisher Scientific sales force and the presentation of first Idylla™ performance data during a workshop at the Association for Molecular Pathology (AMP) meeting on 15 November 2017[60].

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

[60] The study was performed on 53 archived formalin-fixed paraffin-embedded (FFPE) colorectal cancer samples in the Dartmouth Hitchcock Medical Center. Compared to the NGS technology, Idylla™ scored 100% on sensitivity, specificity and positive & negative predictive value. Study results were first presented at the Biocartis Corporate Workshop held at the Association for Molecular Pathology (AMP) 2017 Annual Meeting, 15 November 2017, US.

LifeArc

On 7 June 2017, Biocartis announced to have signed an agreement with LifeArc (formerly known as MRC Technology), a medical research charity, for the development of selected molecular diagnostic tests for Idylla™. This partnership marked an important first step in the breast cancer menu that Biocartis is developing. For each selected test, LifeArc will act as a development contractor, whereas Biocartis will be responsible for the commercialization of the tests under its own label. The first test to be developed under the partnership will be a liquid biopsy test aimed at monitoring of metastatic breast cancer patients for resistance to hormone therapy.

A*STAR

Biocartis signed an agreement with A*STAR[61], 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. On 10 July 2017, Biocartis announced the renewal of its five-year strategic partnership with ETPL (the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research), where parties will co-invest in the development of jointly selected tests. Biocartis is responsible for the commercialization of the tests under its own label, and ETPL as the development partner through Singapore's Diagnostics Development (DxD) Hub. The first assay selected for development under the new partnership is a fully automated solid biopsy assay, operating directly from FFPE tumor tissue and aimed at supporting optimal therapy selection for Her2-targeted therapies , hormone receptor therapies, as well as some novel targets for breast cancer patients.

Genomic Health Inc.

On 13 September 2017, Biocartis and Genomic Health Inc. announced to have signed an exclusive agreement to develop an IVD version of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform that can be performed locally by laboratory partners and in hospitals around the world. The Oncotype DX Breast Recurrence Score test examines the activity of 21 genes in a patient's breast tumor tissue to provide personalized information for tailoring treatment based on the biology of their individual disease. As the only test proven to predict chemotherapy benefit, the Oncotype DX Breast Recurrence Score test is included in all major cancer guidelines worldwide and is considered standard of care for early-stage breast cancer. The strategic collaboration provided Genomic Health with exclusive worldwide rights to develop and commercialize its Oncotype DX Breast Recurrence Score® test on Idylla™, with the option to expand the collaboration to include additional tests in oncology and urology.

Immunexpress

On 24 January 2018, Biocartis and Immunexpress Pty Ltd ('Immunexpress'), a host response molecular diagnostic company committed to improving clinical and economic outcomes for suspected sepsis patients, announced to have entered into a partnership agreement aimed at the development and commercialization of Immunexpress' SeptiCyte™ test for use on Biocartis' sample-to-result Idylla™ platform. Under the partnership, parties will co-develop the SeptiCyte™ Idylla™ test, whereas Immunexpress will take the lead in the commercialization, with an initial focus on the US and the European markets. More information can be found under 'Events after the balance sheet date'.

Microbiome

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

Fast-track diagnostics, a Siemens Healthineers Company

Since May 2015, Biocartis is collaborating with Fast-track diagnostics, a leading provider of multiplex PCR test kits for infectious diseases, to develop a range of syndromic multiplex infectious disease tests for the Idylla™ platform.

[61] 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)

3.3 / Scientific Advisory Board

As a structural way to keep ahead of market trends in oncology MDx testing, Biocartis has established a Scientific Advisory Board. This Board is composed of Key Opinion Leaders in oncology and MDx testing and is headed by Biocartis' Chief Scientific Officer Geert Maertens. Members of this board serve as scientific advisors to Biocartis' product and technology developments and gather regularly to discuss medical and biomarker needs for cancer patients, as well as aid in Biocartis' Idylla™ pipeline priorities, in an independent and unbiased manner. An overview of the members is available on www.biocartis.com.

3.4 / Customers

Biocartis' customers are:

- The pathologist traditionally performs microscopic analysis of tissue to study a disease. Today, the pathologist increasingly also performs molecular pathology, the discipline that determines the molecular changes present in tumors for diagnostic, prognostic or predictive purposes. In this context, he often operates within central, highly skilled laboratories, running a high volume of tests in which they analyze a specific gene mutation related to the diagnosis of certain cancers. Other pathologists however do not run MDx testing today but send these out to specialized MDx labs. Idylla™'s easy workflow and easy interpretation of data allowing highly accurate diagnostic testing with reliable and actionable results, as such enabling complex molecular analysis and testing in house, consequently are essential product features for the different types of pathologists.

- The oncologist operates from a more decentralized (hospital) setting and is in contact with the patient, as such in a key position to impact the treatment plan. Fully automated solutions and rapid turnaround time are as such essential features for the oncologist.

- Central molecular diagnostic testing labs: these are high-volume, specialized labs that provide molecular diagnostic testing services to pathologists and oncologists that send out samples for testing, and who are using Idylla™ as an alternative to existing molecular diagnostic workflows for performance and operational efficiency reasons.

All benefit from more rapid, easy and high precision cancer diagnostics.

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

- Conferences: In 2017, Biocartis participated in 70 oncology conferences worldwide.

- 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: As a minimum, every customer receives the Idylla™ User training at the start at the moment of the instrument placement.

- Dedicated team of Customer support and Customer service employees.

- Regular direct customer communications on the product menu and commercial activities

- Website: With continuous updates.

- Regional customer meetings: In November 2017, Biocartis organized a Nordics meeting for 21 customers from Norway, Denmark and Sweden with the aim to facilitate relationships between customers, to enable a collective approach to validations and to improve the time to first-line treatment.

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 update meetings

- Regular distributor's newsletters with key updates on the Biocartis products

- 24/7 access to an online marketing platform, a one-stop-shop for all product marketing materials

Biocartis is in continuous dialogue with Key Opinion Leaders (KOLs, both oncologists and pathologists) that can assist in driving market adoption through ambassadorship and that provide continuous feedback on the Idylla™ product offering. KOLs activities in 2017 consisted of:

- Abstracts and publications: Biocartis collaborated with KOLs on innovative research and clinical data that translated into more than six abstracts/posters 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: In 2017, Biocartis organized two Meetings with KOL experts to assess current trends and market opportunities in oncology MDx testing. The first one, in March 2017, was on the topic of Liquid Biopsy (Mechelen, Belgium). The second one took place in the context of the ESMO meeting in Madrid, Spain in September 2017 and focused on Solid Tumors in melanoma, lung and colorectal cancer. In total, 13 key experts from key European countries attended to share their insights and knowledge on current trends in molecular diagnostic testing.

3.5 / Suppliers

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

- Risk assessments: Biocartis performs thorough risk assessments to get an overview of potential risks, before starting supplier collaboration.

- Quality agreements: Quality agreements with suppliers outline Biocartis' expectations in terms of technical specifications, quality, safety and environment.

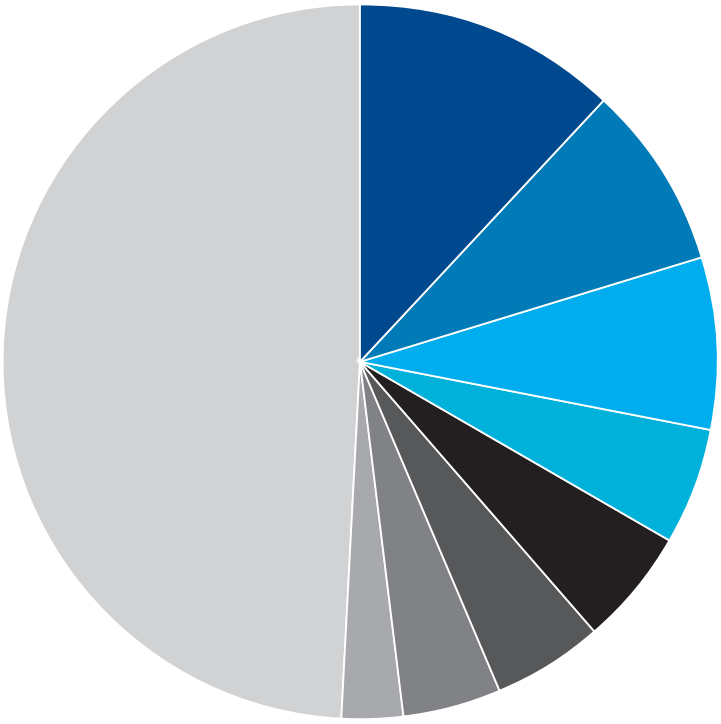
- Performance audits: Regular performance audits ensure that all materials meet expectations for technical specifications, quality, safety and environment.

- Supplier performance: Biocartis monitors and supports its suppliers through various other actions, e.g. product specification documents and audit action plans, to help suppliers meet the required performance criteria.

3.6 / Shareholders

Major shareholders

Biocartis has an international shareholder structure with both large and smaller specialized shareholders in healthcare and life sciences, and a broad base of more local retail investors. Based on the number of shares as at 31 December 2017 and the transparency notifications received until that date, the shareholder structure of the Company is as follows:



JOHNSON & JOHNSON INNOVATION – JJDC, INC. [1]: **12%**
DEBIOPHARM INNOVATION FUND S.A. [2]: **8.3%**
RMM S.A. [3]: **7.8%**
SYCOMORE ASSET MANAGEMENT [4]: **5.3%**
CAPFI DELEN ASSET MANAGEMENT N.V. [5]: **5.2%**
OPPENHEIMERFUNDS, INC. [6]: **5.1%**
PARTICIPATIEMAATSCHAPPIJ VLAANDEREN NV (FLEMISH REGION) [7]: **4.4%**
HITACHI CHEMICAL CO. LTD [8]: **2.8%**
OTHER INSTITUTIONAL AND RETAIL INVESTORS: **49.1%**

[1] Johnson & Johnson Innovation-JJDC, Inc., is a wholly owned subsidiary of Johnson & Johnson. Johnson & Johnson is not a controlled entity.
[2] Debiopharm Innovation Fund S.A[62]. (formerly Debiopharm Diagnostics S.A.) is controlled by Debiopharm Holding S.A., which is controlled by Thierry Mauvernay.
[3] RMM S.A. is controlled by Rudi Mariën.
[4] Sycomore Asset Management is not a controlled entity.
[5] Capfi Delen Asset Management N.V is controlled by Bank Delen, which is ultimately controlled by Stichting Administratiekantoor 'Het Torentje'.
[6] OppenheimerFund, Inc. Is not a controlled entity.
[7] The Flemish Region controls ParticipatieMaatschappij Vlaanderen NV.
[8] 51.2% shares of Hitachi Chemical Co., Ltd[63]. is directly held by Hitachi, Ltd., which is a parent company of Hitachi Chemical Co., Ltd. Hitachi, Ltd. is not a controlled entity.

The articles of association of Biocartis Group NV provide for shareholders notification threshold of 3%, 5% or a multiple of 5% (i.e. 10%, 15%, 20%, etc) of the total number of existing voting rights. All transparency notifications are available on www.biocartis.com.

[62] The transparency notification of Debiopharm Innovation Fund S.A was dated 20 December 2017, referring to the transaction date of 28 November 2017
[63] The transparency notification of Hitachi Chemical Co., Ltd was dated 11 January 2018, referring to the transaction date of 28 November 2017

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 2017, the share capital of the Company amounted to EUR 511,022.72 represented by 51,102,272 shares. In addition, as at such date, 7,717,888 shares could still be issued by the Company as follows:

- **774,755 shares** can be issued upon the exercise of 774,755 outstanding stock options (each stock option having the form of a warrant) that are still outstanding under the '2013 Plan' for employees, consultants and management members, entitling the holders thereof to acquire one new share per option ('2013 Stock Options');

- **255,846 shares** can be issued upon the exercise of 255,846 outstanding stock options (each stock option having the form of a warrant) that are still outstanding under the '2015 Plan' for employees, consultants, management members and directors, entitling the holders thereof to acquire one new share per option ('2015 Stock Options');

- **1,340,000 shares** can be issued upon the exercise of 1,340,000 outstanding stock options (each stock option having the form of a warrant) that are still outstanding under the '2017 Plan' for the CEO, entitling the holder thereof to acquire one new share per option ('2017 Stock Options'); and

- **5,347,287 shares** can be issued pursuant to a conversion option agreement entered into between Koninklijke Philips N.V. ('Philips') and the Company[64] ('Conversion Option').

The total number of fully diluted shares consequently amounted to 56,378,164 as of 31 December 2017. 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'.

Stock based incentive plans and conversion option agreement

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 Philips 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 Philips upon the acceptance of the exercise by the Company at its sole discretion. The number of 5,347,287 shares that can still be issued assumes that all outstanding warrants (entailing the issue of up to 2,370,601 new shares) have been exercised, it being understood that the actual number of shares issuable depends on a number of factors

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."

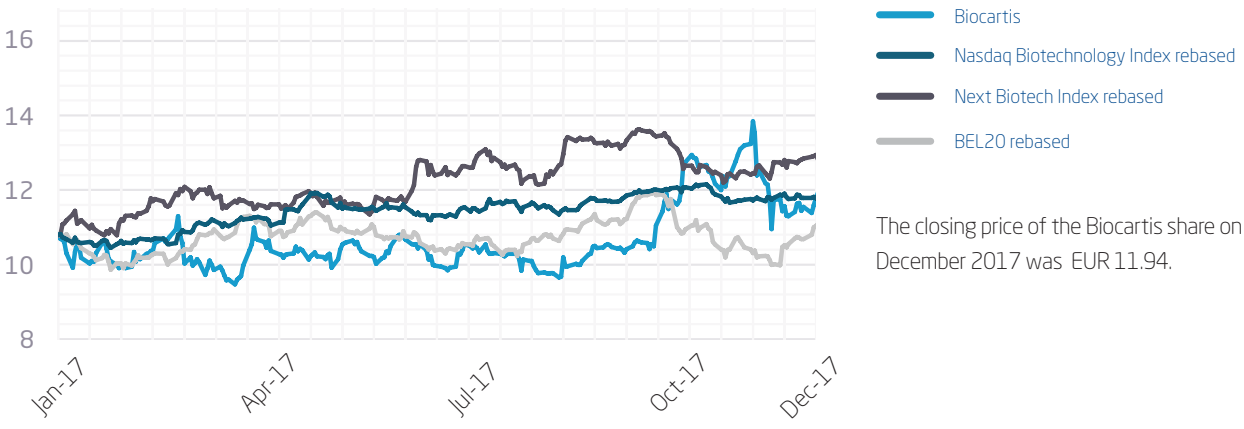
On 25 November 2014, the conversion option agreement was rolled up in order to relate to the Company and the Company's shares. This conversion right can only be exercised by Philips upon acceptance of the exercise by the Company. The price to be paid in relation to the shares upon conversion shall be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

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 perfomance 2017



The closing price of the Biocartis share on 29 December 2017 was EUR 11.94.

* Rebased at Biocartis share price on 2 January 2017 / Source: Bloomberg

Trading volume

Below is a summary of the 2017 trading volumes of Biocartis' share.

BCART	2017	2016	% Change
Average daily volume	77,210	43,539	43%
Average daily value	10.7	9.3	13%
Total traded volume	19,688,660	11,232,944	43%
Total traded value	218,354,801	97,176,297	55%

Source: Bloomberg

Analyst coverage

The Biocartis share was covered by four brokers end of 2017:

BROKER	ANALYST	RATING END 2017	TARGET PRICE END 2017
KBC Securities	Sandra Cauwenberghs/Lenny Van Steenhuyse	Buy	EUR 16.00
Kempen & Co	Alexandru Cogut	Buy	EUR 16.00
Degroof Petercam	Stéphanie Put	Buy	EUR 17.00
Berenberg	Michael Ruzic-Gauthier	Buy	EUR 16.50

Financial calendar 2017

1 March 2018	Full year results 2017
5 April 2018	Publication Annual Report 2017
26 April 2018	Q1 2018 Business Update
11 May 2018	Annual General Meeting Biocartis Group NV
6 September 2018	H1 2018 results
15 November 2018	Q3 2018 Business Update

Investor relations details

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

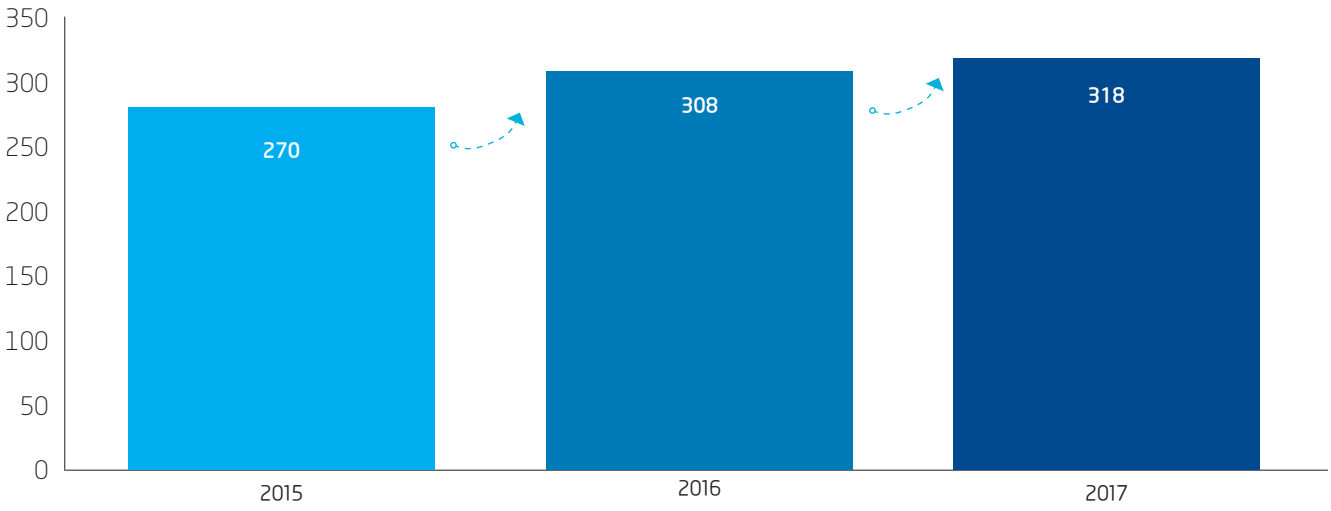
3.7 / Employees

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

- **Sense:** put your heart into what you do
- **Think:** surface tensions, think solutions
- **Share:** respect is an attitude
- **Do:** take responsibility; dare to fail

Biocartis' employees are essential to its success. The Biocartis workforce counted 318 FTEs on 31 December 2017, composed of 21 different nationalities with a balanced level of gender diversity of 50% male and 50% female, stable versus 2016. 90% of the Biocartis employees worked full-time in 2017, versus 92% in 2016.

Biocartis workforce evolution



Diversity & inclusiveness

With 318 employees at work in a company that is active in over 70 countries, the Biocartis culture is global, diverse and innovative. Talented, committed and responsible people with diverse backgrounds are essential for successfully implementing Biocartis' strategy.

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

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

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 provided, containing a wide range of corporate information varying from travel policy, to health, safety & environment and general customer and business topics.

- Biocartis School: these regular 'lunch & learn sessions' for employees stimulate continuous learning on different topics.

- Specific job training: depending on the specific job requirements, this can be discussed upon request.

In 2017, Biocartis employees followed 12,725 training hours. Biocartis furthermore engages with its employees in a participative manner through several channels:

- Quarterly 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

In 2017, Biocartis organized a Family Day at Biocartis headquarters, where employees and their families could enjoy both fun and educational activities on what Biocartis does.

Health & safety (H&S)

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 2017.

In 2017, Biocartis employees followed several H&S trainings, including basic rescue trainings, first-aid refreshment trainings, fire safety & spill training and machine & electrical safety. Biocartis is striving for a zero-tolerance when it comes to accidents at work. In 2017, Biocartis reported no lethal accidents or working accidents causing disability.

CHAPTER 4

Corporate Governance

4.1 / Introduction

The Company applies the Belgian Code on Corporate Governance as published on 12 March 2009 (the 'Corporate Governance Code'), which can be consulted on the website of the Belgian Corporate Governance Committee (www.corporategovernancecommittee.be/). In accordance with the Corporate Governance Code, the Company has adopted a corporate governance charter which came into effect upon the public listing of the Company's shares on 28 April 2015.

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's corporate governance charter was last updated at the meeting of the board of directors held on 20 March 2017. The main changes related to the establishment of a strategy committee within the board of directors and bringing the corporate governance charter in line with the Belgian Law of 7 December 2016 on the organization of the profession and public supervision of statutory auditors that entailed certain changes to the provisions on the composition and tasks of the audit committee. The articles of association and the corporate governance charter are available on the Company's website (https://investors.biocartis.com/en/corporate-governance-overview).

The Company strives to comply with the rules of the Corporate Governance Code as much as possible. Nonetheless, the board of directors is of the opinion that certain deviations from the provisions of the Corporate Governance Code are justified in view of the activities and size of the Company, and the specific circumstances in which the Company operates. These deviations are described below under 'Audit Committee', 'External and internal control' and 'Remuneration of the Directors'.

4.2 / Board of directors

Composition

NAME	POSITION	START OF TERM	END OF TERM
Rudi Mariën[1]	Chairman, non-executive director	2017	2018
Herman Verrelst	Chief executive officer, executive director	2017	2021
Rudi Pauwels[2]	Non-executive director	2015	2018
Hilde Windels[3]	Executive director	2015	2018
Hilde Eylenbosch[4]	Chief commercial officer, executive director	2016	2019
Roald Borré	Non-executive director	2016	2018
Peter Piot	Non-executive, independent director	2015	2018
Renaat Berckmoes[5]	Non-executive, independent director	2015	2018
Mark Shaffar[6]	Non-executive, independent director	2015	2018

[1] Permanently representing Gengest BVBA.
[2] Permanently representing Valetusan Ltd.
[3] Permanently representing Hilde Windels BVBA.
[4] Permanently representing Citros vof.
[5] Permanently representing Be@dvised BVBA.
[6] Permanently representing Shaffar LLC.

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.

Herman Verrelst was appointed as chief executive officer of the Company effective as of 31 August 2017. Herman Verrelst is a seasoned executive and serial entrepreneur with a proven international commercial track-record in molecular diagnostics. Prior to joining Biocartis, Herman Verrelst held the position of vice president and general manager of the genomics and clinical applications division of Agilent Technologies, a global leader in life sciences, diagnostics and applied chemical markets. Herman Verrelst joined Agilent following Agilent's acquisition of Cartagenia, a spin-off of Katholieke Universiteit Leuven (Belgium) focused on software solutions for clinical genetics and molecular oncology, of which Herman Verrelst was CEO and founder. Prior to that, Herman Verrelst was CEO of Medicim as well as founder and CEO of DATA4s.

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) between 2 March 2017 and 31 August 2017. From 2009 to mid-2011, she worked as independent CFO for several private biotech companies. From 1999 to 2008, Mrs. Windels was CFO of publicly-listed DevGen. She also served on the boards of DevGen and FlandersBio and currently serves as a board member of Ablynx, MDxHealth, VIB and Erytech SA. Mrs. Windels holds a Masters in economics from the University of Leuven, Belgium.

Hilde Eylenbosch was appointed as chief commercial officer of Biocartis in October 2016. Hilde 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 focused on industrial projects with a high degree of innovation and the potential to transform, also adding head of equity investments to his responsibilities. He is on the board of different PMV portfolio companies and a member of several advisory boards. Mr. Borré holds a Masters in financial and commercial sciences (specialization accountancy) from EHSAL Management School, Belgium.

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 among others an M.D. from the University of Ghent, Belgium and a Ph.D. in microbiology from the University of Antwerp, Belgium. Furthermore, he is a member of the US National Academy of Medicine and the UK Academy of Medical Sciences and was elected a 2014 TIME Person of the Year.

Renaat Berckmoes is non-executive director at FPIM-SFPI and a partner at Fortino CVA. Mr. Berckmoes 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.

Procedure for the appointment of directors

The directors are appointed for a term of maximum four years by the general shareholders' meeting. They may be re-elected for a new term. When a legal entity is appointed as director, it must appoint amongst its shareholders, directors, managers or employees a permanent representative charged with the performance of the mandate in the name and for the account of the legal entity-director. This permanent representative must be a natural person. In the event the office of a director becomes vacant, the remaining directors can appoint a successor temporarily filling the vacancy until the next general shareholders' meeting. The general shareholders' meeting can dismiss the directors at any time.

Changes to the composition of the board of directors

The annual shareholders' meeting held on 12 May 2017 reappointed Gengest BVBA, permanently represented by Rudi Mariën, as director of the Company for a term of one year, up to and including the closing of the annual shareholders' meeting to be held in 2018. It also confirmed the appointment of Shaffar LLC, permanently represented by Mark Shaffar, and Citros vof, permanently represented by Hilde Eylenbosch, who were both coopted by the board of directors in the course of 2016 after the resignation of respectively Mark Shaffar and Hilde Eylenbosch. On 11 September 2017, Herman Verrelst was appointed as director of the Company for a term up to and including the closing of the annual shareholders' meeting to be held in 2021.

The mandate of all directors, with the exception of the mandate of Herman Verrelst and Citros vof (permanently represented by Hilde Eylenbosch), will end after the annual shareholders' meeting of 2018. The proposal of the board of directors to the annual shareholders' meeting regarding the (re-)appointment of directors will be included in the convening notice of the annual shareholders' meeting. The convening notice will be published on 10 April 2018.

Diversity

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

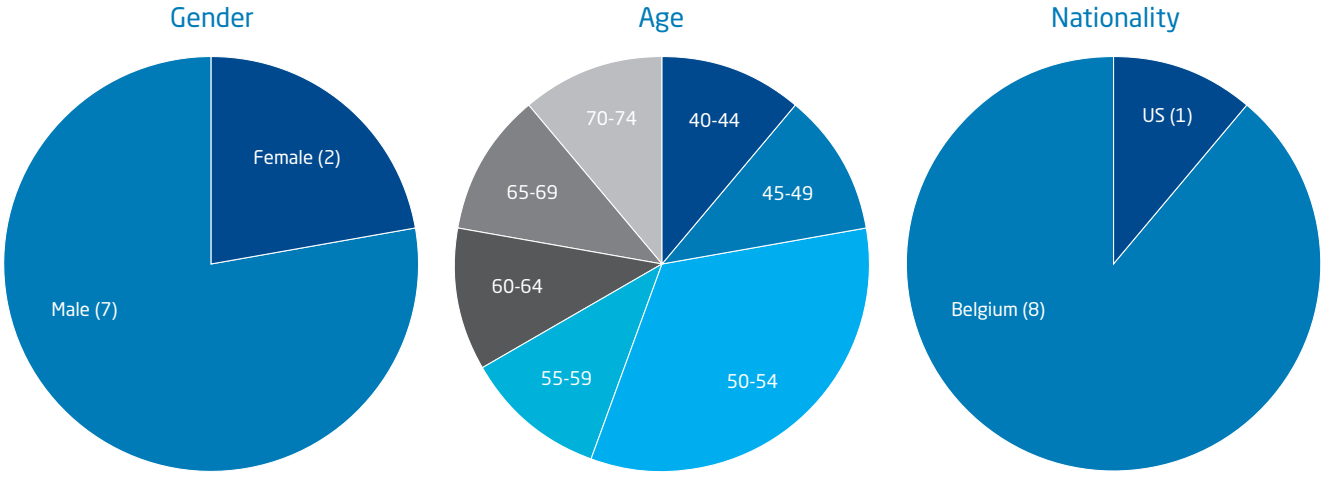
Name	Functional background and expertise	Gender	Age	Nationality
Rudi Mariën[1]	Biotech Investments Pharmaceutical sciences and clinical biology	Male	72	Belgium
Herman Verrelst	Molecular diagnostics Software solutions Entrepreneurship	Male	44	Belgium
Rudi Pauwels[2]	Biotech Molecular diagnostics and virology Entrepreneurship	Male	58	Belgium
Hilde Windels[3]	Finance Biotech Molecular diagnostics	Female	52	Belgium
Hilde Eylenbosch[4]	Marketing Sales Medicine	Female	54	Belgium
Roald Borré	Corporate finance and M&A Investment funds Accounting and auditing	Male	45	Belgium
Peter Piot	Microbiology Infectious diseases International institutions	Male	69	Belgium
Renaat Berckmoes[5]	Corporate finance and M&A Investment funds Accounting and auditing	Male	52	Belgium
Mark Shaffar[6]	Biotech Finance Accounting and auditing	Male	62	United States

(1) Permanently representing Gengest BVBA; / (2) Permanently representing Valetusan Ltd.; / (3) Permanently representing Hilde Windels BVBA; / (4) Permanently representing Citros vof; / (5) Permanently representing Be@dvised BVBA; (6) Permanently representing Shaffar LLC.

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

there is currently sufficient diversity in terms of age. It however believes that in terms of 'functional background and expertise' it would benefit from additional profiles with board experience in internationally operating (listed) companies, experience in commercialization of oncology molecular diagnostics products and/or corporate business development. Moreover, the board is of the opinion that although most board members have operated internationally, it may gain from additional diversity in terms of nationality.

In 2017, Herman Verrelst was the only newly appointed director. The board of directors will make every effort to propose candidate directors who satisfy the gaps in diversity identified above for nomination by the general shareholders' meeting going forward.
In order to ensure compliance with the provisions of Article 518bis of the Belgian Companies Code, the board of directors will make every effort to propose female candidate directors for nomination by the general shareholders' meeting going forward.



Activity report

In 2017, the board of directors held eleven meetings, of which six meetings were held at the registered office of the Company, four meetings were held by telephone conference and one meeting was held in the presence of a notary relating to the launch of a private placement via an accelerated bookbuild offering. The attendance rate (i.e. the attending of board meetings in person or by written proxy to a fellow director) for the board members in function at 31 December 2017 was 100%, save for Valetusan Ltd. (permanently represented by Rudi Pauwels) who was absent during three board meetings and Peter Piot who was absent during two board meetings.

During the meetings of the board of directors, the board among others reviewed the Group's strategy, discussed business development opportunities, discussed and approved the Company's new debt and equity financing, reviewed its corporate governance and adopted a new version of its corporate governance charter, established a new strategy committee, prepared the appointment of a new CEO (including warrant plan 2017), discussed the regular updates of the financial performance and approved the budget for the financial year 2018. 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. The board is in the process of carrying out an internal evaluation relating to its size, composition, performance and interaction with the executive management team and the board committees in accordance with provision 4.11 of the Corporate Governance Code. This is done by way of a questionnaire focusing on the aforementioned topics, the results of which will be discussed during one of the board meetings to be held in the first half of 2018.

Other board mandates

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

Rudi Mariën[1]	Gengest BVBA Biovest Comm.VA DSJ Bruxelles NV LMA BVBA Immo St-Michel NV MyCartis NV MDxHealth myoscience	Oystershell NV Bio-Incubator Gent II NV Argon CVA Jenavalve 4Tech Agrosavfe NV
Herman Verrelst	South Bay Ventures (SBV) BVBA Opdorp Finance BVBA	Icometrix
Rudi Pauwels[2]	Valetusan Ltd. Benaruca SA Benaruca Life Science Investments S.à r.l. Cambenes SA	Riverwells Investments SA Calimontes SL Caruso Inversiones SL
Hilde Windels[3]	Hilde Windels BVBA Ablynx NV MDxHealth NV	Erytech VIB MyCartis NV
Hilde Eylenbosch[4]	Citros vof	Immo Alexandre Wouters NV
Roald Borré	High Wind NV miDiagnostics NV Trividend CVBA Capricorn Cleantech Fund NV	Future Foundations NV Laboratoria Smeets NV Newtec Cy NV Zoefff! BVBA
Peter Piot	None	
Renaat Berckmoes[5]	Fortino Capital Partners NV FPIM-SFPI NV B-Hive NV	Zentrick NV Melitalink Plc Insided BV
Mark Shaffar[6]	Shaffar LLC	

[1] Acting as permanent representative of Gengest BVBA;
[2] Acting as permanent representative of Valetusan Ltd.;
[3] Acting as permanent representative of Hilde Windels BVBA;
[4] Acting as permanent representative of Citros vof;
[5] Acting as permanent representative of Be@dvised BVBA;
[6] Acting as permanent representative of Shaffar LLC.

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 three times in 2017. 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 23 February 2017:

"Prior to discussing the next item, Mr. Rudi Pauwels, Mrs. Hilde Windels and Mrs. Hilde Eylenbosch, permanent representatives and shareholders of respectively Valetusan Limited, Hilde Windels BVBA and Citros vof, directors of the Company, declared that they may have an interest of a financial nature which is conflicting with the decisions that fall within the scope of the powers of the Board of Directors, with respect to the determination of the amount of their variable remuneration regarding performance year 2016 and with respect to the determination of the maximum amount and underlying company and individual goals for their respective variable remuneration packages regarding performance year 2017.

In accordance with Article 523 of the Belgian Companies Code, Mr. Rudi Pauwels, Mrs. Hilde Windels and Mrs. Hilde Eylenbosch have decided that they will refrain from taking part in the deliberations and from voting on this agenda point. Mr. Rudi Pauwels, Mrs. Hilde Windels and Mrs. Hilde Eylenbosch left the meeting.

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.

Following the recommendations of the Remuneration and Nomination Committee, the Board of Directors discussed and deliberated on the variable remuneration for Valetusan Ltd., Hilde Windels BVBA, Citros vof and the other members of the executive management team.

The Board discussed the goals for the members of the executive management team relating to performance year 2016 and assessed the degree to which these goals were achieved in 2016. The Board was of the opinion that overall 65% of the company goals were achieved and RESOLVED to approve the amount of the variable remuneration for each member of the executive management team relating to performance year 2016 as proposed.

Subsequently, the Board was informed by the chairman of the Remuneration and Nomination Committee that the proposed framework for the 2017 bonus plan submitted to the Remuneration and Nomination Committee formed a good basis of discussion, but that a more detailed and comprehensive proposal (including specific goals and the respective weight of each goal) would be submitted to the next meeting of the Remuneration and Nomination Committee and, subsequently, to the Board.

Mr. Rudi Pauwels, Mrs. Hilde Windels and Mrs. Hilde Eylenbosch re-entered the meeting."

More information on the remuneration of Valetusan Ltd., Hilde Windels BVBA and Citros vof in 2017 can be found in the Remuneration Report below.

The conflicts of interest procedure pursuant to Article 523 of the Belgian Companies Code was applied a second time during the board meeting held on 20 March 2017:

"Prior to discussing the next item, each of Mrs. Hilde Windels and Mrs. Hilde Eylenbosch, permanent representatives and shareholders of respectively Hilde Windels BVBA and Citros vof, directors of the Company, declared that they may have an interest of a financial nature which is conflicting with the decisions that fall within the scope of the powers of the Board of Directors, with respect to the determination of the (maximum) amount and underlying company and individual goals for their respective variable remuneration packages regarding performance year 2017.

In accordance with Article 523 of the Belgian Companies Code, each of Mrs. Hilde Windels and Mrs. Hilde Eylenbosch decided that they will refrain from taking part in the deliberations and from voting on this topic. Mrs. Hilde Windels and Mrs. Hilde Eylenbosch subsequently left the meeting.

In accordance with Article 523 of the Belgian Companies Code, the auditor of the Company, Deloitte Bedrijfsrevisoren BV CVBA, permanently represented by Mr. Gert Vanhees, will be informed of

the existence of the conflict of interest. Furthermore, the relevant sections of these minutes will be entirely included in the annual report of the Board of Directors.

Following the recommendations of the Remuneration and Nomination Committee, the Board of Directors discussed and deliberated on the variable remuneration for Hilde Windels BVBA (CEO) and Citros vof (CCO). The proposal is to fix the maximum variable remuneration for the current CEO and the CCO to 20% of their respective annual fixed remuneration for 2017. In order to measure the performance of the CEO and the CCO the proposal is to link rewards to company goals (70%) and individual goals (30%). The company goals for the purposes of the variable remuneration are aligned with the overall company objectives as set by the Board and are translated into goals which can be grouped into five categories: commercial achievements (20%), financial position of the Company (20%), menu development (20%), operational efficiency (20%) and Board discretion (20%). The individual goals relate to business critical objectives that the CEO and CCO, from a company perspective, would most attribute to given amongst others their respective focus areas and leadership position.

The Board considered the proposed variable remuneration mechanism and the KPIs that will be used to measure and determine the variable remuneration for the CEO and CCO to be fully in line with the Company's interests. Therefore, after discussion, the Board RESOLVED to approve the variable remuneration mechanism for the CEO and CCO for 2017 as discussed.

Mrs. Hilde Windels and Mrs. Hilde Eylenbosch rejoined the meeting."

The conflicts of interest procedure pursuant to Article 523 of the Belgian Companies Code was applied a third time during the same board meeting held on 20 March 2017:

"Prior to discussing the next item, it was noted that Mr. Rudi Pauwels, director of the Company and permanent representative and shareholder of Valetusan Limited, declared prior to the meeting to have an interest of a financial nature which is conflicting with the decisions that fall within the scope of the powers of the Board of Directors, in respect of the entry into of the director agreement and the stock option agreement with Valetusan Limited (together the "Agreements").

This conflict of interest results from the fact that Valetusan Limited shall be both a director of the Company and a party to the Agreements. The Agreements will have financial consequences for the Company as, subject to the prior approval by the general shareholders' meeting of the Company (i) the director agreement will require the Company to pay remuneration in cash in an amount of EUR 87,500 per annum to Valetusan Limited for the provision of services under such agreement, and (ii) the stock option agreement will require the Company to grant 15,000 stock options (taking the form of warrants) per annum to Valetusan Limited on each of 1 March 2018, 1 March 2019 and 1 March 2020, subject to the director in question still being the chairman of the Strategy Committee on the respective dates.

Being absent during the Board meeting, Mr. Rudi Pauwels did not take part in the deliberations and voting on this topic, in accordance with Article 523 of the Belgian Companies Code.

In accordance with Article 523 of the Belgian Companies Code, the auditor of the Company, Deloitte Bedrijfsrevisoren BV CVBA, permanently represented by Mr. Gert Vanhees, will be informed of the existence of the conflict of interest. Furthermore, the relevant sections of these minutes will be entirely included in the annual report of the Board of Directors.

The Board of Directors took note of the proposal of the Remuneration and Nomination Committee of the Company regarding the entry into of the Agreements with, and the remuneration of, Valetusan Limited (permanently represented by Mr. Rudi Pauwels).

The Company is of the opinion that Mr. Rudi Pauwels has the experience and expertise to play an important role in defining the longer term strategy of the Company, including a pathway towards a Next-Generation Sequencing based product offering. Moreover, 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 Valetusan Limited and note that the fixed remuneration set out above is the total aggregate remuneration relating to Valetusan Limited's mandate as Board member and chairman/member of the Strategy Committee of the Company (i.e. it includes any and all attendance fees relating to Board meetings of the Company and the fixed remuneration applicable for all non-executive directors pursuant to the decision of the shareholders' meeting of the Company held on 13 April 2015). The Board RESOLVED that the entry into of the Agreements with Valetusan Limited is 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 RESOLVED to approve the entry into of the Agreements with Valetusan Limited, subject to the approval of the relevant provisions thereof by the general shareholders' meeting of the Company."

The procedure pursuant to Article 524 of the Belgian Companies Code was not applied in 2017.

4.3 / Committees of the board of directors

The board of directors has established three 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, 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, and the strategy committee. The terms of reference of these board committees are set out in the Company's corporate governance charter.

Audit committee

Composition

According to Article 526bis of the Belgian Companies Code, at least one member of the audit committee must be an independent director, the members of the audit committee must have a collective expertise relating to the activities of the Company, and at least one member of the audit committee must have the necessary competence in accounting and auditing.

The following four directors are members of the audit committee: Be@dvised BVBA, permanently represented by Renaat Berckmoes (chairman), Roald Borré, Gengest BVBA, permanently represented by Rudi Mariën, and Shaffar LLC, permanently represented by 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.

Activity report

In 2017, 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 audit committee also assessed the declarations regarding internal control and risk management in the annual report 2016. 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 2017 during the last meeting of the audit committee held in 2017. The audit committee further reviewed the performance of the Group presented through the management reporting documentation and it discussed the 2018 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.

Remuneration and nomination committee

Composition

The remuneration and nomination committee consists of three directors: Gengest BVBA, permanently represented by Rudi Mariën (chairman), Be@dvised BVBA, permanently represented by Renaat Berckmoes, and Shaffar LLC, permanently represented by 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 participates to the meetings of the remuneration and nomination committee in an advisory capacity each time the remuneration of another member of the executive management is discussed.

Activity report

In 2017, the remuneration and nomination committee held five meetings which were attended by all three members, resulting in a 100% attendance rate for the remuneration and nomination committee meetings. The remuneration and nomination committee was involved in the search for a new chief executive officer of the Company and made proposals to the board regarding his remuneration package. It was also involved in the search for new candidate board members, which will be proposed to the shareholders' meeting to be held in May 2018. Furthermore, the committee prepared the remuneration report, reviewed and discussed the remuneration of the members of the executive management team and proposed to appoint Benoit Devogelaere as chief technology officer, and Vishal Sikri as general manager US. 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.

Strategy committee

Composition

The strategy committee must consist of at least two directors. Both executive and non-executive directors can be member of the strategy committee. The chief executive officer of the Company shall in any event be a member of the strategy committee. Currently, the strategy committee consists of two directors: Valetusan Ltd., permanently represented by Rudi Pauwels (chairman) and Herman Verrelst.

Activity report

In 2017, the strategy committee held three meetings. During its meetings, the strategy committee discussed topics of particular strategic importance for the Company and reported thereon to the board of directors. In any event, the decision-taking with respect to these matters remains with the board of directors acting as a collegial body.

4.4 / Executive management

Composition

Biocartis' executive management is composed of the chief executive officer and the other members of the executive management. On 31 December 2017, the executive management team was composed as follows:

NAME	AGE	FUNCTION
Herman Verrelst[1]	44	Chief executive officer (CEO)
Ewoud Welten	34	Chief financial officer (CFO)
Hilde Eylenbosch[2]	54	Chief commercial officer (CCO)
Benoit Devogelaere[3]	37	Chief technology officer (CTO)
Ulrik Cordes	47	EVP Pharma Collaborations and Companion Diagnostics
Erwin Sablon	53	Head of R&D and Alliance Management
Susy Spruyt	50	Human Resources Director
Erik Vossenaar	45	VP Business Development
Reginald Van Genechten	52	Head of Manufacturing and Supply Chain
Hilde Windels[4]	52	Executive director

Notes:

[1] Herman Verrelst was appointed as CEO with effect as from 31 August 2017.

[2] Permanently representing Citros vof.

[3] Benoit Devogelaere started as CTO with effect as from 1 December 2017.

[4] Permanently representing Hilde Windels BVBA. Hilde Windels BVBA took over as CEO (ad interim) from Valetusan Ltd. (permanently represented by Rudi Pauwels) on 2 March 2017, and was replaced by Herman Verrelst with effect as from 31 August 2017. Since 1 January 2018, Hilde Windels BVBA is no longer part of the executive management.

Herman Verrelst is the chief executive officer of the Company. See his 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.

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

Benoit Devogelaere is the chief technology officer. He is an experienced molecular diagnostics professional with a proven track record in diagnostic assay development and product innovation. Benoit started his career in the pharmaceutical sector (Johnson and Johnson) in the area of virology. In 2011, he joined Biocartis, leading the company's efforts to develop its first CE-IVD marked molecular diagnostic oncology tests. In 2013, he joined Cartagenia, a provider of diagnostic software, as R&D Operating Manager to further expand the Cartagenia product portfolio. In 2015, following the acquisition of Cartagenia by Agilent Technologies (NYSE: A), a global leader in life sciences, diagnostics and applied chemical markets, Benoit relocated to Silicon Valley in the US where he took up extended cross-functional responsibilities related to portfolio strategy, product roadmapping and technology scouting. End of 2017, Benoit relocated back to Belgium to join Biocartis as chief technology officer. Benoit holds a Master in biological engineering and a PhD in medical sciences (University of Leuven, Belgium).

Hilde Windels was the deputy chief executive officer until 2 March 2017 and the chief executive officer (ad interim) until 31 August 2017. She is an executive director of the Company. See her biography under 'board of directors'.

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 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 among 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. Prior to joining Biocartis, Mr. Sablon held the position of director project management at Ablynx NV (Ghent, Belgium) from 2008 to 2010. He also gained extensive experience in in vitro diagnostics (IVD) development of molecular diagnostic assays during his 18 years at Innogenetics NV (Ghent, 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, among others, head of technical operational excellence at McNeil (US based, part of Johnson & Johnson) 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.

Diversity

The board of directors has not yet established a diversity policy with respect to the executive management team in 2017 because it wanted the new chief executive officer, who was only appointed as such with effect as of 31 August 2017, to be involved in this process. It is anticipated that such policy will be established in the course of 2018.

4.5 / Share capital and shares

Issue of shares by the Company in 2017

On 1 January 2017, the share capital of the Company amounted to EUR 446,481.05, represented by 44,648,105 shares. In the course of 2017, there were two capital increases resulting from the exercise of warrants under the stock option plan 2013, resulting in the issuance of 54,167 new shares, an increase of the share capital of EUR 541,67 and an increase of the issuance premium account of EUR 439,884.79. In addition, on 1 December 2017, the Company issued 6,400,00 new shares in the framework of the closing of a private placement via an accelerated bookbuild offering launched on 28 November 2017 within the framework of the authorized capital, resulting in an increase of the share capital of EUR 64,000.00 and an increase of the issuance premium account of EUR 79,936,000.00. Consequently, on 31 December 2017, the total share capital of the Company amounted to EUR 511,022.72, represented by 51,102,272 shares. An overview of the major shareholders of the Company on 31 December 2017 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.

Number and form of shares of the Company

Of the 51,102,272 shares of the Company outstanding at 31 December 2017, 10,192,802 were registered shares and 40,909,470 were dematerialized shares. All shares belong to the same class and are freely transferable. All shares are issued and fully paid-up.

Rights attached to shares of the Company

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

Subject to certain exceptions, no shareholder may, pursuant to Article 545 of the Belgian Companies Code, cast a greater number of votes at a general shareholders' meeting of the Company than those voting rights that such shareholder has notified to the Company and the Belgian Financial Services and Markets Authority ('FSMA'), in accordance with the applicable rules laid down in the Belgian Law of 2 May 2007 on the disclosure of major shareholdings, at least 20 calendar days prior to the date of the general shareholders' meeting. In general, pursuant to the aforementioned Law of 2 May 2007 and the Company's articles of association, a notification to the Company and the FSMA is required by all natural and legal persons in each case where the percentage of voting rights in the Company held by such persons reaches, exceeds or falls below the threshold of 3%, 5%, 10%, and every subsequent multiple of 5%, of the total number of voting rights in the Company. Furthermore, in certain instances, voting rights can be suspended by a competent court or by the FSMA.

Right of the board of directors to increase the share capital of the Company

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

The general shareholders' meeting further decided that the board of directors, when exercising its powers under the authorized capital, is authorized to restrict or cancel the statutory preferential subscription rights of the shareholders (within the meaning of Article 592 and following of the Belgian Companies Code). This authorization includes the restriction or cancellation of the preferential subscription rights for the benefit of one or more specific persons (whether or not employees of the Company or its subsidiaries). The authorization is valid for a term of five years as from the date of the publication of the authorization in the Annexes to the Belgian State Gazette *(Belgisch Staatsblad/Moniteur belge)*, i.e., until 13 May 2020.

On 21 November 2016, the Company increased its share capital with an amount of EUR 40,589.17 in the framework of the closing of a private placement via an accelerated bookbuild offering launched on 17 November 2016 within the framework of the authorized capital. On 1 December 2017, the Company increased its share capital with an amount of EUR 64,000.00 in the framework of the closing of a private placement via an accelerated bookbuild offering launched on 28 November 2017 within the framework of the authorized capital. 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 286,850.96.

Modifications to the articles of association and share capital

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

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

Purchase and sale of treasury shares

In accordance with the Belgian Companies Code, the Company may purchase, subject to the provisions of the Belgian Companies Code, its own shares and dispose thereof if authorized by a prior decision of an extraordinary shareholders' meeting approved by a majority of 80% of the votes cast, at a meeting where at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required attendance quorum is not present or represented at the first meeting, a second meeting needs to be convened. The second general shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special majority requirements, however, remain applicable. The aforementioned rules are also applicable to the acquisition of shares of the Company by its subsidiaries. The board of directors is currently not authorized by an extraordinary shareholders' meeting to purchase or sell its own shares. On 31 December 2017, neither the Company nor any subsidiary of the Company held any shares in the Company.

Public takeover bids

Public takeover bids for the Company's shares and other securities giving access to voting rights (such as warrants and convertible bonds, if any) are subject to supervision by the FSMA. Any public takeover bid must be extended to all of the Company's voting securities, as well as all other securities giving access to voting rights. Prior to making a bid, a bidder must publish a prospectus which has been approved by the FSMA prior to publication.

The Belgian Law on public takeover bids of 1 April 2007 provides that a mandatory bid must be launched if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting for their account, directly or indirectly holds more than 30% of the voting securities in a company having its registered office in Belgium and of which at least part of the voting securities are admitted to trading on a regulated market or on a multilateral trading facility designated by the Belgian Royal Decree of 27 April 2007 on public takeover bids. The mere fact of exceeding the relevant threshold through the acquisition of shares will give rise to a mandatory bid, irrespective of whether the price paid in the relevant transaction exceeds the current market price. The duty to launch a mandatory bid does not apply in certain cases set out in the aforementioned Belgian Royal Decree of 27 April 2007 such as (i) in case of an acquisition if it can be shown that a third party exercises control over the Company or that such party holds a larger stake than the person holding 30% of the voting securities or (ii) in case of a capital increase with preferential subscription rights decided by the Company's general shareholders' meeting.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose significant shareholdings and merger control, which may apply to the Company and which may create hurdles to an unsolicited tender offer, merger, change in management or other change in control. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of the Company's shares. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their shares at a premium.

Pursuant to Belgian company law, the board of directors of Belgian companies may in certain circumstances, and subject to prior authorization by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (pursuant to the authorized capital) or through share buy-backs (i.e. purchase of own shares). In principle, the authorization of the board of directors to increase the share capital of the Company through contributions in kind or in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the securities of the Company. The general shareholders' meeting can, however, under certain conditions, expressly authorize the board of directors to increase the capital of the Company in such case by issuing shares in an amount of not more than 10% of the existing shares of the Company at the time of such public takeover bid. Such authorization has not been granted to the board of directors of the Company.

The Company's articles of association do not provide for any specific protective mechanisms against public takeover bids.

The Company is a party to the following significant agreements which take effect, alter or terminate upon a change of control over the Company following a takeover bid:

- The EUR 15.0m subordinated loan agreement dated 19 July 2016 entered into between PMV NV (formerly PMV-Tina Comm.VA, liquidated), FPIM Federale Participatie- en Investeringsmaatschappij NV, the Company and Biocartis NV, of which the change of control clause was approved by the annual shareholders' meeting of 2017 and whereby the lenders will, for a period of 30 days after becoming aware that a change of control will take place or has taken place, have the right to require an early repayment of the outstanding principal amount of the loan (including the cash interest and capitalized interest accrued on the loan until the early repayment date).

- The EUR 17.5m credit contract dated 10 October 2017 entered into between KBC Bank NV, the Company and Biocartis NV, of which the change of control clause will be submitted for approval by the annual shareholders' meeting to be held in 2018 and whereby KBC Bank NV is entitled, without the need to have prior recourse to the courts or to give prior notice, to terminate or suspend both the utilized and the unutilized portion of the credit facility and its forms of utilization in whole or in part with immediate effect from the date the letter advising such termination or suspension is sent upon a substantial change in the shareholder structure of the borrowers that could affect the composition of the management bodies or the overall risk assessment by the bank.

- The EUR 10.0m credit contract dated 6 October 2017 entered into between BNP Paribas Fortis NV, the Company and Biocartis NV, of which the change of control clause will be submitted for approval by the annual shareholders' meeting to be held in 2018 and whereby BNP Paribas Fortis NV is entitled, without the need to give prior notice, to terminate or suspend both the utilized and the unutilized portion of the credit facility and its forms of utilization in whole or in part with immediate effect upon a substantial change in the shareholder structure of the borrowers that could affect the composition of the management bodies (and the persons entrusted with the management and daily management) or the overall risk assessment by the bank.

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

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

4.6 / External and internal control

External control

The Company's statutory auditor is Deloitte Bedrijfsrevisoren BV ovve CVBA, represented by Gert Vanhees, auditor. The statutory auditor performs the external audit of the consolidated and statutory accounts of the Company and of its Belgian subsidiary (Biocartis NV). The statutory auditor has been appointed for the statutory term of three years at the Company's incorporation on 24 November 2014, and, upon recommendation by the Company's audit committee, the reappointment of the auditor will be submitted for approval by the annual shareholders' meeting to be held in 2018.

In 2017, a total amount of EUR 122,563.01 was paid to the statutory auditor. This amount includes the following elements: EUR 100,000 for audit fees, EUR 16,200 for work performed in relation to legal mission work of the Company, and EUR 6,363.01 for tax related work.

Internal control

Biocartis has taken different steps to identify the most important risks that it is exposed to and to keep these risks at an acceptable level. The different risks have been identified in this annual report under the section 'risks related to our business'. The control activities of Biocartis include the measures taken by it to ensure that the most important risks which were identified are controlled or mitigated. Biocartis manages some of these risks by entering into insurance contracts covering such risks.

As indicated in this annual report, the board of directors has set up an audit committee that gives guidance and controls the financial reporting of the Group. It ensures the presence of sufficient internal control mechanisms and, in co-operation with the statutory auditor of the Group, investigates questions in relation to accounting and valuation rules. The audit committee more specifically reviews the financial accounts of the Company, the management reporting and budgets and gives its recommendation with regard to these documents to the board of directors. Given the current size and complexity of the Company's business, as well as the policies and internal processes it has in place, no independent internal audit function has been established. The need for this function will be reviewed annually.

Biocartis has set up control policies and risk management systems to ensure that the main business risks are properly identified, managed and disclosed. The objectives of the Biocartis internal control framework are achieving effectiveness and efficiency of operations, reliability of financial reporting, compliance with applicable laws and regulations and the safeguarding of assets. To this end, Biocartis has established a number of instruments that are discussed on a regular basis in the audit committee and are presented to the board of directors:

- Long term financial planning and annual budgets: at least once per year, the management of Biocartis prepares the annual budget. This is 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.

- Time registration on projects and activities to monitor staff resource allocation as compared to planning.

- Statutory financial and tax reporting per legal entity and IFRS financial accounts on a consolidated level: management prepares and presents to the audit committee and the board of directors these accounts at least every six months.

In order to ensure the quality and reliability of the financial information, Biocartis has established and is continuously improving its key standardized information flow processes, consistent throughout the organization. The most important financial processes are designed to ensure data consistency and comparability, as well as to detect potential anomalies. These processes include amongst others expenditure, revenue, inventory, fixed assets, financial closing and treasury processes.

Management defines the values as well as the skills and job descriptions needed for all functions and tasks within the organization. Biocartis is organized around four key activities (research & development, manufacturing, commercial and G&A) and for all functions clear areas of responsibility are defined, as well as horizontal communication processes ensuring involvement of different functions in more complex and multilayered issues.

In addition, Biocartis has developed a vast set of procedures and workflows on key business cycles that are all documented through a unique IT system. The system is designed to help meet the quality levels required for Biocartis' products and is one of the elements used by the quality department to ensure product and process compliance with the regulatory framework. Further details on the quality management system are provided under 'Products'.

Before commercializing its products, Biocartis performs the necessary tests to reach the level of quality acceptance. In order to try to assure the best possible quality standards during production, Biocartis has installed an in-house quality team that is present in the different stages of product development and manufacturing.

CHAPTER 5

Remuneration report

5.1 / 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.

5.2 / Remuneration policy

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 is reviewed against market practice at regular occasions, in particular at the occasion of the search for potential new board members. Their remuneration is composed of a fixed fee and an attendance fee. In addition, the independent directors are entitled to warrants which are not linked to any performance criteria. The directors who are also a member of the executive management team are remunerated for their executive management mandate only, and not for their director mandate. The remuneration of the CEO and the other members of the executive management team consists of an annual fixed base salary, a variable remuneration (cash bonus), participation in stock option plans and certain other components. The variable remuneration is structured so as to link rewards to corporate and/or individual performance of the executives. 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.

Relative importance of each component of the remuneration

For 2017, Herman Verrelst's fixed remuneration as CEO was equal to EUR 125,000 (plus a one-time sign-on bonus of EUR 50,000) and his variable remuneration could be maximum EUR 62,500 (being 50% of his fixed remuneration). As from 2018, his annual fixed remuneration will be equal to EUR 375,000 and his variable remuneration will be maximum EUR 187,500, being 50% of his annual fixed remuneration. A first installment equal to 50% of such annual bonus will be linked to a one year performance period, a second installment equal to 25% of such annual bonus will be linked to a two year performance period and a third installment equal to 25% of such annual bonus will be linked to a three year performance period.

For 2017, the variable remuneration of the former CEO (Hilde Windels BVBA, permanently represented by Hilde Windels), the CCO and the CFO could be maximum 20% 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 2017 could be maximum 15% of their respective annual fixed remuneration of the year for which the variable remuneration is awarded. In addition, the members of the executive management team 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.

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

The stock options granted under the 2008 Plan and the warrants granted under the 2013 Plan and 2015 Plan are not linked to any performance criteria, except for the warrants granted to Benoit Devogelaere, CTO of Biocartis, of which 50% are not linked to any performance criteria (time-based vesting), while the other 50% will vest if and to the extent certain objective and verifiable key performance indicators are achieved. 50% of the warrants granted to Herman Verrelst under the 2017 Plan are not linked to any performance criteria (time-based vesting), while the other 50% will vest if and to the extent of the CEO achieving certain objective and verifiable key performance indicators. The stock options and warrants are not considered as variable remuneration, nor as fixed remuneration or annual remuneration pursuant to Articles 520ter, 524bis, 525 and 554 (as applicable) of the Belgian Companies Code. More information can be found under 'Characteristics of the stock option and warrant plans'.

Remuneration policy for the next two financial years (2018-2019)

The Company currently has no plans to substantially deviate from the general principles of the remuneration policy used in 2017, as described in this Remuneration Report, in the next two financial years.

5.3 / Remuneration of the Directors

Principles

The remuneration of the non-executive directors 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 Herman Verrelst, Hilde Windels BVBA (permanently represented by Hilde Windels) and Citros vof (permanently represented by Hilde Eylenbosch). The annual shareholders' meeting held on 12 May 2017 resolved that Valetusan Ltd., permanently represented by its permanent representative Rudi Pauwels, is entitled to a fixed fee of EUR 87,500 per annum for its role as chairman of the strategy committee.

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 (except for Valetusan Ltd., as set out above)

Attendance fees:

In addition to the annual fixed fees mentioned above, each non-executive director (except for Valetusan Ltd.) 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. Part of the warrants under the 2015 Plan 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 granting of warrants to independent directors is contrary to provision 7.7 of the Corporate Governance Code that provides that non-executive directors should not be entitled to performance related remuneration such as among others stock related long-term incentive schemes. The Company justifies this as it allows to limit the portion of remuneration in cash that it would otherwise need to pay to attract or retain internationally renowned experts with the most relevant skills, knowledge and expertise, as this is customary for directors active in companies in the biotech and life sciences industry, and as the portion of the remuneration payable in warrants is limited. The board of directors is of the opinion that the granting of warrants has no negative impact on the functioning of the independent directors.

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

Remuneration of the members of the Board of Directors in 2017

Based on what is set out above, the remuneration of the directors for the performance of their director mandate in 2017 is as follows:

DIRECTOR	ANNUAL FIXED FEES	ATTENDANCE FEES	TOTAL
Gengest BVBA, represented by Rudi Mariën	EUR 24,000	EUR 22,500	EUR 46,500
Be@dvised BVBA, represented by Renaat Berckmoes	EUR 12,000	EUR 21,500	EUR 33,500
Roald Borré[1]	EUR 8,500	EUR 22,000	EUR 30,500
Shaffar LLC, represented by Mark Shaffar	EUR 8,500	EUR 22,500	EUR 31,000
Peter Piot	EUR 8,500	EUR 12,000	EUR 20,500
Valetusan Ltd., represented by Rudi Pauwels[2]	N/A	N/A	EUR 72,917

Notes:

[1] Borré renounced his historical and future remunerations as director and member of the audit committee of the Company, and indicated that these amounts are to be paid to charity.

[2] The annual shareholders' meeting held on 12 May 2017 resolved that Valetusan Ltd., permanently represented by Rudi Pauwels, is entitled to EUR 87,500 per annum. The amount mentioned covers the period March 2017 – December 2017, i.e. 10/12 of EUR 87,500.

As indicated above, Herman Verrelst, Hilde Windels BVBA and Citros vof are not remunerated for their director mandate.

During 2017, each of Peter Piot, Shaffar LLC (permanently represented by Mark Shaffar) and Be@dvised BVBA (permanently represented by 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 2017, each of these independent directors held 10,000 warrants, and none of them exercised any warrants granted to them.

5.4 / Remuneration of the members of the executive management team

Principles

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

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

Herman Verrelst took over the role of CEO of the Company effective as from 31 August 2017. For the period between 31 August 2017 and 31 December 2017, the variable remuneration of the CEO was structured so as to link rewards 100% to company goals (no individual goals). The CEO's variable remuneration could be maximum 50% of his fixed remuneration for the period between 31 August 2017 and 31 December 2017. For 2017, the variable remuneration of the former CEO (Hilde Windels BVBA), the CFO and the CCO was structured so as to link rewards to company goals (70%) and to individual goals (30%). The former CEO's, the CFO's and the CCO's variable remuneration could be maximum 20% of their respective annual fixed remuneration of the year for which the variable remuneration was awarded (i.e. 2017). The variable remuneration of the other members of the executive management team was structured so as to link rewards to company goals (60%) and individual goals of the respective executives (40%). Their variable remuneration could be maximum 15% of their respective annual fixed remuneration of the year for which the variable remuneration was awarded (i.e. 2017).

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 2017 were aligned with the overall company objectives as set by the board of directors and were translated into goals which can be grouped into the following categories: commercial achievements, menu development, financial health of the Company, and realization of operational efficiencies. Each of these goals accounted for 20%, with the remaining 20% being at board discretion. 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 among 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 was assessed in the beginning of the first subsequent year (i.e. 2018) by the remuneration and nomination committee and finally established by the board of directors.

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

Remuneration of the members of the executive management team in 2017

The following remuneration and compensation was paid to the CEO and the other members of the executive management with respect to 2017:

AMOUNTS IN EUR[1]	HERMAN VERRELST[2]	HILDE WINDELS BVBA[3]	VALETUSAN LTD.[4]	OTHER EXECUTIVES
Annual base salary	EUR 137,228.26	EUR 104,320.00	EUR 58,250.00	EUR 1,392,216.58
Variable remuneration	EUR 45,000.00	EUR 40,896.00	-	EUR 171,928.15
Company car	-	-	-	EUR 67,012.69
Group insurance[5]	-	-	-	EUR 65,281.99
Expat expenses	-	-	-	EUR 9,773.89
Other elements[6][7]	EUR 50,000.00	-	-	EUR 18,491.45
Total	EUR 232,228.26	EUR 145,216.00	EUR 58,250.00	EUR 1,724,704.75

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. Employer social security contributions amounted to EUR 178,670.68. The value of the share-based payments equals EUR 538.954,06.

[2] Herman Verrelst acted as CEO as from 31 August 2017. However, his managing director contract entered into effect on 21 August 2017.

[3] Hilde Windels BVBA (permanently represented by Hilde Windels) acted as CEO (ad interim) between 2 March 2017 and 31 August 2017.

[4] Valetusan Ltd. (permanently represented by Rudi Pauwels) acted as CEO until 2 March 2017.

[5] The Biocartis group insurance package is a defined contribution plan covering life (pension), decease, disability and premium relief.

[6] Herman Verrelst was entitled to a sign-on bonus in an amount of EUR 50,000.00.

[7] The other elements include meal vouchers, medical plan and representation allowances.

In 2017, 1,527,000 warrants were granted to and accepted by members of the executive management team under the 2013 Plan and the 2017 Plan as follows: 1,340,000 warrants were granted to Herman Verrelst under the 2017 Plan, and 187,500 warrants were granted to Benoit Devogelaere under the 2013 Plan. In total, 20,000 warrants were exercised by members of the executive management team in 2017 (i.e. by Mr. Erwin Sablon), and 2,000 stock options under the 2008 Plan were exercised by Mr. Erik Vossenaar. No stock options or warrants granted to the members of the executive management team expired or became null and void during 2017.

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 2017:

Name	Granted	Vested	Exercised	Total held	Exercise	Price Plan
Herman Verrelst	1,340,000	0	0	1,340,000	EUR 9.92	2017 Plan
Rudi Pauwels[1]	-	-	-	-	-	-
Hilde Windels	100,000	100,000	0	100,000	EUR 8.1309	2013 Plan
Hilde Eylenbosch[2]	62,500	16,926	0	62,500	EUR 8.4967	2015 Plan
Ewoud Welten	62,500	36,456	0	62,500	EUR 13.28	2015 Plan
Ulrik Cordes	62,500	62,500	0	62,500	EUR 8.1309	2013 Plan
Erwin Sablon	30,000	30,000	30,000	0	EUR 8.1309	2013 Plan
Susy Spruyt	10,000	5,616	0	10,000	EUR 12.77	2015 Plan
Erik Vossenaar	12,000	12,000	2,000	10,000	CHF 4.14	2008 Plan
	18,000	18,000	0	18,000	EUR 8.1309	2013 Plan
Reginald Van Genechten	62,500	27,342	0	62,500	EUR 11.52	2015 Plan
Benoit Devogelaere	187,500	0	0	187,500	EUR 12.14	2013 Plan

Notes:

(1) Permanently representing Valetusan Ltd.

(2) Permanently representing Citros vof.

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

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

The CEO, CCO and Hilde Windels BVBA (permanently represented by Hilde Windels) are self-employed. Their contracts contain customary provisions regarding remuneration, non-competition and confidentiality.

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

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

The 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 from a relocation fee in case of termination in certain circumstances.

Claw-back right of the Company relating to variable remuneration

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

Severance payments for departing members of the executive management

Rudi Pauwels (permanently representing Valetusan Ltd.) resigned as chief executive officer of the Company with effect as of 2 March 2017. In connection with such resignation, Valetusan Ltd. entered into a termination agreement, providing for a severance payment equal to a gross amount of EUR 175,000 (paid over a six month period).

5.5 / Characteristics of the stock option and warrant plans

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

2008 Plan

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

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

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

On 31 December 2017, a total number of 40,101 stock options are still outstanding under the 2008 Plan, entitling the holders to acquire 40,101 shares of the Company. All stock options are vested.

2013 Plan

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

The 2013 Plan is a dilutive plan, implying that new shares are issued upon the exercise of the respective 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 vesting of 50% of the warrants granted to Benoit Devogelaere is time-based (15,625 warrants will vest on each of the first and second anniversary dates of the date of grant and 31,250 warrants will vest on each of the third and fourth anniversary dates of the date of grant), while the other 50% will vest if and to the extent certain objective and verifiable key performance indicators are achieved. The exercise windows of the 2013 Plan are 16-31 March, 16-30 September and 1-15 December.

Prior to the IPO of the Company, a total number of 720,340 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 2017, a total of 987,840 stock options have been granted of which 762,595 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 12,160 stock options can still be granted under the 2013 Plan.

2015 Plan

On 15 January 2015, an option plan was established pursuant to which 217,934 options were issued. This plan was cancelled by the general shareholders' meeting of the Company on 13 April 2015 and replaced on the same date by a new stock option plan (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 is 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 2017, a total of 247,500 stock options have been granted of which 240,412 are outstanding (i.e. stock options under the 2015 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 15,434 stock options can still be granted under the 2015 Plan.

2017 Plan

On 11 September 2017, a warrant plan was established pursuant to which 1,340,000 warrants were issued and granted to Herman Verrelst, chief executive officer of the Company. The 2017 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective warrants. The key features of the warrants under the 2017 Plan are as follows: (i) each warrant can be exercised for one share, (ii) the warrants are granted for free, i.e. no consideration is due upon the grant of the warrants, (iii) the warrants have a term of five years as from 11 September 2017, (iv) the exercise price of the warrants is determined at the time of the grant of the warrants (i.e., EUR 9.92), and (v) 50% of the warrants will vest over a period of four years (12.5% of the warrants will vest on each of the first four anniversary dates of the date of grant), while the other 50% of the warrants will vest if and to the extent of the CEO achieving certain objective and verifiable key performance indicators. The exercise windows of the 2017 Plan are 16-31 March, 16-30 September and 1-15 December.

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

CHAPTER 6

Consolidated Annual Accounts

6.1 / Consolidated financial statements as of and for the years ended 31 December 2017 and 2016

6.1.1 / Consolidated income statement

In EUR 000	Notes	Years ended 31 December, 2017	2016
Revenue			
Collaboration revenue	6.2.4	7,739	5,278
Product sales revenue	6.2.4	12,936	6,767
Service revenue	6.2.4	282	53
		20,957	12,098
Other operating income			
Grants and other income	6.2.5	2,153	1,674
Total operating income		**23,110**	**13,772**
Operating expenses			
Cost of sales	6.2.6	-8,673	-5,701
Research and development expenses	6.2.7	-39,594	-42,091
Marketing and distribution expenses	6.2.8	-11,600	-10,324
General and administrative expenses	6.2.9	-6,832	-5,827
		-66,699	**-63,943**
Operating loss for the year		**-43,589**	**-50,171**
Financial income	6.2.11	-2	86
Financial expense	6.2.11	-1,714	-674
Foreign exchange gains/(losses), net	6.2.11	-20	2
Financial result, net		**-1,736**	**-586**
Loss for the year before taxes		**-45,325**	**-50,757**
Income taxes	6.2.28	3,365	980
Loss for the year after taxes		**-41,960**	**-49,777**
Loss for the year		**-41,960**	**-49,777**
Attributable to owners of the Company		-41,960	-49,777
Attributable to non-controlling interest			
Earnings per share			
Basic and diluted loss per share from continuing operations	6.2.12	-0.93	-1.21

6.1.2 / Consolidated statement of other comprehensive income

In EUR 000	Notes	Years ended 31 December, 2017	2016
Loss for the year		**-41,960**	**-49,777**
Actuarial gain (loss) on defined benefit plan	6.2.23	45	19
Tax impact actuarial gain (loss)		-15	-6
Total comprehensive loss for the year		**-41,930**	**-49,764**
Attributable to owners of the Company		-41,930	-49,764
Attributable to non-controlling interest		0	0

6.1.3 / Consolidated balance sheet

In EUR 000	Notes	As of 31 December, 2017	2016
Assets			
Non-current assets			
Intangible assets	6.2.13	10,267	9,921
Property plant and equipment	6.2.14	26,199	23,088
Participating interests	6.2.15	5,052	5,052
Other long term receivables		11	11
Deferred tax assets	6.2.16	6,572	3,090
		48,102	41,162
Current assets			
Inventory	6.2.17	9,060	9,829
Trade receivables	6.2.18	6,892	2,935
Other receivables	6.2.18	2,856	2,201
Other current assets	6.2.19	1,517	1,932
Cash and cash equivalents*	6.2.20	112,765	83,246
		133,090	100,143
Total assets		**181,191**	**141,305**
Equity and liabilities			
Capital and reserves			
Legal share capital	6.2.21	511	446
Historical share capital adjustment	6.2.21	- 221,232	-221,232
Share premium	6.2.21	630,670	554,065
Share based payment reserve	6.2.22	2,381	1,716
Accumulated deficit	6.2.21	- 280,046	-238,088
Other comprehensive income	6.2.21	-45	-19
Total equity attributable to owners of the Company		132,239	96,889
Non-current liabilities			
Provisions	6.2.23	16	47
Financial debt	6.2.24	31,359	27,709
Deferred income	6.2.26	10	142
Accrued charges	6.2.27	1,767	1,610
		33,152	29,508
Current liabilities			
Financial debt	6.2.24	4,029	3,698
Trade payables	6.2.25	5,555	6,293
Deferred income	6.2.26	2,777	1,963
Other current liabilities	6.2.25	3,439	2,954
		15,800	14,908
Total equity and liabilities		**181,191**	**141,305**

*Cash and cash equivalents for 31 December 2017 include EUR 1.2 million restricted cash related to KBC Lease financing

6.1.4 / Consolidated cash flow statement

In EUR 000	Notes	Years ended 31 December, 2017	2016
Operating activities			
Loss for the period		-41,960	-49,777
Adjustments for			
Depreciation and amortization	6.2.13/6.2.14	5,096	4,848
Impairments	6.2.14	0	207
Tax income in profit and loss	6.2.28	-3,365	-980
Financial result, net	6.2.11	1,736	813
Net movement in retirement benefit obligation	6.2.23	-31	47
Share based payment expense	6.2.22	665	371
Other comprehensive income		-38	-28
Changes in working capital			
Net movement in inventories	6.2.17	769	-3,991
Net movement in trade and other receivables and other current assets	6.2.18/6.2.16	-4,197	1,105
Net movement in trade payables & other current liabilities	6.2.25	-95	-2,659
Net movement in deferred income	6.2.26	682	-3,049
Interests paid		-562	-105
		-41,300	-53,198
Taxes paid	6.2.28	-105	-114
Cash flow used in operating activities		-41,405	-53,312
Investing activities			
Interest received		-2	79
Purchases of property, plant & equipment	6.2.14	-3,157	-9,123
Purchases of intangible assets	6.2.13	-1,161	-1,927
Proceeds from sale and lease back of property, plant and equipment	6.2.14	0	1,629
Cash flow from / (used in) investing activities		-4,320	-9,342
Financing activities			
Proceeds from borrowings	6.2.24	0	15,000
Proceeds from the lease financing of property, plant and equipment	6.2.24	0	3,978
Net proceeds from the issue of common shares, net of transaction costs	6.2.21	76,669	31,398
Repayment of borrowings	6.2.24	-1,375	-8,539
Bank charges		-38	-33
Cash flow from financing activities		75,256	41,804
Net increase / (decrease) in cash and cash equivalents		29,531	-20,850
Cash and cash equivalents at the beginning of the period		83,246	104,087
Effects of exchange rate changes on the balance of cash held in foreign currencies		-12	10
Cash and cash equivalents at the end of the period*		112,765	83,247

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

6.1.5 / Consolidated statement of changes in equity

		Attributable to owners of the Company							
In EUR 000	Notes	Legal share capital	Historical share capital adjustment	Share premium	Share based payment reserve	Gains and losses on defined benefit plans	Accumulated deficit	Total equity attributable to the owners of the Company	Total equity
Balance as at 1 January 2016		405	-221,232	522,707	1,345	0	-188,310	114,916	114,916
Loss for the period	6.2.21						-49,777	-49,777	-49,777
Other comprehensive income	6.2.21					-19		-19	-19
Total comprehensive income	6.2.21	-	-	-	-	*-19*	*-49,777*	*-49,796*	*-49,796*
Share issue - exercise of stock options on 7 April 2016	6.2.21			366				366	366
Share issue - private placement 21 November 2016	6.2.21			32,634				32,634	32,634
Cost related to private placement	6.2.21	41		-1,642				-1,601	-1,601
Share-based payment expense	6.2.22				371			371	371
Balance as at 31 December 2016		446	-221,232	554,065	1,716	-19	-238,088	96,889	96,889
Balance as at 1 January 2017		446	-221,232	554,065	1,716	-19	-238,088	96,889	96,889
Loss for the period							-41,960	-41,960	-41,960
Other comprehensive income	6.2.21					-26	0	-25	-25
Total comprehensive income	6.2.21					*-26*	*-41,960*	*-41,985*	*-41,985*
Share-based payment expense	6.2.22				665			665	665
Share issue - exercise of stock options on 5 October 2017	6.2.21	0		176				176	176
Share issue - private placement 28 November 2017	6.2.21	64		79,936				80,000	80,000
Costs related to private placement	6.2.21			-3,771				-3,771	-3,771
Share issue - exercise of stock options on 21 December 2017	6.2.21	0		264				264	264
Consolidation translation difference	6.2.21						2	2	2
Balance as at 31 December 2017		511	-221,232	630,670	2,381	-45	-280,846	132,240	132,240

6.2 / Notes to the consolidated financial statements

6.2.1 / General Information

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

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

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 established subsidiaries in Mechelen (Belgium), Eindhoven (The Netherlands), Lausanne (Switzerland) and New Jersey (US). The Group has so far been funded by a combination of private and public equity, upfront licensing fees 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 27 February 2018 by the board of directors of the Company (the 'board of directors').

6.2.2 / Summary of significant accounting policies

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

6.2.2.1 / Statement of compliance

The consolidated financial statements of the Group for the year ended 31 December 2017 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.

6.2.2.2 / 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 2017 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.

6.2.2.3 / 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 2017:

- Annual improvements to IFRS Standards 2014-2016 Cycle: Amendments to IFRS 12 (applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed by the EU)

- 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 by the 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 by the EU)

As per 31 December 2017, the management of the Group has re-investigated the impact of the initial application of IFRS15 and concluded that the application will not have a significant impact on the timing or value of the Group's revenue, which was also concluded per 31 December 2016 and 30 June 2017.

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 2017, are listed in note 6.2.35.

6.2.2.4 / Consolidation principles

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries as at 31 December 2017.

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.

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

All transactions between Group companies have been eliminated upon consolidation.

6.2.2.5 / 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.

6.2.2.6 / 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;
- 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.

6.2.2.7 / 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 intercalary interests, 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.

6.2.2.8 / 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.

6.2.2.9 / 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.

6.2.2.10 / 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.

6.2.2.11 / Cash and cash equivalents

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

6.2.2.12 / 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'.

6.2.2.13 / 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.

6.2.2.14 / 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.

6.2.2.15 / Revenue recognition

The Group recognizes revenues from the sale of the Idylla™ platform, related cartridges and services as well as revenues generated from collaboration arrangements.

Transactions with customers and collaboration partners may involve multiple elements. The Group evaluates whether the elements 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.

Collaboration revenue

Revenues from collaboration agreements may include upfront payments, milestone payments and/or income from R&D services.

Upfront fees

Unless up-front fees are paid in exchange for products delivered or services performed and, therefore, substantial risks and rewards have been transferred to the buyer in a separate transaction, such fees are not recognized as revenue up front but rather deferred as unearned revenue (even if they are non-refundable) and 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.

Milestone payments

A contingent consideration received by the Group upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part either on the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with the Group's performance required to achieve the milestone or the increase in value to the collaboration resulting from the Group's performance, related solely to the Group's past performance, and is reasonable relative to all of the other deliverables and payments within the overall collaboration arrangement.

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.

R&D Services

Cost reimbursements resulting from collaboration agreements, or a similar type of compensation received for costs incurred under R&D collaborations are recorded as R&D services as the related costs are incurred and upon agreement by the parties involved. The corresponding expenses are generally recorded under research and development expenses. Revenues from R&D Services are in general recognized over the duration of the collaboration agreement, if relevant subject to when the required services are provided or costs are incurred.

Product related revenue

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.

Service revenue

Under service revenue, Biocartis classifies the revenue generated by service contracts as well as the revenue generated by one-off repairs.

6.2.2.16 / Grants

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

R&D grants

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

Investment grants

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

6.2.2.17 / 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.

6.2.2.18 / 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.

6.2.3 / Critical accounting estimates, assumptions and judgments

6.2.3.1 / 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 2017, 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 2019.

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 as from 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 6.2.25.

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 6.2.23.

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.. If there are no future obligations an upfront fee is immediately recognized. 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 6.2.2.6.

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.

6.2.3.2 / 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 2017.

6.2.4 / Revenue

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

	Years ended 31 December,	
In EUR 000	2017	2016
Collaboration revenue		
R&D services	670	255
Upfront license revenue	4,569	4,691
Milestone revenue	2,500	332
	7,739	**5,278**
Product related revenue		
Idylla™ System Sales revenue	3,390	2,464
Idylla™ System Rental revenue	1,230	288
Cartridge revenue	8,316	4,015
	12,936	**6,767**
Service revenue		
Service revenue	282	53
	282	**53**
Total	**20,957**	**12,098**

6.2.4.1 / Collaboration revenues

License fees, milestone payments and R&D services are earned under the Group's collaboration and development agreements as outlined below.

Janssen Pharmaceutica

The Group's main collaboration agreement is a license and development agreement with Janssen Pharmaceutica 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 milestone and upfront license payments under this collaboration were recognized in collaboration revenues in 2017.

Amgen

On 3 February 2016, Biocartis NV, a subsidiary of the Company, and Amgen entered into a collaboration agreement to evaluate Idylla™ RAS testing as a tool for rapid decentralized testing in several geographies. This collaboration was expanded in December 2016 with a new agreement that includes up to 10 European countries and that will enable several dozen additional selected hospitals to accelerate access to RAS biomarker information using Biocartis' Idylla™ platform and RAS tests. Product revenue recognized under this agreement is shown under product related revenue as it relates to the placement of Idylla™ systems and cartridges.

On 4 December 2017, Biocartis announced the signing of a companion diagnostic (CDx) development agreement with Amgen for the Idylla™ RAS biomarker tests aimed at the registration of these test with the US Food and Drug Administration (FDA) as a CDx test for Amgen's drug Vectibix® (panitumumab). The elements included in this CDx agreement consist of milestone payments and R&D services.

For the financial year 2017, the Group recognized R&D services under this CDx agreement.

Post the reporting period, on 9 January 2018, Biocartis announced a new CDx development agreement with Amgen (signed end of 2017) aimed at the development of Idylla™ CDx biomarker tests for a novel oncology compound to be used in the treatment of certain solid tumors. The elements included in this CDx agreement consist of milestone payments, license fees and R&D services.

For the financial year 2017, the Group recognized R&D services under this CDx agreement.

Merck KGaA (Darmstadt, Germany)

On 7 January 2016, Biocartis NV, a subsidiary of the Company, signed a collaboration agreement with Merck KGaA (Darmstadt, Germany) (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 elements included in this agreement consist of milestone revenue and R&D Services as well as product related revenue linked to the actual commercialization of the tests under the collaboration.

For the financial year 2017, the group recognized milestone revenue and product related revenue under this agreement. Product revenue recognized under this agreement is shown under product related revenue as it relates to the placement of Idylla™ systems and cartridges.

Genomic Health

On 13 September 2017, Biocartis and Genomic Health, Inc. announced an exclusive agreement to develop an IVD version of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform that can be performed locally by laboratory partners and in hospitals around the world. The strategic collaboration will provide Genomic Health with exclusive worldwide rights to develop and commercialize its Oncotype DX Breast Recurrence Score® test on the Idylla™ platform, with the option to expand the collaboration to include additional tests in oncology and urology. As part of the agreement, Genomic Health has made a payment of approximately USD 3.3m to Biocartis. Additional payments to Biocartis will be made as certain developmental and commercial milestones will be achieved in the future. Upon commercialization, Genomic Health will make royalty payments to Biocartis based on net sales. Consequently, the elements included in this agreement consist of upfront license revenue, milestone revenue and R&D services as well as product related revenue.

For the financial year 2017, the group recognized USD 3.3m of license revenue and R&D services under this agreement. Product revenue recognized under this agreement is shown under product related revenue as it relates to the placement of Idylla™ systems and cartridges.

Immunexpress

On 24 January 2018, Biocartis and Immunexpress Pty Ltd, announced a partnership agreement (signed end of 2017) aimed at the development and commercialization of Immunexpress' SeptiCyte™ test for use on the Idylla™ platform. Under the partnership, parties will co-develop the SeptiCyte™ Idylla™ test, whereas Immunexpress will take the lead in the commercialization, with an initial focus on the US and the European markets. In return, the group is entitled to license revenue and royalties. The elements included in this agreement consist of upfront license revenue, milestone revenue and R&D services as well as product related revenue.

For the financial year 2017, the group realized upfront license revenue under this agreement.

6.2.4.2 / Product sales

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

	Years ended 31 December,	
In EUR 000	2017	2016
Commercial revenue	12,748	5,691
Research & Development revenue	187	1,076
Total	12,936	6,767

6.2.4.3 / Revenues by major countries and customers

	Years ended 31 December,	
In EUR 000	2017	2016
Country of domicile	**2,565**	**1,196**
Belgium	2,565	1,196
Total all foreign countries, of which	**18,392**	**10,902**
United States of America	6,802	3,921
Spain	1,985	2,365
Rest of the world	9,604	4,615
Total	**20,957**	**12,098**

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

The Group has recognized revenues from three customers representing at least 10% of the total revenues. These customers account for EUR 8.4m of the revenues in 2017 (2016: one customer for EUR 4.3m).

6.2.5 / Other operating income

	Years ended 31 December,	
In EUR 000	2017	2016
R&D project support (IWT grants)	1,844	1,592
Other project grants	62	20
Other income	247	62
Total	**2,153**	**1,674**

6.2.6 / Cost of sales

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

	Years ended 31 December,	
In EUR 000	2017	2016
Staff costs	-1,952	-1,115
Material, lab consumables & small equipment	-4,407	-3,123
Depreciation and amortization	-1,435	-532
Royalty expense	-785	-499
Provision for doubtful debt	0	-382
Other	-93	-50
Total	**-8,673**	**-5,701**

6.2.7 / Research & Development expenses

In EUR 000	Years ended 31 December, 2017	2016
Staff costs	-19,027	-20,667
Subcontracting	-2,922	-4,589
Laboratory expenses	-1,935	-2,226
Platform and cartridge prototype costs	-6,153	-4,631
Consultancy	-1,873	-1,479
Quality and regulatory	-115	-67
Intellectual property	-595	-763
Facilities, office & other	-3,567	-2,735
ICT	-1,299	-1,502
Travel, training & conferences	-575	-615
Depreciation and amortization	-3,276	-4,155
Capitalized systems for internal use	1,744	1,341
Total	**-39,594**	**-42,091**

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.

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

6.2.8 / Marketing & Distribution expenses

In EUR 000	Years ended 31 December, 2017	2016
Staff costs	-6,833	-5,576
Subcontracting	-243	-876
Sales and promotional expenses	-652	-1,215
Business development	-506	-155
Consultancy	-112	-289
Facilities, office & other	-846	-409
Travel, training & conferences	-1,978	-1,634
Depreciation and amortization	-430	-170
Total	**-11,600**	**-10,324**

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

6.2.9 / General & Administrative expenses

In EUR 000	Years ended 31 December, 2017	2016
Staff costs	-4,003	-3,498
External advice	-985	-654
Facilities, office & other	-923	-746
Human resources	-689	-670
Travel, training & conferences	-243	-270
Depreciation and amortization expenses	11	11
Total	**-6,832**	**-5,827**

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

6.2.9 / Personnel Expenses

In EUR 000	Years ended 31 December, 2017	2016
Short term employee benefits	-30,383	-29,779
Post-employee defined contribution expense	-611	-619
Termination benefits	-157	-87
Share based compensation	-665	-371
Total	**-31,816**	**-30,856**

The headcount can be presented as follows:

	As of 31 December 2017	2016
Operations staff	123	115
Research and development staff	134	128
Marketing and distribution staff	50	48
General and administrative staff	24	26
Total headcount	**331**	**317**
Average full time equivalents	316	308

6.2.11 / Financial income and expense

In EUR 000	Years ended 31 December, 2017	2016
Interest income	-2	79
Other financial income	0	7
Total	**-2**	**86**
Interest expense	-1,250	-447
Other financial expense	-463	-226
Total	**-1,714**	**-674**
Foreign exchange gains/(losses), net	-20	2
Total	**-20**	**2**
Financial result, net	**-1,736**	**-586**

6.2.12 / Loss per share

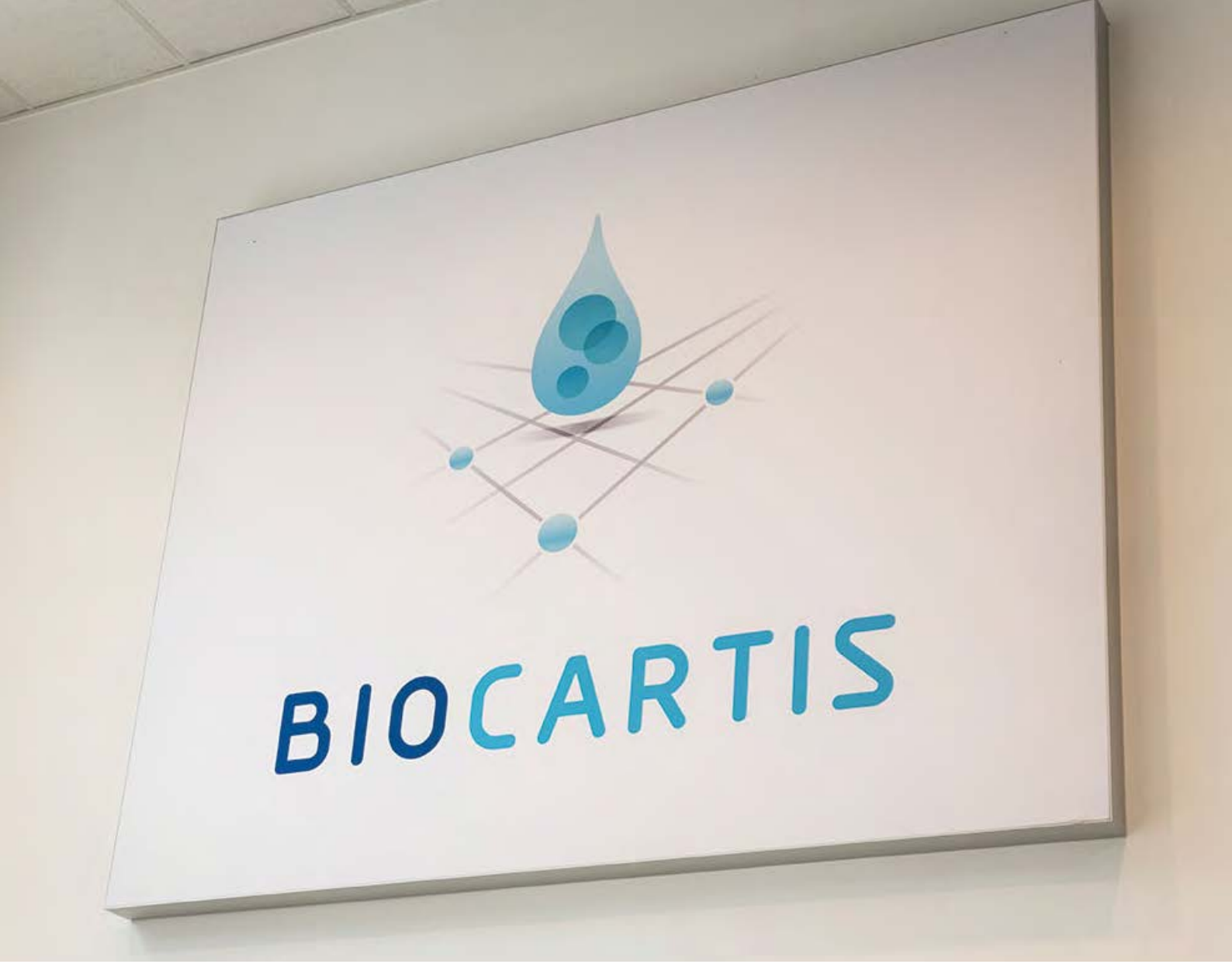
The Company has stock option plans that may be settled in common shares of the Company and which are considered anti-dilutive given that the Group's operations were loss making over the reporting period. As such, the basic and diluted earnings per share are equal. The basis for the basic and diluted earnings per share is the net loss for the year attributable to the owners of the Company.

	Years ended 31 December,	
	2017	2016
Profit/loss for the period attributable to the owners of the Company (in EUR 000)	-41,960	-49,777
Weighted average number of ordinary shares for basic loss per share (in number of shares)	45,149,567	41,022,042
basic loss per share (EUR)	**-0.93**	**-1.21**

6.2.13 / Intangible assets

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

In EUR 000	Patents and licenses	ICT software	Total
Year ended 31 December 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	-1,207	-5,523
Net carrying value	**9,717**	**204**	**9,921**
Year ended 31 December 2017			
Opening net carrying value	9,717	204	9,922
Additions	1,000	161	1,161
Disposals	0	0	0
Disposal depreciations	0	0	0
Amortization expense	-699	-116	-815
Closing net carrying value	**10,018**	**249**	**10,267**
As at 31 December 2017			0
Cost	15,034	1,572	16,606
Accumulated amortization	-5,016	-1,323	-6,338
Net carrying value	**10,018**	**249**	**10,267**



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 2017 is EUR 6m (2016: EUR 6.5m). The remaining useful life is 11 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 2017, the group recognized a variable consideration liability, based on contractual obligation with a corresponding increase of the licenses from Philips related to the 'Idylla™-Enrich' technology for EUR 1m.

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.

6.2.14 / 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 EUR000	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	**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**
Opening net carrying value	**639**	**783**	**1,313**	**2,396**	**426**	**1,121**	**230**	**13,698**	**1,342**	**1,140**	**23,089**
Additions	53	111	252	1,136	53	193	0	3,824	512	1,835	**7,969**
Disposals	0	0	0	-69	0	0	0	-423	0	-85	**-577**
Disposal depreciation	0	0	0	30	0	2	0	0	0	16	**48**
Depreciation charge of the period	-194	-276	-711	-807	-72	-337	-5	0	-1,588	-339	**-4,329**
Transfers gross 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	**499**	**618**	**854**	**2,687**	**407**	**979**	**225**	**17,099**	**265**	**2,566**	**26,199**
As at 31 December 2017											
Cost	1,645	2,013	6,881	4,827	733	2,629	243	17,099	7,648	2,973	**46,691**
Accumulated depreciation	-1,147	-1,395	-6,026	-2,141	-325	-1,650	-18	0	-7,383	-407	**-20,492**
Net carrying value	**499**	**618**	**854**	**2,687**	**407**	**979**	**225**	**17,099**	**265**	**2,566**	**26,199**

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

6.2.15 / Financial participation

In 2015, the Group acquired a financial participation of 13.5% in MyCartis NV through a contribution in kind for an amount of EUR 5.1 million by Debiopharm Diagnostics SA. The participation is not accounted for under the equity method as the Group has no significant influence over MyCartis NV. The stake in MyCartis NV has decreased to 7.10% per 31 December 2017 because the Group did not participate in the additional capital increases as from 2016 in MyCartis NV. No impairment has been made per 31 December 2017.

	As of 31 December,	
In EUR 000	2017	2016
Recognition amount	5,052	5,052
Total	5,052	5,052

6.2.16 / Deferred tax assets

Deferred taxes relate to the investment tax credit on research and development and amount to EUR 6.6m per 31 December 2017 (2016: EUR 3.1m). Recognized research and development tax credits in Belgium increased with EUR 3.4m in 2017 from EUR 1.0m in 2016 as a consequence of an adjusted fiscal treatment for certain historical IP investments.

	As of 31 December,	
In EUR 000	2017	2016
Tax credit research and development	6,567	3,074
Other	5	16
Total	6,572	3,090

6.2.17 / Inventory

The inventory can be analyzed as follows:

	As of 31 December,	
In EUR 000	2017	2016
Inventory		
Raw materials	4,184	4,881
Semi-finished products	611	1,151
Finished products	4,265	3,796
Total	9,060	9,829
Amount recognized as an expense	-8,673	-5,319

Finished products include cartridges and systems held for expected commercialization, including systems placed under trial at customers under the Company's early adaptor program.

As per 31 December 2017, EUR 0.4 m of the total inventory value was older than 12 months for which EUR 0.1m impairment was taken. It is the expectation that a significant part of the current inventory is sold within the next 12 months.

6.2.18 / Trade and other receivables

Trade and other receivables can be analyzed as follows:

	As of 31 December,	
In EUR 000	2017	2016
Trade receivables	7,275	3,318
Allowance for doubtful receivables	-383	-383
Total	**6,892**	**2,935**

	As of 31 December,	
	2017	2016
VAT receivables	1,662	1,304
Other receivables	1,195	897
Total	**2,856**	**2,201**

Trade receivables have increased from EUR 3.3 million per 31 December 2016 to EUR 7.3 million per 31 December 2017. Approximately half of the total trade receivable balance is related to a limited number of parties. The credit concentration risk is limited in view of the creditworthiness of these partners. The other half consists of many small outstanding balances.

At the reporting date, the Group has approximately EUR 1.1 million trade and other receivables that were past due but were not impaired. In 2016 EUR 0.4 million of trade receivables were impaired.

Other receivables include VAT receivables and amongst others amounts recorded for the capital grant by STS.

6.2.19 / Other current assets

Other current assets can be analyzed as follows:

	As of 31 December,	
In EUR 000	2017	2016
Accrued grant income	639	769
Other accrued income	0	6
Deferred charges	878	1,157
Total	**1,517**	**1,932**

Other current assets include accrued income mainly related to Flemish government grants for EUR 0.6 m (2016: EUR 0.8m). 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.

6.2.20 / Cash and cash equivalents

The cash and cash equivalents can be analyzed as follows:

In EUR 000	As of 31 December, 2017	2016
Cash and cash equivalents		
Cash at bank and on hand	111,565	82,046
Total cash and cash equivalents	111,565	82,046
Total restricted cash	1,200	1,200
Total cash and cash equivalents for cash flow purposes	112,765	83,246

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.

6.2.21 / 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 2016 and 31 December 2017 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 preference 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 '000 EUR
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 Augustus 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
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
Share issue - exercise of stock options on 5 October 2017					21,667		0
Capital increase - private placement 28 November 2017					6,400,000		64
Share issue - exercise of stock options on 21 December 2017					32,500		0
At 31 December 2017	0	0	1,367	1,035	51,102,272	0	511

The following capital transactions took place at the Company from 1 January 2017 until 31 December 2017:

- **On 5 October 2017**, the Company raised EUR 0.2m following the exercise of 21,667 stock options. The amount is fully paid by an increase in share capital of EUR 0.0002m and an increase in share premium of EUR 0.2m.
- **On 28 November 2017**, the Company raised EUR 80m following a private placement, fully paid by an increase in share capital of EUR 0.064m and an increase in share premium of EUR 79,9m.
- **On 21 December 2017**, the Company raised EUR 0.3m following the exercise of 32,500 stock options. The amount is fully paid by an increase in share capital of EUR 0.0003m and an increase in share premium of EUR 0.3m.

Capital increase expenses

The Group has incurred EUR 3.8m expenses in connection with the capital increase of 28 November 2017, 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 Idylla™-Enrich technology acquisition, Philips, a shareholder of the Company, has been granted two conversion options, of which one remains outstanding per 31 December 2017. 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.

6.2.22 / Share based compensation

The table below provides an overview of the movement in stock options since 1 January 2016:

		SOP 2008	SOP 2013	SOP 2015	SOP 2017	Total
Total outstanding at 31 December 2015		**67,702**	**654,512**	**72,500**	**0**	**861,714**
Options granted	+			160,000		160,000
Options exercised	-	25,601	45,000			70,601
Options forfeited	-		20,221			87,221
Options cancelled	-					0
Total outstanding at 31 December 2016		**42,101**	**589,291**	**232,500**	**0**	**863,892**
Options granted	+	0	237,500	15,000	1,340,000	1,592,500
Options exercised	-	2,000	54,167	0	0	56,167
Options forfeited	-	0	10,029	7,088	0	17,117
Options cancelled	-	0	0	0	0	0
Total outstanding at 31 December 2017		**40,101**	**762,595**	**240,412**	**1,340,000**	**2,383,108**

2008 Plan

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

In total 2,000 options were exercised in 2017 at CHF 4.14 exercise price (rounded) and a weighted average share price of EUR 11.42 at the moment of the exercise of the options. A total of 40,101 options are still outstanding per 31 December 2017. The weighted average remaining contractual life is 1.8 years.

The key terms of the 2008 Plan are as follows:

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

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

2013 Plan

The 2013 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options. A maximum of 1,000,000 shares can be issued to employees, consultants and management of the Group, of which 987,840 options were granted per 31 December 2017.

In total 54,167 options were exercised in 2017 at an exercise price of EUR 8.1309 with a weighted average share price of EUR 10.64 at the moment of the exercise of the options. In 2017 10,029 options were forfeited.

A total of 762,595 options are still outstanding per 31 December 2017 of which:

- **495,095 options** have an exercise price of EUR 8.1309
- **30,000 options** have an exercise price of EUR 13.28
- **50,000 options** have an exercise price of EUR 10.442
- **187,500 options** have an exercise price of EUR 12.14

The weighted average remaining contractual life is 5.1 years.

The key terms of the 2013 Plan are:

- Options have the form of warrants of the Company
- Options are granted for free
- Exercise price: the board of directors determines the exercise price when the stock options are granted to a selected participant.
- Granted stock options only become exercisable after vesting and can only be exercised during the full remaining lifetime of the stock options and then only during the following periods:
  (i) as of 16 March until 31 March,
  (ii) as of 16 September until 30 September,
  (iii) and as of 1 December until 15 December.
- Option term: 10 years after the creation of the plan (expiry is in 2023) but upon grant of the option contractually reduced to 7 years.
- Vesting: time based vesting over 4 years (on a monthly basis; that is 1/48 per month), subject to acceleration in case of a change of control event.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumptions:

	Grants 2013	Grants July 2014	Grants November 2014	Grants August 2015	Grants July 2017	Grants December 2017
Number of warrants granted	680,340	20,000	20,000	30,000	50,000	187,500
Number of warrants not vested at 31/12/2017	640	4,810	8,352	13,984	44,795	187,500
Exercise price	EUR 9.35	EUR 9.35	EUR 8.13	EUR 13.28	EUR 10.44	EUR 12.14
Expected dividend yield	0	0	0	0	0	0
Expected stock price volatility	25%	30%	30%	31%	36%	35%
Risk-free interest rate	0.7%	0.2%	0.1%	0.1%	0.3%	0.2%
Expected duration	3.5 years	2.8 years	2.6 years	2.3 years	3.5 years	3.5 years
Forfeiture rate	0%	0%	0%	0%	0%	0%
Fair value	EUR 1.78	EUR 1.87	EUR 1.56	EUR 2.70	EUR 2.53	EUR 2.80

The weighted average risk-free interest rates used are based on government bond rates at the date of grant with a term equal to the expected life of the options. The stock price volatility is determined by reference to the Nasdaq Biotech Index (NBI).

2015 Plan

On 15 January 2015, an option plan was established, pursuant to which 217,934 options were issued. This plan was cancelled by the general shareholders' meeting of the Company on 13 April 2015 and replaced on the same date by a new stock option plan (the "2015 Plan"), enabling the Company to grant a maximum of 262,934 stock options (each stock option having the form of a warrant) to selected staff members (consisting of employees, consultants and members of the management) and directors. The 2015 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options.

In total 15,000 options were granted in 2017 at weighted average exercise price of EUR 10.27. No options were exercised but 7,088 options were forfeited which makes that there are 240,412 options are outstanding per 31 December 2017. The weighted average remaining contractual life is 6.3 years.

The key features of the stock options under the 2015 Plan are as follows:

- Options have the form of warrants of the Company
- Options are granted for free.
- Exercise price: The board of directors shall determine the exercise price at the time of the grant of the stock options, based upon the stock exchange price of the underlying shares at the time of the grant or an average price calculated over a previous period.
- Option term: the stock options have a term of 10 years when they were created, but this term will be contractually reduced to seven years.
- Vesting: time based vesting over 4 years (on a monthly basis; that is 1/48 per month), subject to acceleration in case of a change of control event.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumptions:

	Grants 2015	Grants January 2016	Grants March 2016	Grants May 2016	Grants August 2016	Grants November 2016	Grants May 2017
Number of warrants granted	72,500	10,000	62,500	15,000	10,000	62,500	15,000
Number of warrants not vested at 31/12/2017	28,972	4,384	35,158	0	7,088	45,574	0
Exercise price	EUR 13.28	EUR 12.77	EUR 11.52	EUR 9.72	EUR 7.25	EUR 8.50	EUR 10.27
Expected dividend yield	0	0	0	0	0	0	0
Expected stock price volatility	31%	34%	36%	36%	38%	38%	37%
Risk-free interest rate	0.5%	0.8%	0.4%	0.4%	0.7%	0.9%	0.5%
Expected duration	3.4 years	4.6 years	4.6 years	4.5 years	4.4 years	4.2 years	3.9 years
Forfeiture rate	0%	0%	0%	0%	0%	0%	0%
Fair value	EUR 3.29	EUR 3.85	EUR 4.13	EUR 2.08	EUR 2.52	EUR 2.74	EUR 3.19

The weighted average risk-free interest rates used are based on government bond rates at the date of grant with a term equal to the expected life of the options. The stock price volatility is determined by reference to the Nasdaq Biotech Index (NBI).

2017 Plan

On 11 September 2017, a warrant plan was established pursuant to which 1,340,000 warrants were issued and granted to Herman Verrelst, chief executive officer of the Company. The 2017 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective warrants.

In 2017, 1,340,000 warrants were granted. No warrants were exercised nor were any warrants forfeited. The key features of the warrants under the Warrant plan 2017 are as follows:

- Warrants are granted for free.
- Exercise price: EUR 9.92.
- Warrant term: determined at the time of the grant of the warrants (i.e., EUR 9.92),
- Vesting: 50% of the warrants will vest over a period of four years (12.5% of the warrants will vest on each of the first four anniversary dates of the date of grant), while the other 50% of the warrants will vest if and to the extent of the CEO achieving certain objective and verifiable key performance indicators.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumptions:

	Grants December 2017
Number of warrants granted	1,340,000
Number of warrants not vested at 31/12/2017	1,340,000
Exercise price	EUR 9.92
Expected dividend yield	0
Expected stock price volatility	32%
Risk-free interest rate	-0.3%
Expected duration	2.5 years
Forfeiture rate	0%
Fair value	EUR 2.14

Accounting for share-based payment

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

	Years ended 31 December,	
In EUR 000	2017	2016
Share based compensation	665	371
Total	665	371

6.2.23 / Defined Benefit Plans

The Defined Benefit plans are calculated via the application of the Projected Unit Credit (PUC) method as from 2016. No change in calculation method in the present year.

	Years ended 31 December,	
In EUR 000	2017	2016
Provisions for pensions and similar obligations	16	47
Total	16	47

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 2016	**47**
Service cost	611
Pension expense/income	-4
Company contributions	-676
Benefits paid/ Transfer	-1
Actuarial gains/losses	39
As per 31 December 2017	**16**

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

	2017
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:

	2017
Discount rate + 0.5%	15
Discount rate - 0.5%	-12

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 pension plan contains 415 active and 84 passive affiliates.

6.2.24 / Financial debt

The financial debt can be analyzed as follows:

	Years ended 31 December,	
In EUR 000	2017	2016
PMV & FPIM	16,331	15,263
Lease company	14,723	12,022
Bank	305	425
Total non current	**31,359**	**27,709**
PMV & FPIM	0	0
Lease company	3,909	3,581
Bank	120	118
Total current	**4,029**	**3,698**

In 2013, Biocartis NV refinanced about 50% of its Idylla™ semi-automated cartridge manufacturing line in Mechelen (Belgium) via a sale and lease back operation. The lease had an initial term of 5 years at a 3.35% interest rate and included a purchase option of EUR 0.2m. In 2015, the term was extended until 1 June 2021 to align with the new 2015 lease as described below. The purchase option

was also reduced to EUR 0.1m. As a security, a debt service reserve account is to be maintained, starting at EUR 2.5m, decreasing over time according to the following milestones: fundraising 2013, CE approval, FDA approval. The current debt service reserve account amounts to EUR 1.2m.

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

In 2016, Biocartis NV obtained a lease financing facility for the development of a second cartridge production line in Mechelen, for EUR 15m, provided by a lease company, the amount is almost fully withdrawn per 31 December 2017. The interest applicable for this leasing facility equals approx. 1.87% and the leasing includes a purchase option of 1% of the financed amount.

In 2016, Biocartis NV and the Company also obtained a subordinated loan of EUR 15m provided by a consortium of PMV (Participatie Maatschappij Vlaanderen) and the Belgian 'Federal Holding and Investment Company' (FPIM). Both PMV and FPIM granted a loan of EUR 7.5m each, bearing an interest rate of 7% and with a maturity date at 30 September 2021 (except in case of extension of the loan upon the Company's request or voluntary or mandatory early repayment). The interest on the loans is capitalized during the first three years of the agreement and accrued in the consolidated balance sheet at the year-end. The agreement contains a set of business covenants, which require obtaining the lenders' approval for certain major transactions outside the ordinary course of business.

End of Q3 2017, Biocartis reached agreement with KBC and BNP Paribas Fortis to replace the Company's EUR 25m committed multiple purpose credit facility (partially guaranteed by the Flemish Government) with a new committed multiple purpose credit facility of EUR 27.5m (not covered by a government guarantee). The new committed multiple purpose credit facility consists of a EUR 18.5m rollover credit line and a EUR 9m working capital credit line, and has lower overall financing costs compared to the previous facility.

In addition, the Group also has access to a bank guarantee line of EUR 0.5m of which EUR 0.5m has been taken up for rental guarantees as per 31 December 2017, and an credit line with a bank of EUR 0.6m for currency hedging, of which EUR 0m has been taken up as per 31 December 2017.

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

Loan	Year	Nominal amount (In EUR 000)	Secured (s) Non secured (ns)	Interest rate	Maturity date
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	15,000	S	1.87%	1/12/2021
PMV	2016	7,500	S	7.00%	30/09/2021
FPIM	2016	7,500	S	7.00%	30/09/2021

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

In EUR 000	As of 31 December, 2017		2016	
	Minimum lease payments	Present value of minimum lease payments	Minimum lease payments	Present value of minimum lease payments
Financial lease				
< 1 year	4,212	3,909	3,829	3,581
>1 and < 5 years	15,260	14,723	12,450	12,022
> 5 years	0	0	0	0
Total	**19,472**	**18,632**	**16,279**	**15,603**
Less interests	-840		-676	
Present value	**18,632**	**18,632**	**15,603**	**15,603**

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

In EUR 000	PMV & FPIM	Lease company	Bank
As per 31 December 2016	**15,263**	**15,603**	**543**
Changes from financial cash flows	0	-1,206	-118
Changes arising from obtaining or losing control of subsidiaries or other business	0	0	0
Changes due to the effect of changes in FX rates	0	0	0
Changes in fair value	0	0	0
Capitalized interest	1,068	0	0
Lease additions	0	4,235	0
As per 31 December 2017	**16,331**	**18,632**	**425**

6.2.25 / Trade payables and other current liabilities

	As of 31 December,	
In EUR 000	2017	2016
Trade payables	5,555	6,293
Total trade payables	**5,555**	**6,293**

	As of 31 December,	
In EUR 000	2017	2016
Provision vacation pay and end-of-year premium & other social debt	3,404	2,920
VAT payable	35	4
Other	0	30
Other current liabilities	**3,439**	**2,954**

6.2.26 / Deferred income

In EUR 000	Years ended 31 December, 2017	2016
Grants	1,213	268
Partner income	1,575	1,837
Total	**2,862**	**2,106**
Current	2,777	1,963
Non-current	10	142

Deferred partner income includes upfront payments from collaboration partners in relation to the strategic licensing, development and commercialization collaborations.

	Deferred partner income
As per 31 December 2015	**5,107**
Invoiced	1,668
Recognized in profit or loss	-4,939
As per 31 December 2016	**1,837**
Invoiced	1394
Recognized in profit or loss	-1,656
As per 31 December 2017	**1,574**

6.2.27 / Accrued Expenses

Accrued expenses primarily include accruals for rental charges.

6.2.28 / Taxes

6.2.28.1 / Composition of tax expense

In EUR 000	Years ended 31 December, 2017	2016
Current income tax	118	114
Deferred income tax	-3,483	-1,094
Income tax expense (profit) recognized in loss for the period	**-3,365**	**-980**

6.2.28.2 / Tax reconciliation

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

	Years ended 31 December,	
In EUR 000	2017	2016
Loss before taxes	**-45,325**	**-50,757**
Income tax credit calculated at 33,99%	-14,262	-17,253
Effect of different tax rates	3	3
Effect of income that is exempt from taxation	-5,339	-4,331
Effect of expenses that are non-deductible in determining tax profit	494	428
Effect of unused tax losses and tax offsets not recognized as deferred tax assets	19,105	21,152
Effect of previously unrecognized and unused tax losses	0	0
Effect of tax credit for research and development	-3,493	-1,088
Effect of capital tax in Biocartis SA	105	114
Other	24	-6
	-3,364	**-980**
Adjustments recognized in the current year in relation to the current tax of prior years	0	0
Income tax expense (profit) recognised in loss for the period	**-3,365**	**-980**

6.2.28.3 / 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 250.8m (2016: EUR 194.8m). The tax losses related to Biocartis SA amount to EUR 36.9m in 2017 (2016: EUR 39.1m) with the following expiration years. Each annual tax loss expires seven years after the fiscal period it has been realized.

In EUR 000	Tax losses	Expiry year
	7,299	2020
	28,793	2021
	709	2023
	98	2024
	36,899	

The tax losses of Biocartis NV for EUR 199.0m per 31 December 2017 (2016: EUR 146.4m) in Belgium will not expire as they can be carried forward indefinitely.

6.2.28.4 / Recognized deferred tax assets

The Group has R&D tax credit carry-forwards in Belgium for a total amount of EUR 6.6m (2016: EUR 3.1m) for which a deferred tax asset of EUR 6.6m (2016: EUR 3.1m) has been recognized as the recognition criteria have been met as from 2014.

6.2.29 / Financial risk management

6.2.29.1 / 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.

6.2.29.2 / 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.

6.2.29.3 / 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 2017 and 2016.

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

	Years ended 31 December,	
In EUR 000	2017	2016
Liabilities		
CHF – Switzerland	0	7
USD - United States	43	112
GBP - Great Britain	3	5
Assets		
CHF – Switzerland	11	50
USD - United States	2,908	262
GBP - Great Britain	200	57

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 2017:

	Years ended 31 December,	
In EUR 000	2017	2016
Carrying value		
Merck KGaA	525	648
Amgen	2,295	83
VAT receivable	1,662	1,300
Capital grant	1,195	897
Other trade and other receivables	4,072	2,207
	9,748	5,135

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 a multiple purpose credit facility of EUR 27.5m, as described in note 6.2.24.

In addition, the Group also has access to a bank guarantee line of EUR 0.5m of which EUR 0.5m has been taken up for rental guarantees as per 31 December 2017, and an credit line with a bank of EUR 0.6m for currency hedging, of which EUR 0m has been taken up as per 31 December 2017.

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 EUR 000):

	As of 31 December,					
	2017			2016		
In EUR 000	Trade payables	financial debt	other current liabilities and accrued expense	Trade payables	financial debt	other current liabilities and accrued expense
Less than 1 month	5,555	540	3,439	6,293	305	2,954
1-3 months		630			612	
3 months to 1 year		2,859			2,781	
1-5 years		31,359	663		27,709	715
5+ years		0	1,105		0	894
Total	**5,555**	**35,388**	**5,206**	**6,293**	**31,407**	**4,563**

6.2.30 / 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 2017 and 2016.
- The fair value of the participation in MyCartis is not significantly different than its carrying value on 31 December 2017 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 2017 and 2016.

	Carrying value		Fair value	
In EUR 000	31 Dec 2017	31 Dec 2016	31 Dec 2017	31 Dec 2016
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)	9,748	5,136	9,748	5,136
Other long term receivables	11	11	11	11
Other current assets	1,592	1,932	1,592	1.932
Total loans and other receivables	**11,351**	**7,079**	**11,351**	**7,079**
Cash & cash equivalents				
cash & cash equivalents*	112,765	83,246	112,765	83,246
Total cash & cash equivalents	**112.765**	**83,246**	**112,765**	**83,246**
Financial liabilities measured at amortized cost				
Loans & Borrowings	35,388	31,407	34,675	34,979
Trade payables	5,555	6,293	5,555	6,293
Other liabilities and accrued charges	5,206	4,563	5,206	4,563
Total financial liabilities measured at amortized cost	**46,149**	**42,264**	**45,436**	**45,835**

*Cash and cash equivalents for 31 December 2017 include EUR 1.2 million restricted cash related to KBC Lease financing

6.2.31 / 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.

6.2.32 / Commitments

6.2.32.1 / Capital commitments

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

	As of 31 December,	
In EUR 000	2017	2016
ICT software	10	37
ICT equipment	53	3
Laboratory equipment	1	434
Manufacturing equipment	46	59
Furniture and fixtures	2	16
Leasehold improvements	60	106
Equipment under construction	2,246	6,307
Assets held under Lease	0	0
Total	**2,419**	**6,962**

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 2017.

6.2.32.2 / Operating commitments

The Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 6.0m. It is expected that the majority of the commitments will be fulfilled in 2018.

6.2.32.3 / 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 2017 under its leasing contracts per nature and maturity is summarized in the table below.

In EUR 000	As of 31 December,			
	2017		2016	
	Rent/Lease facilities	Car Lease	Rent/Lease facilities	Car Lease
not later than 1 year	1,677	821	1,588	1,066
more than 1 year and less than 5 years	4,516	880	5,226	1,712
more than 5 years	3,009	0	5,539	0
Total	**9,202**	**1,700**	**12,353**	**2,778**

In EUR 000	As of 31 December,	
	2017	2016
Payments recognized as an expense		
minimum lease payments	2,084	1,528
Total	**2,084**	**1,528**

6.2.33 / 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.

6.2.33.1 / Remuneration of directors and members of the executive management

In EUR 000	Years ended 31 December,	
	2017	2016
Short-term employee benefits (salaries, social security bonuses and fringe benefits)	2,509	2,447
Post -employment benefits (Group insurance)	65	68
Share based payment	539	278
Total	**3,113**	**2,793**

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 2017 and 2016 under the ESOP 2013, 2015 and 2017 plan, the roll forward of the options granted to key management is included in the remuneration report.

6.2.33.2 / Subsidiaries

Details of the Company's subsidiaries at 31 December 2017 are as follows:

Name of subsidiary	Principal activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2017	2016
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%**
Biocartis US Inc.	Develop and market diagnostic platforms	2500 Plaza, 25th Floor, Suite 2547 Jersey City, NJ 07311 USA	100%	N/A

* All shares held by Biocartis SA, except for one share held by Biocartis BV.

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

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

6.2.34 / Events after the balance sheet date

Four important events were announced after the reporting date.

- **Second CDx partnership Amgen** – On 9 January 2018, Biocartis announced a new companion diagnostic (CDx) development agreement with Amgen, a leading biotechnology company (NASDAQ: AMGN), aimed at the development of Idylla™ CDx biomarker tests for a novel oncology compound to be used in the treatment of certain solid tumors.

- **Collaboration Immunexpress** – On 24 January 2018, Biocartis and Immunexpress Pty Ltd ('Immunexpress'), a host response molecular diagnostic company, announced a partnership agreement aimed at the development and commercialization of Immunexpress' SeptiCyte™ test for use on the Idylla™ platform. The SeptiCyte™ LAB test, recently received 510(k) clearance from the US FDA for use on a manual PCR instrument, aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS[65]) systemic inflammation in critically ill patients on their first day of their admission in the ICU (intensive care unit). Under the partnership, parties will co-develop the SeptiCyte™ Idylla™ test, whereas Immunexpress will take the lead in the commercialization, with an initial focus on the US and the European markets.

[65] Systematic inflammatory response syndrome.

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

- **EIB financing facility** – On 1 March 2018, Biocartis announced to have obtained a EUR 24m debt financing facility from the European Investment Bank. The financing facility is supported by InnovFin – EU Finance for Innovators' Infectious Diseases Finance Facility, with the financial backing of the European Union under its research and innovation programme Horizon 2020. It can be used to part-finance up to 50% of further investments in infectious diseases diagnostics solutions.

There were no further important events between 31 December 2017 and the approval date of this annual report.

6.2.35 / Standards and interpretations published, but not yet applicable for the annual period beginning on 1 January 2017

- Annual improvements to IFRS Standards 2014-2016 Cycle: Amendments to IFRS 1 and IAS 28 (applicable for annual periods beginning on or after 1 January 2018, but not yet endorsed in the EU)
- 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 the 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)
- IFRS 17 Insurance Contracts (applicable for annual periods beginning on or after 1 January 2021, 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 the EU)
- Amendments to IFRS 4 Applying IFRS 9 Financial Instruments with IFRS 4 Insurance Contracts (applicable for annual periods beginning on or after 1 January 2018)
- Amendments to IFRS 9 Prepayment Features with Negative Compensation (applicable for annual periods beginning on or after 1 January 2019, but not yet endorsed in the EU)
- Amendments to 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 the EU has been postponed)
- Amendments to IAS 28 Long term interests in Associates and Joint Ventures (applicable for annual periods beginning on or after 1 January 2019, but not yet endorsed in the 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)
- IFRIC 23 Uncertainty over Income Tax Treatments (applicable for annual periods beginning on or after 1 January 2019, but not yet endorsed in the EU)

IFRS 16 leases

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:

Reagent rental contracts

Under its reagent rental contracts, the Group bundles the following multiple elements together: the use of the Idylla™ system, the servicing of the system and the consumption of Idylla™ cartridges. The use of the Idylla™ system is considered to be lease under IAS 17 and therefore the consideration under the reagent rental agreement will have to be allocated between the lease component and the other components (servicing and consumption of Idylla™ cartridges) using a relative fair value approach. The majority of the Group's reagent rental contracts have minimum purchase requirements, which however may not be contractually enforceable and are cancellable with a notice period, therefore the lease component present in these contracts generally qualify as an operating lease and the lease payments are generally to be considered as contingent payments. As explained in 7.2.2.15 Revenue Recognition, the total Idylla™ cartridge price includes a cost for the use of the Idylla™ system by the customer. Customers are invoiced based on received sales orders for Idylla™ cartridges. Revenue allocated the Idylla™ cartridges will only be recognized when the Idylla™ system is delivered to the customer and the customer obtained control over the cartridges.

Regular sales contracts

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

As a conclusion, both in terms of amounts and timing of the revenue recognized in the Group's product related income, the application of IFRS 15 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.

Collaboration contracts

Under its research and development collaboration contracts, the Group regularly provides a license and further development services. The consideration in these contracts mainly consist of a non-refundable upfront fee, milestone payments, compensation for research and development services and royalties. The group assesses if the license provided can be considered as being distinct in the context of the contract. If not, the license will have to be bundled with the research and development services.

The recognition of development milestones might be different from what is currently applied under IAS 18. If one would conclude the license is not a distinct performance obligation, the receipt of a development milestone will have to be recognized pro rata the completion of the research and development services to be provided under the agreement. If the license is considered to be distinct performance obligation under the agreement, the recognition of a development milestone will depend on the nature of the license. If the license is a right to use, the portion of the milestone allocated to the license will recognized at the moment of reaching the development milestone criteria; if the license is a right to access, the portion of the milestone allocated to the license will recognized at the moment of reaching the development milestone criteria over the license period. The Group will apply IFRS 15 under the modified retrospective approach as of 1 January 2018. Any possible impact on applying IFRS 15 at the date of transition will therefore be accounted for under the opening retained earnings of 1 January 2018.

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

CHAPTER 7

Statutory Annual Accounts

7.1 / Abbreviated statutory annual accounts

The statutory annual accounts of Biocartis Group NV are presented in an abbreviated form. The full statutory annual accounts, drawn up in accordance with Belgian GAAP, are still to be filed with the National Bank of Belgium. The statutory auditor, Deloitte Bedrijfsrevisoren CVBA, represented by Gert Vanhees, has issued an unqualified audit opinion regarding the statutory annual accounts. A copy of the statutory annual accounts and this annual report can be obtained upon request. An electronic version of these documents is available on the Biocartis website (www.biocartis.com).

7.2 / 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.

7.3 / Income statement and balance sheet Biocartis Group NV

Income Statement

In EUR 000	Years ended 31 December, 2017	2016
Revenues	4,457	3,348
Other operating income	1,257	70
Total operating income	**5,714**	**3,418**
Services and other goods	-1,776	-1,319
Salaries, social security contributions and pensions	-3,809	-1,981
Other operating expenses	-7	-3
Operating expenses	**-5,592**	**-3,304**
Financial income	1,498	1,037
Financial expenses	-4,921	-2,023
Result from continuing operations	**-3,301**	**-871**
Income taxes	17	-17
Net result	**-3,284**	**-889**

Balance Sheet

In EUR 000	As of 31 December, 2017	2016
Financial fixed assets	228,822	227,320
Non-current assets	**228,822**	**227,320**
Trade receivables	63	21
Other receivables	161,492	107,592
Cash and cash equivalents	91,895	68,627
Transitory accounts	29	49
Current assets	**253,479**	**176,289**
Total assets	**482,302**	**403,609**
Legal share capital	511	446
Share premium	477,581	397,205
Accumulated deficit	-13,348	-10,064
Total equity	**464,782**	**387,588**
Financial debt	16,331	15,263
Non-current liabilities	**16,331**	**15,263**
Financial debt	-	-
Trade payables	687	348
Provision taxes	131	258
Salaries, social security contributions and pensions	408	153
Current liabilities	**1,188**	**759**
Total equity and liabilities	**482,302**	**403,609**

7.4 / Discussion of statutory accounts

Income Statement

Total operating income in 2017 amounted to EUR 5.7m (2016: EUR 3.4m) and consists mainly of expense recharges to the Biocartis Group NV subsidiaries. Operating expenses recorded in the period under review amounted to EUR 5.6m (2016 EUR 3.3m) and consist of salaries, social security contributions and pensions expenses for EUR 3.8m (2016: EUR 2.0m) and of expenses for services and other goods of EUR 1.7m (2016: EUR 1.3m). Services and other goods mainly consist of recurring general and administrative expenses.

Financial income amounted to EUR 1.5m (2016: EUR 1m) 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 4.9m (2016: EUR 2.0m) and relate to the non-recurring expenses made in relation of the capital increases of Biocartis NV in November 2017 for EUR 3.8m (November 2016: EUR 1.6m) and interest charges on the PMV loan.

The net result after taxes for the period ended 31 December 2017 amounts to EUR 3.3m (2016: EUR 0.9m).

Balance sheet

Assets

The financial fixed assets consist of shares in the Biocartis Group NV subsidiaries for EUR 223.8m and a financial participation in a third party company MyCartis NV for EUR 5.1m.

Other receivables amounted to EUR 161.5m (2016: EUR 107.6m) and mainly relate to receivables on the Biocartis Group NV subsidiaries, mainly related to financial advances. Cash and equivalents amounted to EUR 91.9m per 31 December 2016 (2016: EUR 68.6m). Deferred charges relate to prepaid expenses.

Equity

Total equity per 31 December 2016 amounted to EUR 464.8m (2016: EUR 387.6m) and the legal share capital and share premium amount to respectively EUR 0.5m (2016: EUR 0.4m) and EUR 477.6m (2016: EUR 397.2m).

Following movements in equity were recorded during the reporting period:

- Capital increase following the execution of stock options of 5 October 2017 for an amount of EUR 217. The share premium account was increased with EUR 175,956.
- Capital increase on 28 November 2017 for an amount of EUR 64,000. The share premium account was increased with EUR 79,936,000.
- Capital increase following the execution of stock options of 21 December 2017 for an amount of EUR 325. The share premium account was increased with EUR 263,929.

Financial debt

In 2016, Biocartis Group NV obtained a new loan of EUR 15m provided by a consortium of PMV (Participatie Maatschappij Vlaanderen) and the Belgian 'Federal Holding and Investment Company' (FPIM). Both PMV and FPIM granted a loan of EUR 7,5m each, bearing interest rate of 7% and with a maturity date at 30 September 2021. The interest on the loans is capitalized during the first three years of the agreement and accrued in the consolidated balance sheet at the year-end.

Other liabilities

As per 31 December 2017, trade payables amounted to EUR 0.6m (2016: EUR 0.3m), provision for taxes to EUR 0.1m (2016: EUR 0.3m) and payables for salaries, social security contributions and pensions to EUR 0.4m (2016: EUR 0.2m).

Total assets and liabilities

Total assets and on the other hand total liabilities amounted per 31 December 2017 to EUR 482.3m (2016: EUR 403.6m).

7.5 / Appropriation of results

The statutory accounts of the Company reported a net loss of EUR -3.3m for the year 2017. The Board of Directors proposes to carry forward the statutory net loss of EUR -3.3m of 2017 to the following financial year.

7.6 / 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 2017, Biocartis Group NV raised EUR 80 m in the context of a private placement and on top of that the company raised EUR 0.5 m through the exercising of warrants. Taken into account the strong cash position of the Company at the end of 2017 as well as the expectations for 2018, 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 2019, and thus that the application of the valuation rules going concern is justified.

CHAPTER 8

Auditor's report

Biocartis Group NV

Statutory auditor's report to the shareholders' meeting for the year ended 31 December 2017

The original text of this report is in Dutch

In the context of the statutory audit of the consolidated financial statements of Biocartis Group NV ("the company") and its subsidiaries (jointly "the group"), we hereby submit our statutory audit report to you. This report includes our report on the consolidated financial statements together with our report on other legal and regulatory requirements. These reports are one and indivisible.

We were appointed in our capacity as statutory auditor by the shareholders at the establishment of the company on 24 November 2014 in accordance with the proposal of the board of directors issued upon recommendation of the Audit Committee. Our mandate will expire on the date of the shareholders' meeting approving the consolidated financial statements for the year ending 31 December 2017. We have performed the statutory audit of the consolidated financial statements of Biocartis Group NV for three consecutive years.

Report on the audit of the consolidated financial statements

Unqualified opinion

We have audited the consolidated financial statements of the group, which comprise the consolidated balance sheet as at 31 December 2017, the consolidated income statement, the consolidated statement of other comprehensive income, the consolidated statement of changes in equity and the consolidated cash flow statement then ended, as well as the summary of significant accounting policies and other explanatory notes. The consolidated balance sheet shows total assets of 181.191 (000) EUR and the consolidated income statement shows a consolidated net loss for the year then ended of 41.960 (000) EUR.

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 2017 and of its consolidated results and its consolidated cash flow for the year then ended, in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

Basis for the unqualified opinion

We conducted our audit in accordance with International Standards on Auditing (ISA). Our responsibilities under those standards are further described in the "Responsibilities of the statutory auditor for the audit of the consolidated financial statements" section of our report. We have complied with all ethical requirements relevant to the statutory audit of consolidated financial statements in Belgium, including those regarding independence.

We have obtained from the board of directors and the company's officials the explanations and information necessary for performing our audit.

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

Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

KEY AUDIT MATTERS	HOW OUR AUDIT ADDRESSED THE KEY AUDIT MATTERS
Revenue recognition	
Revenue for the year 2017 amounts to EUR 20.957k EUR and consist of: - Product related revenues including various combinations of instruments and cartridges in multiple element sales agreements, operational reagent rental agreements and rental agreements; and - Collaboration revenues for research and development (R&D) c ollaboration agreements including simultaneous transactions and multiple element arrangements such as licenses and R&D services which are remunerated via combinations of upfront payments, milestone payments and royalties The correct application of revenue recognition accounting standards to the separate elements of a customer's contract are complex and require judgement and interpretation by management, especially given the industry specific nature and variety of the agreements. Moreover, Biocartis aims to achieve ambitious revenue growth targets, which increases the risk for inappropriate revenue recognition. The company's disclosures about revenue is included in note *6.2.2.15 Revenue recognition* and *6.2.4 Revenue of the consolidated financial statements*.	We considered the appropriateness of the Group's revenue recognition principles in accordance with the applicable IFRS standard. We obtained an understanding of the underlying processes and preventive and detective internal controls. We read the relevant agreements to assess whether the company correctly applied the Group's revenue recognition principles and we challenged the reasonableness of the judgements made by Management in determining the relevant assumptions utilized in calculating recognized revenue. We tested a sample of transactions of revenue recognized in the income statement (revenue) and the balance sheet (deferred income) for accuracy and appropriate recognition based on the agreements, recognition principles and Managements estimates and judgements.

Responsibilities of the board of directors for the consolidated financial statements

The board of directors is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium, and for such internal control as the board of directors determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements the board of directors is responsible for assessing the group's ability to continue as a going concern, disclosing, as applicable, matters to be considered for going concern and using the going concern basis of accounting unless the board of directors either intends to liquidate the group or to cease operations, or has no other realistic alternative but to do so.

Responsibilities of the statutory auditor for the audit of the consolidated financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISA will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISA, we exercise professional judgment and maintain professional skepticism throughout the audit.

We also:

- identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from an error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;

- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the group's internal control;

- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management;

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

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

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

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

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

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

Report on other legal and regulatory requirements

Responsibilities of the board of directors

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

Responsibilities of the statutory auditor

As part of our mandate and in accordance with the Belgian standard complementary (Revised in 2018) to the International Standards on Auditing (ISA), our responsibility is to verify, in all material respects, the director's report on the consolidated financial statements and other matters disclosed in the annual report, as well as to report on these matters.

Aspects regarding the directors' report on the consolidated financial statements

In our opinion, after performing the specific procedures on the directors' report on the consolidated financial statements, this report is consistent with the consolidated financial statements for the period ended 31 December 2017 and it has been established in accordance with the requirements of article 119 of the Companies Code.

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

Statements regarding independence

No prohibited non-audit services, as referred to by the law, have been performed and our audit firm and, if applicable, our network of audit firms, remained independent from the company during the performance of our mandate.

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

Other statements

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

Zaventem, 28 March 2018

The statutory auditor

DELOITTE Bedrijfsrevisoren / Réviseurs d'Entreprises
BV o.v.v.e. CVBA / SC s.f.d. SCRL
Represented by Gert Vanhees

CHAPTER 9
Glossary

Assay
In the field of diagnostics, an assay is a process or method aimed at determining the presence or amount (quantitative assay) of a certain substance in a sample.

Biopsy (solid/liquid)
The Idylla™ platform is capable of processing both solid biopsies (FFPE tissue which is the standard tissue type for solid tumor diagnostics, and fresh (frozen) tissue samples) and liquid biopsies. These are easier to obtain sample types such as blood plasma or urine. Liquid biopsy based assays will facilitate monitoring of treatments and disease progression, and possible earlier disease detection.

Serine/threonine-protein kinase B-raf (BRAF)
BRAF is a protein that, in humans, is encoded by the BRAF gene. The BRAF protein is involved in sending signals within cells and in cell growth. Certain inherited BRAF mutations cause birth defects. Alternatively, other acquired mutations in adults may cause cancer.

CE-mark
The CE-mark is a mandatory conformance mark on many products placed on the market in the European Union. With the CE-marking on a product, the manufacturer ensures that the product is in conformity with the essential requirements of the applicable European Union directives. The letters "CE" stand for 'Conformité Européenne' ('European Conformity').

ctDNA
This is circulating tumor DNA.

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

CLIA
The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease (source: https://wwwn.cdc.gov/clia/).

Deoxyribonucleic acid (DNA)
DNA is a nucleic acid molecule that contains the genetic instructions used in the development and functioning of living organisms.

Epidermal growth factor receptor (EGFR)
EGFR is a protein found on the surface of certain cells which can cause them to divide. It is found in abnormally high levels on the surface of many types of cancer cells.

Emergency Use Authorization (EUA)
This is an authorisation given by the FDA Commissioner pursuant to section 564 of the US Federal Food, Drug, and Cosmetic Act, as amended (the 'FD&C Act'), which allows unapproved medical products or unapproved uses of approved medical products to be used in the United States in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear threat agents when there are no adequate, approved, and available alternatives.

Formalin fixed, paraffin embedded (FFPE)
FFPE tissues are samples, typically from suspected tumors, that are fixed or mixed with formalin to preserve the structural integrity of the sample. The sample is then embedded into a type of paraffin wax so that it can be sliced into very fine slices, 5-10 microns thick. Treating samples in this manner enables the samples to be stained with dyes to analyse abnormalities in tissue that is suspected of cancer.

US Food and Drug Administration (FDA)
The FDA is a federal agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the regulation and supervision of, among other things, medical devices.

Immunoassay
Immunoassays are assays that measure biomarkers through antigen-antibody interaction technologies. In most cases such assays are used to measure biomarkers of the immune system itself, e.g. HCV or HIV antibodies produced by the bodies, which are detected by means of HCV or HIV antigens.

Influenza
Also known as 'the flu' is a highly contagious respiratory tract infection caused by the family of influenza viruses.

In vitro diagnostics or In vitro diagnosis (IVD)
IVD is a diagnostic test outside of a living body in contrast to "in vivo", in which tests are conducted in a living body (for example an X-ray or CT-scan).

Kirsten rat sarcoma-2 virus oncogene (KRAS)
KRAS is a protein that, in humans, is encoded by the KRAS gene. Like other members of the Ras family, the KRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyse guanosine triphosphate),

and is an early player in many signal transduction pathways. The protein product of the normal KRAS gene performs an essential function in normal tissue signalling, and the mutation of a KRAS gene is associated with the development of many cancers.

MDSAP (Medical Device Single Audit Program)

The MDSAP allows medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program's main mission is to "...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."

Metastatic Colorectal Cancer (mCRC)

Colorectal Cancer (CRC) is the second most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually. According to the International Agency for Research on Cancer, an estimated 694,000 deaths from CRC occur worldwide every year, accounting for 8.5% of all cancer deaths and making it the fourth most common cause of death from cancer.

Molecular diagnostics (MDx)

MDx is a form of diagnostic testing used to detect specific sequences in DNA or RNA that may or may not be associated with disease. Clinical applications of MDx include infectious disease testing, oncology, pharmacogenomics and genetic disease screening.

Micro satellite instability (MSI)

MSI is a genetic hyper-mutability condition resulting from MMR that is functioning abnormally.

Multiplexing

The simultaneous detection of more than one analyte or biomarker from a single sample.

Neuroblastoma RAS viral (v-ras) oncogene (NRAS)

NRAS is a protein that is encoded, in humans, by the NRAS gene. Like other members of the Ras family, the NRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyse guanosine triphosphate), and is an early player in many signal transduction pathways. The protein product of the normal NRAS gene performs an essential function in normal tissue signaling, and the mutation of a NRAS gene is associated with the development of many cancers.

Next-Generation Sequencing (NGS)

Sequencing is the process of determining the precise order of nucleotides within a DNA molecule. It includes any method or technology that is used to determine the order of the four bases—adenine, guanine, cytosine, and thymine—in a strand of DNA. The high demand for low-cost sequencing has driven the development of high-throughput sequencing technologies that parallelize the sequencing process, producing thousands or millions of sequences concurrently. High-throughput sequencing technologies are intended to lower the cost of DNA sequencing beyond what is possible with standard dye-terminator methods.

Polymerase chain reaction (PCR)

The specific and exponential amplification of DNA sequences by consecutive thermal cycling steps. Real-time PCR is a form of PCR whereby the amplified sequences are made visible by means of fluorescent labelling in real time, i.e., as they become synthesized. Real-time PCR can be used to estimate the quantity of target DNA sequences in a multiplexed way. PCR and real-time PCR can also be used to detect and quantify RNA sequences after a DNA copy has been made from the RNA sequence by means of a reverse transcriptase enzyme.

Protein

Polypeptide chain built from the 20 natural amino acids. Proteins are synthesized from a messenger RNA copy of a gene and can have many functions in the cytoskeleton of the cell, enzymatic, messenger functions in cells and blood such as immune cytokines, DNA binding proteins that regulate expression, etc.

Respiratory Syncytial Virus (RSV)

RSV is a major cause of lower respiratory tract infection that is a frequent infection in children.

Research Use Only (RUO)

This is a category of non-approved (i.e. no CE-marking and FDA approval) medical device products that can solely be used for research purposes. Many producers introduce their products first as RUO and/or IUO products, prior to obtaining 510(k) clearance or PMA approval.

Ribonucleic acid (RNA)

RNA, like DNA, is a nucleic acid molecule. RNAs have a variety of different functions in living cells. They can have a scaffolding role in the build-up of complexes (ribosomes, SNRPs), provide sequence recognition (translation, RNA spicing), have catalytic function (ribozymes), act as messengers for protein synthesis (mRNAs), regulate gene expression (miRNAs) or make up the genome of certain viruses.

Sepsis

Severe overall inflammatory response of the body to an infection.

Notes

Biocartis NV
Generaal de Wittelaan 11 B3
2800 Mechelen - Belgium
T +32 15 632 000
ir@biocartis.com www.biocartis.com

Ref: BC_AR_2017 / Design: will@mediaclan.it