



PRESS RELEASE

REGULATED INFORMATION
Thursday, 1 March 2018, 07:02 CET

BIOCARTIS ANNOUNCES 2017 RESULTS AND 2018 OUTLOOK

Mechelen, Belgium, 1 March 2018 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its operational highlights and financial results for 2017, prepared in accordance with IFRS as adopted by the European Union as well as selected post period events and its outlook for 2018.

Key messages 2017 results

- **Commercial product revenues:** increased year-over-year with 124% to EUR 12.7m.
- **Total operating income:** equaled EUR 23.1m in 2017 compared to EUR 13.8m in 2016, representing a year-over-year increase of 68%.
- **Commercial cartridge consumption:** increased year-over-year with about 2.8 times to over 71k Idylla™ cartridges.
- **Installed base:** 258 Idylla™ instruments were added to the installed based, bring the total to close to 650 as per year-end.
- **Test menu:** four new CE-markings in 2017; Idylla™ NRAS Mutation Test, Idylla™ EGFR Mutation Test, Idylla™ ctKRAS Mutation Test and Idylla™ ctNRAS-BRAF Mutation Test.
- **Cash position:** cash and cash equivalents amounted to EUR 112.8m as per 31 December 2017. In addition, the Company has a multiple purpose credit facility of EUR 27.5m at its disposal on which no drawdowns were made as per year-end, bringing total available funds to approx. EUR 140m.

2018 outlook

- **Cartridge consumption:** target of doubling commercial cartridge volume in 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.
- **Cash position:** in the range of EUR 50m – EUR 60m by 2018 year end, excluding drawdowns on the Company's multiple purpose credit facility.

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 2017 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)330 336 9105 (standard international), followed by the confirmation code 8419378.

*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 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 RoW¹ 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,

¹ RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan.

Biocartis and its distribution partner Fisher Healthcare² 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 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 authorizations.
- *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 collaborations³ 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.

Idylla™ test menu highlights

- *Breast cancer menu* – In 2017, Biocartis initiated its test menu for breast cancer, the most common cancer among women worldwide⁴, with the development initiation of three tests, all in collaboration with renowned partners:
 - Partnership LifeArc⁵: 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*STAR⁶: 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.

² Fisher HealthCare is part of Thermo Fisher Scientific Inc.

³ 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.

⁴ One in eight women is diagnosed with breast cancer in her lifetime. Source: World Health Organization, www.breastcancer.org, last consulted on November 2017.

⁵ 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.

⁶ Partnership is signed with ETPL, the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research.

- *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 instability⁷) 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 KGaA⁸ (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 centers⁹.
 - 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 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 immunotherapies¹⁰.
- *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 easier¹¹, 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) clearance¹² 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.

Organizational and operational 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 Cartagena 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.

⁷ 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.

⁸ Merck KGaA, Darmstadt, Germany.

⁹ The collaboration does not include the US, China and Japan.

¹⁰ 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).

¹¹ 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.

¹² 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).

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 27.5m¹³ (not covered by a government guarantee). As per 31 December 2017, no drawdowns were made on this credit facility.
- *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 'key figures for 2017' below for more details on the 2017 financials.

Commenting on the 2017 results, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"2017 was a year of transition for Biocartis, building further momentum in its commercialization efforts with the aim to support the global adoption of the Idylla™ platform. Most important in that respect was the announcement in March 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 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!"*

Post-period events

- *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 (SIRS¹⁴) 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 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.

¹³ Of which EUR 3m for guarantees.

¹⁴ Systematic inflammatory response syndrome.

- *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.

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) FFPE¹⁵ sample preparation and target enrichment capabilities on Idylla™ (the ‘Idylla™ NGS Prep Panels’) to complement its menu of Idylla™ qPCR¹⁶ 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](#).

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 (RUO¹⁷), 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.

Key figures for 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 is presented in the paragraph ‘Financial information’ at the end of this press release.

¹⁵ Formalin fixed, paraffin embedded.

¹⁶ Quantitative Polymerase Chain Reaction or real-time PCR.

¹⁷ RUO = Research Use Only.

| 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 equivalents¹ | 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

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 VLAIO¹⁸ 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%.

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.

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

Balance sheet

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.

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.

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

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.

¹⁸ The Flanders organization for Innovation & Entrepreneurship.

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.

Cash flow statement

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.

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.

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.

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

Financial calendar 2018

- 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

Webcast and presentation

Biocartis will host a conference call with live webcast, during which the 2017 results will be presented, followed by a Q&A session. This event will be held today, 1 March 2018 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)330 336 9105 (standard international) with confirmation code 8419378. 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 5 April 2018. The statutory auditor, Deloitte Bedrijfsrevisoren /Reviseurs d'Entreprises, represented by Gert Vanhees, has confirmed that its audit procedures, which have been substantially completed, have not revealed any material adjustment that should be made in the accounting information included in this press release.

Consolidated Balance Sheet

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

Consolidated Cash Flow Statement

In EUR 000

| | <u>Years ended 31 December,</u> | |
|--|---------------------------------|----------------|
| | <u>2017</u> | <u>2016</u> |
| Operating activities | | |
| Loss for the period | -41,960 | -49,777 |
| Adjustments for | | |
| Depreciation and amortization | 5,096 | 4,848 |
| Impairments | 0 | 207 |
| Tax income in profit and loss | -3,365 | -980 |
| Financial result, net | 1,736 | 813 |
| Net movement in retirement benefit obligation | -31 | 47 |
| Share based payment expense | 665 | 371 |
| Other comprehensive income | -38 | -28 |
| Changes in working capital | | |
| Net movement in inventories | 769 | -3,991 |
| Net movement in trade and other receivables and other current assets | -4,197 | 1,105 |
| Net movement in trade payables & other current liabilities | -95 | -2,659 |
| Net movement in deferred income | 682 | -3,049 |
| Interest & other financial expenses paid | -562 | -105 |
| | -41,300 | -53,198 |
| Taxes paid | -105 | -114 |
| Cash flow used in operating activities | -41,405 | -53,312 |
| Investing activities | | |
| Interest received | -2 | 79 |
| Purchases of property, plant & equipment | -3,157 | -9,123 |
| Purchases of intangible assets | -1,161 | -1,927 |
| Proceeds from sale and lease back of property, plant and equipment | 0 | 1,629 |
| Cash flow from / (used in) investing activities | -4,320 | -9,342 |
| Financing activities | | |
| Proceeds from borrowings | 0 | 15,000 |
| Proceeds from the lease financing of property, plant and equipment | 0 | 3,978 |
| Net proceeds from the issue of common shares, net of transaction costs | 76,669 | 31,398 |
| Repayment of borrowings | -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 |

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

Consolidated Statement of Changes in Shareholder Equity

Attributable to owners of the Company

| In EUR 000 | Legal share capital | Historical share capital adjustment | Share premium | Share based payment reserve | Gains & 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 | | | | | | -49,777 | -49,777 | -49,777 |
| Other comprehensive income | | | | | -19 | | -19 | -19 |
| <i>Total comprehensive income</i> | | | | | -19 | -49,777 | -49,796 | -49,796 |
| Share issue - exercise of stock options on 7 April 2016 | | | | | | | | |
| Share issue - private placement 21 November 2016 | | | 366 | | | | 366 | 366 |
| Cost related to private placement | | | 32,634 | | | | 32,634 | 32,634 |
| Share-based payment expense | 41 | | -1,642 | | | | -1,601 | -1,601 |
| | | | | 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 | | | | | | 0 | -25 | -25 |
| <i>Total comprehensive income</i> | | | | | -26 | -41,960 | -41,985 | -41,985 |
| Share-based payment expense | | | | 665 | | | 665 | 665 |
| Share issue - exercise of stock options on 5 October 2017 | 0 | | 176 | | | | 176 | 176 |
| Share issue - private placement 28 November 2017 | 64 | | 79,936 | | | | 80,000 | 80,000 |
| Costs related to private placement | | | -3,771 | | | | -3,771 | -3,771 |
| Share issue - exercise of stock options on 21 December 2017 | 0 | | 264 | | | | 264 | 264 |
| Consolidation translation difference | | | | | | 2 | 2 | 2 |
| Balance as at 31 December 2017 | 511 | -221,232 | 630,670 | 2,381 | -45 | -280,046 | 132,240 | 132,240 |

--- END ---

More information:

Renate Degrave
Manager Corporate Communications & Investor Relations
e-mail rdegrave@biocartis.com
tel +32 15 631 729
mobile +32 471 53 60 64
[@Biocartis](https://twitter.com/Biocartis)
www.linkedin.com/Biocartis

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 September 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 offers fourteen oncology assays and two infectious disease assays in Europe. More information: www.biocartis.com. Press Photo Library available [here](#). Follow us on [Twitter](https://twitter.com/Biocartis_): @Biocartis_.

Forward-looking statements

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

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.