



PRESS RELEASE

REGULATED - INSIDE INFORMATION

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## BIOCARTIS ANNOUNCES 2016 RESULTS, 2017 OUTLOOK AND CHANGE IN CEO POSITION

**Mechelen, Belgium, 2 March 2017** – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its operational highlights and financial results for 2016, prepared in accordance with IFRS as adopted by the European Union. Furthermore, the Company today provides its outlook for 2017 and announces a change in the Company's CEO position.

### Overview of key messages

#### 2016 results

- **Installed base:** Installed base Idylla™ instruments more than doubled in 2016 by adding a total of 224 instruments. Total installed base year end was close to 390 instruments.
- **Cartridge consumption:** Commercial cartridge volume in 2016 increased to over 25,000 cartridges which represents approx. 7.5 times the total commercial volume of 2015.
- **Test menu:** On market oncology menu expanded to 7 tests.
- **Revenues:** Total 2016 operating income amounted to EUR 13.8m. Product revenues in 2016 amounted to EUR 6.8m, representing an increase of 88% compared to 2015.
- **Cash position:** Cash and cash equivalents on 31 December 2016 amounted to EUR 83.2m.

#### Guidance 2017

- **Installed base:** 640 Idylla™ instruments by the end of 2017, based on 250-275 new instrument placements.
- **Cartridge consumption:** commercial cartridge volume in 2017 to be at least three times 2016 volume.
- **Cash position:** Around EUR 40m by 2017 year end.

#### Change in CEO position

Rudi Pauwels has expressed his preference to focus on the longer term strategy of the Company, including a pathway towards a Next-Generation Sequencing based product offering. Therefore, the Board has decided that Rudi Pauwels will take on the role of Chairman of a new Strategy Committee of the Board and that he will pass on the role of CEO to a successor. The Company is confident that a successor can be announced in the next few months. Hilde Windels, currently Deputy CEO, will assume the role of CEO until a successor is on board.

*Biocartis will host a conference call with live webcast presentation today at 14:00 CET / 13:00 BST (UK) / 08:00 EDT (US) to discuss the 2016 results. Click [here](#) to access the live webcast.*

*To participate in the questions and answers session, please dial 5-10 minutes prior to the start time the number +44(0)20 3427 1901 (standard international), followed by the confirmation code 9539312.*

*The conference call and webcast will be conducted in English.  
A replay of the webcast will be available on the [Biocartis investors' website](#) shortly after.*

## Commercial highlights

- *Installed base* - A total of 224 Idylla™ instruments were added to the installed base in 2016, resulting in a total installed base of close to 390 instruments per year end 2016. This compared to an installed base of 165 instruments at the beginning of 2016 and the latest 2016 guidance of adding at least 175 instruments. The three key drivers behind the installed base growth in 2016 were menu expansion, an increased awareness by end customers on the excellent performance of the Idylla™ technology (as demonstrated in recent published comparative studies<sup>1</sup>) and the growing interest from pharmaceutical companies. The growth in installed base end of 2016 was also driven by the regulatory upgrade, i.e. the CE-marking of the Idylla™ NRAS-BRAF Mutation Test.
- *Cartridge consumption* - In line with the installed base growth and menu expansion, commercial Idylla™ cartridge consumption in 2016 was over 25,000 cartridges, which is approx. 7.5 times the total commercial cartridge volume of 2015.
- *Amgen collaboration* - On 3 February 2016, Biocartis announced a collaboration with Amgen to evaluate Idylla™ RAS testing as a tool for rapid decentralized testing in a range of countries<sup>2</sup>. This collaboration was expanded in December 2016 to include up to 10 new European countries and will enable several dozen additional selected hospitals to accelerate patient access to RAS biomarker information using Biocartis' Idylla™ platform and RAS tests.
- *Commercial footprint* - During 2016, Biocartis further executed the expansion of its global commercial footprint by obtaining new market authorizations for 8 additional geographies and signing 9 new distribution agreements. More specifically, on 17 November 2016, Biocartis announced its partnership with Thermo Fisher Scientific Inc. to distribute in the US its Idylla™ platform and accompanying assays, with a first focus on oncology products. Both parties expect to start commercial roll-out in the US as of H2 2017. Biocartis has retained the option to sell both its Idylla™ platform and assays via direct sales channels into the US market.

## Idylla™ test menu highlights

- **Colorectal cancer menu** - During 2016, Biocartis significantly expanded and strengthened its colorectal cancer menu by:
  - Completing its offering of metastatic colorectal cancer (mCRC) tests for clinical use on the Idylla™ platform with the CE-marking of its solid biopsy Idylla™ NRAS-BRAF Mutation Test on 15 December 2016. Biocartis' mCRC offering follows the most recent clinical guidelines and opens routes towards faster treatment selection.
  - Entering into a collaboration with Merck KGaA (Merck) for the development and commercialization of a new liquid biopsy RAS biomarker test for patients with mCRC that was announced on 7 January 2016. This comprises two Idylla™ assays of which the first one, the Idylla™ ctKRAS Mutation Assay was launched in December 2016 under a Research Use Only (RUO) label and is Biocartis' second liquid biopsy test. The second assay under the agreement, the Idylla™ ctNRAS-BRAF-EGFR492 Mutation Assay (RUO) was launched on 2 March 2017. Biocartis and Merck plan to implement the Idylla™ liquid biopsy RAS test in numerous medical centers across the world<sup>3</sup> following CE-marking of both tests, expected in H2 2017.
  - Signing an exclusive licensing of a recently detected set of ectodomain mutations in the Epidermal Growth Factor Receptor (EGFR)<sup>4</sup> that convey resistance to certain anti-EGFR therapies in colorectal cancer from Dr. Montagut (Hospital del Mar, Barcelona, Spain), Dr. Bardelli and Dr. Arena (University of Torino, Italy), entered into on March 2016. The aim is to integrate these novel biomarkers (which complement the EGFR S492R marker licensed by Biocartis in 2013) into molecular diagnostic tests for the Idylla™ platform, to enable physicians to monitor therapy resistance in patients and thereby allowing for optimizations of treatment regimes.
- **Lung cancer menu** - On 21 June 2016, Biocartis launched the first test of its lung cancer menu with the Idylla™ EGFR Mutation Assay (RUO). This advanced, fully automated molecular test is designed to detect over 50 EGFR mutations which commonly occur in lung cancer on the basis of only a single slice of tumor<sup>5</sup> tissue. Its extreme ease-of-use allows for testing irrespective of location or laboratory expertise level and, as such, this assay has the potential to enable more wide-spread testing of lung cancer specimens.
- **Performance studies** - During 2016, a total of eight different promising publications<sup>6</sup> were issued on the

<sup>1</sup> See further under 'Performance studies'. An overview of the publications can be found on [www.biocartis.com](http://www.biocartis.com).

<sup>2</sup> The collaboration announced on 3 February 2016 focused on selected reference hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey.

<sup>3</sup> The collaboration does not include the US, China and Japan.

<sup>4</sup> It concerns a new set of mutations in the EGFR ectodomain. While the commonly known EGFR mutations reside in the kinase domain of the EGFR receptor, which is located inside the cell, the EGFR ectodomain is the portion of the receptor located outside the cell, and represents the true receptor function where EGF binds, and where anti-EGFR antibodies for the treatment of colorectal cancer such as cetuximab and panitumumab engage the EGFR receptor and prevent EGF binding.

<sup>5</sup> The analysis is done based on a slice of FFPE (formalin fixed paraffin embedded) tumor.

<sup>6</sup> Janku et al. BRAF Mutation Testing in Cell-Free DNA from the Plasma of Patients with Advanced Cancers Using a Rapid, Automated Molecular Diagnostics System. *Mol Cancer Ther* (2016) 15(6): 1-8; Schreuer et al. Quantitative assessment of BRAF V600 mutant cell-free tumor DNA from plasma as a diagnostic and therapeutic biomarker in patients with BRAF V600 mutant melanoma. *ASCO* 2015; De Biase et al. 'Fully Automated PCR detection of KRAS Mutations on Pancreatic Endoscopic Ultrasound Fine

performance of Idylla™ oncology tests, four of them were presented at the renowned international oncology conferences ASCO and ESMO. This included a comparative study<sup>7</sup> organized by AstraZeneca, a global biopharmaceutical company, where 12 different KRAS mutation detecting technologies, including Next-Generation Sequencing (NGS) and quantitative Polymerase Chain Reaction (PCR), were compared for the detection of KRAS mutations, using blinded samples. This study confirmed the best-in-class status of the Idylla™ KRAS technology.

- US FDA achievements - Two important achievements were realized with the US Food and Drug Administration (FDA) in 2016:
  - On 1 June 2016, Biocartis received Emergency Use Authorization by the US FDA for the Idylla™ Ebola Virus Triage Test (Idylla™ EBOV Test) that runs on the Idylla™ platform. This test was co-developed by Biocartis, Janssen Diagnostics (a division of Janssen Pharmaceutica NV) and the Belgian Institute of Tropical Medicine.
  - On 22 December 2016, Biocartis completed the 510(k) submission<sup>8</sup> to the US FDA of its Idylla™ platform, comprising of the Idylla™ Instrument and the Idylla™ Console. This submission was done in parallel with the 510(k) submission by Biocartis' strategic partner Janssen Diagnostics of the Janssen Idylla™ Respiratory (IFV-RSV) Panel Test.

### Operational highlights

- Strengthening management team - Hilde Eylenbosch, who joined Biocartis' Board of Directors in May 2016, took over the position of Chief Commercial Officer as of 17 November 2016. Ulrik Cordes (the Company's previous Chief Commercial Officer since September 2013) transitioned on that date into the function of EVP Pharma Collaborations and Companion Diagnostics, aimed at building a strong complementary and companion diagnostic business. Furthermore, during Q1 2016, Biocartis strengthened its manufacturing expertise with the appointment of Reginald Van Genechten as Head of Manufacturing and Supply Chain.
- Cartridge manufacturing – During 2016, Biocartis together with its partners continued the works on a second cartridge manufacturing line. The aim is to have this line operational by the end of 2017. It should provide for an additional annual cartridge capacity of over 1 million Idylla™ cartridges.

### Financial highlights

- Product sales revenues – Total product sales revenues in 2016 increased with approx. 88% to EUR 6.8m from EUR 3.6m in 2015. This increase was predominantly driven by cartridge sales that amounted to EUR 4.0m in 2016, representing over 3 times the 2015 cartridge sales of EUR 1.3m. System sales increased with approx. 20% from EUR 2.3m in 2015 to EUR 2.8m in 2016.
- Equity raise – On 17 November 2016, Biocartis successfully raised EUR 32.7m of gross proceeds by means of a private placement via an accelerated bookbuild offering of 4,058,917 new shares (being approximately 10% of the Company's outstanding shares) at an issue price of EUR 8.05 per share.
- Debt financing – On 20 July 2016, Biocartis announced it had attracted EUR 55m of non-dilutive financing consisting of a EUR 40m bank and lease financing facility as well as a new subordinated loan of EUR 15m. The bank and lease financing facility consists of EUR 15m lease financing and EUR 25m multiple purpose credit lines (the credit lines are partially guaranteed by the Flemish Government). Biocartis' total debt outstanding amounted to EUR 31.4m as per 31 December 2016, compared to EUR 10.8m as per 31 December 2015.
- Cash flow – Biocartis' cash flow from operational and investment activities amounted to EUR -62.7m in 2016, compared to EUR -32.8m in 2015, mainly driven by increased operational expenses and higher investments for cartridge manufacturing expansion. Given a cash flow from financing activities in 2016 of EUR 41.8m, the total net cash flow of 2016 amounted to EUR -20.9m.
- Cash position – Biocartis' cash position as per 31 December 2016 amounted to EUR 83.2m compared to EUR 104.1m as per 31 December 2015.
- Additional details – see 'key figures for 2016' below for more details on the 2016 financials.

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Needle Aspirates'. J Clin Pathol 2016; Reijmans et al. ESMO 2016, published on 6 October 2016; De Luca et al., J Clin Pathol 2016; J.L. Sherwood et al., KRAS – ESMO Abstract 91 P: "Implications of key differences across 12 KRAS mutation detection technologies and their relevance in clinical practice", publicly available on <https://cslide.ctimeetingtech.com/library/esmo/browse/itinerary/5286/2016-10-10#2z95w>; Ellen Vercauteren et al., NRAS – ESMO Abstract 1175P: "Ultra-rapid, sensitive, and fully automated extended RAS testing for metastatic colorectal cancer – evaluation of an NRAS/BRAF/EGFR492 module", publicly available on <https://cslide.ctimeetingtech.com/library/esmo/browse/itinerary/5286/2016-10-10#2z95w>; Preliminary Performance Study based on Research data. Martin Reijmans et al., EGFR – ESMO Abstract 1173P: "Fully automated and sensitive detection of EGFR exon 18, 19, 20 and 21 mutational status in less than 2.5 hours from a single FFPE slice", publicly available on <https://cslide.ctimeetingtech.com/library/esmo/browse/itinerary/5286/2016-10-10#2z95w>; Jérôme Solassol et al., "Multi-Center Evaluation of the Fully Automated PCR-Based Idylla™ KRAS Mutation Assay for Rapid KRAS Mutation Status Determination on Formalin-Fixed Paraffin-Embedded Tissue of Human Colorectal Cancer", available for download: <http://journals.plos.org/plosone/article/asset?id=10.1371/journal.pone.0163444.PDF>.

<sup>7</sup> James L. Sherwood, "Implications of Key Differences Across 12 KRAS Mutation Detection Technologies and Their Relevance in Clinical Practice", first presented at ESMO in October 2016.

<sup>8</sup> 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).

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

### Post-period events

- Companion diagnostics (CDx) – In January 2017, Biocartis signed a first companion diagnostics partnership with an undisclosed pharmaceutical company (ranked amongst the global top 10 pharmaceutical companies by sales) for the joint development of an Idylla™ CDx test for an undisclosed phase II oncology compound.
- Change CEO position – Today, on 2 March 2017, Biocartis announced a change in the CEO position of the Company.
- Launch of the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Test – On 2 March 2017, Biocartis launched the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (Research Use Only<sup>9</sup>), an important milestone the partnership with Merck<sup>10</sup> as well as the Company’s third liquid biopsy test for oncology.

### Outlook 2017

- Target of growing the total installed base to 640 Idylla™ instruments by adding 250-275 new instrument placements, driven by the ongoing menu and geographical expansion.
- Annual commercial cartridge consumption in 2017 is targeted to grow to over three times the 2016 volume.
- 510(k) approval from the US FDA is expected for the Idylla™ Instrument, the Idylla™ Console and the Idylla™ Respiratory (IFV-RSV) Panel Test.
- Menu expansion is aimed at further completing Biocartis’ core oncology menu in the course of 2017:
  - CE-marking Idylla™ EGFR Mutation Test (Q2 2017);
  - CE-marking Idylla™ NRAS Mutation Test (Q2/Q3 2017): this test will give more flexibility to customers and will allow for price differentiation with the Idylla™ NRAS-BRAF Mutation Test in geographies where BRAF testing for mCRC patients is not reimbursed;
  - CE-marking Idylla™ ctKRAS Mutation Test and Idylla™ ctNRAS-BRAF Mutation Test as part of the partnership with Merck (H2 2017); and
  - Launch of a liquid biopsy version of the Idylla™ EGFR Mutation Assay (RUO, H2 2017). Note: this product will be initially launched on the basis of a manual DNA extraction protocol anticipating a fully automated ctEGFR Mutation Assay that is also under development.
- Biocartis targets a cash position by the end of 2017 of around EUR 40m.

### Update test menu strategy

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

- Biocartis is observing a stronger than expected traction of the Idylla™ platform in oncology. This traction is primarily fueled by Biocartis’ unique position in providing FFPE<sup>11</sup>-based sample-to-result solutions, strong performance data of Idylla™ tests, and Biocartis’ potential to benefit from the promises of liquid biopsy testing, immuno-oncology therapies and Next-Generation Sequencing (NGS). This has led to increased interest from customers and pharmaceutical companies. Therefore, the Company has decided to increase its focus on oncology and to turn this positive momentum into solid market share and revenue growth which:
  - From a menu perspective, should result in a faster and broader expansion of the Company’s oncology offering into comprehensive menus for colorectal, lung, breast, urology and related tumors from a biomarker point of view, as well as expansion into immunotherapy and DNA repair fields<sup>12</sup>. This is

<sup>9</sup> Research Use Only.

<sup>10</sup> Merck KGaA, Darmstadt, Germany.

<sup>11</sup> FFPE = formalin fixed paraffin embedded.

<sup>12</sup> Disruptions in DNA repair pathways predispose cells to accumulating DNA damage. A growing body of evidence indicates that tumors accumulate progressively more mutations in DNA repair proteins as cancers progress. DNA repair mechanisms greatly affect the response to cytotoxic treatments, so understanding those mechanisms and finding ways to turn dysregulated repair processes against themselves to induce tumor death is the goal of all DNA repair inhibition efforts. Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4125008/>, last updated on 14 February 2017.

facilitated by capturing the potential of oncology test development with collaboration partners, including CDx partnerships; and

- From a commercialization perspective, entails entering into additional commercial and regulatory collaborations with pharmaceutical and biotech companies to further accelerate worldwide market adoption of Idylla™.
- Idylla™ is designed to be extremely versatile and therefore the Company remains committed to valorize the potential of the platform in other areas. This especially holds true for infectious diseases given the unique position Idylla™ has within the field of syndromic panels and bloodstream infections (including sepsis). Both areas will remain the focus of Biocartis within this market. However, going forward the Company's infectious disease strategy could include more partnership elements.

Additional background on the summarized menu update will be provided during today's webcast presentation at 14:00 CET.

### Change in CEO position

*After having fulfilled the CEO position for 10 years, Founder Rudi Pauwels has expressed his preference to the Board to focus on the longer term strategy of the Company, including a pathway towards a Next-Generation Sequencing based product offering. The board has decided that Rudi will take on the role of Chairman of a new Strategy Committee of the Board and that Hilde Windels will assume the role of CEO until a successor for Rudi Pauwels is on board. Since the appointment of Hilde Windels as Deputy CEO in 2015, Rudi Pauwels was already more focused on the strategy and vision of Biocartis, whereas the day to day execution was delegated to Hilde Windels. The Company is confident that a successor can be announced in the next few months.*

**Rudi Pauwels, Founder of Biocartis, commented:** *"Ten years ago, we embarked on a journey to develop high precision molecular diagnostic solutions that by design would be more accessible to laboratories and healthcare settings around the globe. I had the pleasure to work intensely together with a great team on the development of the Idylla™ platform that has its roots at Philips. The CE-marking late 2014 was the beginning of the commercial phase and, fueled by a growing number of tests, the Idylla™ solution is now increasingly finding its way to customers in Europe and around the world. I am particularly pleased to see that the hard work during the development has translated into great performance of our first tests. Building further on these foundations, Biocartis must now increasingly focus on worldwide commercial expansion and on the pathway towards building significant top line revenue. I therefore feel it is time for me to hand over the torch as CEO and I am happy that Hilde Windels, with whom I have been working side-by-side over the last 6 years, is taking over from me as interim CEO. This will allow me to increase my focus on innovation and strategy even more, in another capacity. I look forward to continue to be involved with Biocartis and to assist the Company in its roll-out of innovative products and breakthrough solutions that I believe can make a significant contribution to the growing role of molecular diagnostics in healthcare."*

**Rudi Mariën, Chairman of Biocartis, added:** *"We are thankful for Rudi's dedication to Biocartis over the past years. Without him, Biocartis would not have been what it is today. Under his leadership, the Company launched its flagship program Idylla™, successfully raised EUR 115m in its IPO and established promising partnerships with healthcare leaders including amongst others Johnson and Johnson, Abbott, Amgen, Merck and Thermo Fisher Scientific. We are pleased to see that Rudi will remain active on the Board, which will enable Biocartis to continue to benefit from his visionary views and insights on how to continue to deliver on our promises while remaining at the forefront of innovation."*

### Key figures for 2016

The tables below show an overview of the key figures and a breakdown of operating income for 2016. A consolidated income statement, balance sheet, cash flow statement and statement of changes in equity of Biocartis Group NV is presented in the paragraph 'Financial information' at the end of this press release.

Key figures (EUR 1,000)	2016	2015	% Change
<b>Total operating income</b>	<b>13,772</b>	<b>14,951</b>	<b>-8%</b>
Cost of sales	-5,701	-2,642	116%
Research & Development expenses	-42,091	-36,554	15%
Marketing & Distribution expenses	-10,324	-8,747	18%
General & Administrative expenses	-5,827	-6,662	-13%
<b>Operating expenses</b>	<b>-63,943</b>	<b>-54,606</b>	<b>17%</b>
<b>Operational result</b>	<b>-50,171</b>	<b>-39,655</b>	<b>27%</b>

Net financial result	-586	-790	-26%
Income tax	980	648	51%
<b>Net result</b>	<b>-49,777</b>	<b>-39,797</b>	<b>25%</b>
Cash flow from operating activities	-53,312	-27,335	95%
Cash flow from investing activities	-9,342	-5,436	72%
Cash flow from financing activities	41,804	125,943	-67%
<b>Net cash flow</b>	<b>-20,850</b>	<b>93,172</b>	<b>-122%</b>
<b>Cash and cash equivalents<sup>1</sup></b>	<b>83,247</b>	<b>104,087</b>	<b>-20%</b>
Financial debt	31,407	10,815	190%

<sup>1</sup> Including EUR 1.2m of restricted cash (as a guarantee for KBC lease financing)

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

#### *Income statement*

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

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

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

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

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

Marketing and Distribution expenses increased from EUR 8.7m in 2015 to EUR 10.3m in 2016 (18.0% increase)

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

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

The operational result in 2016 amounted to a loss of EUR 50.2m compared to a loss of EUR 39.7m in 2015. As a result of the foregoing, the loss for the year after taxes increased from EUR 39.8m in 2015 to EUR 49.7m in 2016.

#### *Balance sheet*

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

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

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

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

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

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

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

#### *Cash flow statement*

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

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

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

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

#### **Financial calendar 2017**

- Capital Markets Day - 2 March 2017
- Publication annual report 2016 - 30 March 2017
- Q1 2017 business update - 27 April 2017
- Annual General Meeting Biocartis Group - 12 May 2017
- H1 2017 results – 7 September 2017
- Q3 2017 business update – 16 November 2017

#### **Webcast and presentation**

Biocartis will host a conference call with live webcast, during which the 2016 results will be presented, followed by a Q&A session. This event will be held today, 2 March 2017 at 14:00 CET / 13:00 BST (UK) / 08:00 EDT (US). Access the webcast by clicking [here](#). If you would like to participate in the Q&A, please dial +44(0)20 3427 1901 (standard international) with confirmation code 9539312. A replay of the webcast will be available on the [Biocartis investors' website](#) shortly after.

#### **Financial information**

The consolidated financial statements have been prepared in accordance with IFRS, as adopted by the EU. The financial information included in this press release is an extract from the full IFRS consolidated financial statements, which will be published on 30 March 2017. The statutory auditor, Deloitte Bedrijfsrevisoren /Reviseurs d'Entreprises, represented by Gert Vanhees, has substantially completed the audit procedures on the IFRS consolidated statements as of and for the year ended 31 December 2016, and has confirmed that the consolidated balance sheet, the consolidated statements of comprehensive income, cash flow and changes in shareholders' equity, included in this press release, are consistent in all material aspects with the consolidated accounts from which they have been derived.

## Consolidated Income Statement

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

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

## Consolidated Balance Sheet

In EUR000	As of 31 December,	
	2016	2015
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	9,921	8,987
Property plant and equipment	23,088	14,245
Participating interests	5,052	5,052
Other long term receivables	11	11
Deferred tax assets	3,090	1,986
	41,162	30,281
<b>Current assets</b>		
Inventory	9,829	5,837
Trade receivables	2,935	5,852
Other receivables	2,201	1,063
Other current assets	1,932	1,258
Cash and cash equivalents	83,246	104,087
	100,143	118,097
<b>Total assets</b>	<b>141,305</b>	<b>148,378</b>
<b>Equity and liabilities</b>		
<b>Capital and reserves</b>		
Legal share capital	446	405
Historical share capital adjustment	-221,232	-221,232
Share premium	554,065	522,708
Share based payment reserve	1,716	1,345
Accumulated deficit	-238,088	-188,310
Other comprehensive income	-19	0
<b>Total equity attributable to owners of the Company</b>	96,889	114,916
<b>Non-current liabilities</b>		
Provisions	47	0
Financial debt	27,709	2,662
Deferred income	142	1,342
Accrued charges	1,610	1,580
	29,508	5,585
<b>Current liabilities</b>		
Financial debt	3,698	8,152
Trade payables	6,293	13,927
Deferred income	1,963	3,812
Other current liabilities	2,954	1,986
	14,908	27,877
<b>Total equity and liabilities</b>	<b>141,305</b>	<b>148,378</b>

## Consolidated Cash Flow Statement

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

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

\*\* The presentation of the consolidated cash flow statement of the year ended 31 December 2015 has changed compared to what has been published in the annual report of 2015, predominantly related to activities for cartridge manufacturing expansion. The implemented changes were all qualified as reclassifications. Details will be included in the 2016 annual report.

## Consolidated Statement of Changes in Shareholder Equity

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

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**More information:**

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**About Biocartis**

Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis launched the Idylla™ platform in 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis has eight oncology tests and two infectious disease tests in its product menu. More information: [www.biocartis.com](http://www.biocartis.com). Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis\_.

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