PRESS RELEASE

REGULATED INFORMATION
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# BIOCARTIS ANNOUNCES 2018 RESULTS AND 2019 OUTLOOK

**Mechelen, Belgium**, **28 February 2019 –** Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its operational highlights and financial results for 2018, prepared in accordance with IFRS as adopted by the European Union as well as selected post period events and its outlook for 2019.

**Key messages 2018 results**

- **Total operating income:** Product revenues increased year-over-year with 46% to EUR 18.8m. Total operating income amounted to EUR 28.7m (year-over-year increase of 24%).
- **Installed base:** 326 Idylla™ instruments added to the installed base, bringing the total to over 970 as per year-end. Post-period, the total installed base crossed the 1,000 instrument milestone.
- **Commercial cartridge consumption:** Amounted to 133k Idylla™ cartridges, representing a year-over-year increase of approx. 87%.
- **Commercialization**: First year of successful commercialization in the US and completion of a global commercial footprint with establishment of a joint venture for the Chinese market and, post-period, announcement of selection of commercialization partner for the Japanese market.
- **Partners**: Expansion of partnership with Genomic Health into the urology space and announcement of agreement with pharmaceutical partner AstraZeneca in the lung cancer domain.
- **MSI testing:** Promising initial market adoption of the Idylla™ MSI Assay, launched as RUO[1] on 17 July 2018.
- **Cash position:** Cash and cash equivalents amounted to EUR 64m as per 31 December 2018. Post-period, on 23 January 2019, Biocartis announced the completion of a EUR 55.5m equity raise.

**2019 guidance**

- **Installed base:** Targeting an installed base growth of around 350 new instrument placements, bringing the total installed based end of 2019 to over 1,300.
- **Cartridge volume:** Targeting a commercial volume of 210k-225k Idylla™ cartridges, representing a year-over-year increase of around 60% to 70%.
- **Cash position:** Targeted cash position in the range of EUR 55m – EUR 65m by 2019 year end.

*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 2018 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)844 571 88 92 (standard international), followed by the confirmation code 1775755. 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.*

**Commenting on the 2018 results and 2019 guidance, Herman Verrelst, Chief Executive Officer of Biocartis, said:** *"Driven by our first full year of commercialization in the US as well as a strong continued performance in our European and RoW[2] markets, we managed to significantly expand our customer base and to further ramp-up our commercial cartridge volume in 2018. Through the establishment of our joint venture in China as well as the recent signing of a commercialization agreement for the Japanese market, we now have a commercial network in all major MDx markets worldwide. During 2019, we anticipate to further strengthen our assay menu for colorectal and lung cancer and to gear-up for important assay launches in 2020. Furthermore, we will transition the bulk of our commercial volume to our second cartridge manufacturing line in Mechelen. These investments in menu and manufacturing will allow us to significantly boost our gross margins from 2020 onwards."*

[1] Research Use Only, not for use in diagnostic procedures.
[2] RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan.

**Commercial highlights**

- *Installed base* – The installed base of Idylla™ instruments increased to 973 as per year-end as a result of 326 new installations in 2018. The majority of new placements in 2018 were realized in the European and US market. Post-period, driven by continued installed base growth, predominantly in the US market, the total installed base of Idylla™ instruments amounts to over 1,000.
- *Cartridge volume* – In 2018, Biocartis realized a commercial volume of approx. 133k Idylla™ cartridges, a year-over-year increase of approx. 87%. The European and RoW markets contributed most to the absolute volume growth.
- *European commercialization* – Over 2018, European direct markets showed an increase in installed base that was above expectation as well as a strong ramp-up of commercial cartridge volumes. This performance was the consequence of an increased usage of Idylla™ in first line testing by customers in key European markets, a strong overall contribution from pharmaceutical collaborations and the launch of the Idylla™ MSI Assay (RUO).
- *US commercialization* – 2018 was the first full year of commercialization in the US during which the US direct sales team, in combination with the Fisher Healthcare sales team, realized a promising initial US installed base and was able to attract high profile customers such as Memorial Sloan Kettering Cancer Center and Dartmouth-Hitchcock Medical Center. Furthermore, and as part of the aim to accelerate market adoption several US based studies[3] of Idylla™ assays were published of which eight were presented at the Association for Molecular Pathology Conference in the US in November 2018.
- *RoW distribution markets* – RoW realized a strong ramp-up in cartridge volumes in 2018, mainly driven by the 57 new market authorizations for Idylla™ products that Biocartis added in 2018 across 18 geographies. The increase in RoW performance was also the result of the strategy focused on those geographies that are of interest to pharmaceutical partners.
- *China commercialization* - On 3 September 2018, Biocartis and Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, announced entering into a joint venture aimed at the commercialization of the Idylla™ platform in mainland China, within the field of oncology. The joint venture is 50% owned by Biocartis and 50% owned by Wondfo. The initial activities of the joint venture are focused on the local manufacturing, commercialization and registration with the Chinese Regulatory Authorities (CFDA) of the existing Idylla™ molecular oncology assays for amongst others colorectal and lung cancer. This is a first important step in unlocking Idylla™'s commercial potential in the Chinese molecular diagnostics market, being one of the fastest growing in the world and expected to reach a total value of USD 1.5bn by the end of 2022[4].
- *Japan commercialization* – In 2018, Biocartis selected its commercialization partner for Japan, resulting into signing of a distribution agreement with Nichirei Bioscience as announced post the reporting period (see below), on 7 January 2019.

**Menu and partnership highlights**

- *Colorectal cancer menu*
  - Launch Idylla™ MSI Assay (RUO) – On 17 July 2018, Biocartis launched its innovative Idylla™ MSI Assay (RUO) that provides information on the MSI status (i.e. MSI-High or Microsatellite stable) of a tumor within approximately 150 minutes from just one slice of FFPE[5] tumor tissue, without requiring a reference sample and based on a novel set of seven exclusively licensed MSI biomarkers. Several multi-center studies comparing the Idylla™ MSI Assay to the standard methods showed a >95% concordance between results as well as a significantly lower failure rate[6]. Once validated for diagnostic use the test is expected to significantly strengthen Biocartis' colorectal cancer test menu. Since MSI is an independent factor that may predict a patient's response to certain immunotherapies, it provides Biocartis with further opportunities to enter into the field of immuno-oncology.
  - EGFR ectodomain mutations - On 28 August 2018, Biocartis announced that it has obtained exclusive worldwide license rights for highly innovative EGFR ectodomain mutations that have been shown to determine response to targeted therapy for patients with metastatic colorectal cancer (mCRC).
- *Lung cancer menu*
  - Collaboration AstraZeneca - On 29 November 2018, Biocartis announced to have entered into an agreement with AstraZeneca, a global science-led biopharmaceutical company (LON: AZN), aimed at obtaining faster lung cancer molecular diagnostic biomarker results in Europe. Pursuant to the agreement, a prospective lung cancer study with the Idylla™ EGFR Mutation Test (CE-IVD) will be conducted in selected European countries.

3 All study abstracts can be found in the AMP Abstract Book available on https://amp18.amp.org/abstracts-posters/.
4 Source: DataMintelligence, "Global Molecular Diagnostics Market 2018-2025".
5 Formalin-fixed, paraffin embedded.
6 Maertens G. et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42; De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268; De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639)>.

- Idylla™ ctEGFR Assay - During 2018, Biocartis further progressed the development of the liquid biopsy version of the Idylla™ EGFR Mutation Assay (RUO).This test is an important addition to Biocartis' lung cancer menu as liquid biopsy EGFR testing is included in guidelines for situations where no tumor tissue is available for testing.
- Idylla™ GeneFusion Panel – During 2018, Biocartis in concertation with its network of Key Opinion Leaders (KOLs) finalized the panel composition of the Idylla™ GeneFusion Panel. This panel is intended for the qualitative detection of different gene fusions (e.g. ALK and ROS1) in human non-small cell lung cancer FFPE[7] tissue samples. Together with the Idylla™ EGFR Mutation Test (CE-IVD), these tests will cover the majority of actionable lung cancer mutations, making the GeneFusion Panel as such a key addition to Biocartis' lung cancer menu.

- *Breast cancer menu* - On 3 June 2018, Biocartis' partner Genomic Health, Inc. (NASDAQ: GHDX) announced the results of the long-awaited TAILORx study, the largest ever breast cancer treatment trial, which provided definitive evidence that the Oncotype DX Breast Recurrence Score® test identified the vast majority of early stage breast cancer patients who receive no benefit from chemotherapy, and can be effectively treated with endocrine therapy alone. Additionally, the trial established that chemotherapy may provide life-saving benefit to an important minority of patients. These results are expected to be an important driver in the market adoption and reimbursement of the future Oncotype DXi IVD Breast Recurrence Score™ test in Europe. During 2018, Genomic Health and Biocartis reached an important milestone in the development of that test by demonstrating feasibility on the Idylla™ platform.Early access sites were selected with the aim to initiate validation studies in the second half of 2019 and to launch the Oncotype DXi IVD Breast Recurrence Score™ test in 2020, beginning in France and Germany.
- *Prostate cancer menu* – On 3 December 2018, Biocartis and Genomic Health announced to have expanded their exclusive collaboration into the field of urology aimed at the development of an in vitro diagnostic (IVD) version of the Oncotype DX Genomic Prostate Score® (GPS™) Test[8] on the Idylla™ platform and potentially additional cancer tests that can be performed locally by laboratory partners and in hospitals around the world. Post the reporting period, on 5 February 2019, Genomic Health announced the publication of results from a multi-center, prospective validation study of the Oncotype DX® Genomic Prostate Score® (GPS™) test in newly diagnosed men with clinically low-risk prostate cancer who elected immediate radical prostatectomy after receiving the test. Published in Urology[9], the study results prospectively validated the GPS test as an independent predictor of adverse pathology at the time of surgery as a measure of disease aggressiveness for men with clinically low- or intermediate-risk prostate cancer.
- *Performance studies* – During 2018, Biocartis announced the publication of several studies demonstrating the high performance of Idylla™ and its oncology molecular diagnostic tests, among which:
  - Eight Idylla™ performance study abstracts[10] were selected for presentation at the Association for the Molecular Pathology Conference (AMP), the leading meeting of professionals in the field of molecular diagnostics in the US, which took place between 1-3 November 2018 in San Antonio, Texas (US). The studies were performed by renowned US oncology key opinion leaders from the Memorial Sloan Kettering Cancer Center (New York), Dartmouth–Hitchcock Medical Center (New Hampshire), AstraZeneca and the University of Alabama.
  - Two performance studies on Idylla™ MSI Biomarkers[11] selected for publication at the American Society of Clinical Oncology (ASCO) Annual Meeting conference, taking place between 1-5 June 2018, Chicago (IL), US[12].

[7] Formalin fixed, paraffin embedded.
[8] The Oncotype DX GPS test is the only commercially available tissue biopsy-based, multi-gene test that has been clinically validated to assess the aggressiveness of prostate cancer in men with clinically low-risk or favorable intermediate-risk cancer at the time of diagnosis, helping to make better informed and more personalized treatment decisions. The vast majority of men currently diagnosed with low-risk prostate cancer undergo surgery or radiation treatment, although there is only a three percent chance that their disease will become life-threatening. In response to this issue, Genomic Health's tissue biopsy-based, multi-gene test has been clinically validated to predict aggressive cancer at the time of diagnosis, helping to identify those men who need immediate surgery or radiation therapy versus those who can confidently choose active surveillance. The result is a more precise and accurate assessment of risk, which helps more men avoid the lifelong complications associated with treatments they do not need, while directing aggressive therapy to those men who require immediate treatment. Source: website Genomic Health, last consulted on 28 November 2018.
[9] Source: https://c212.net/c/link/?t=0&l=en&o=2365856-1&h=4238720714&u=https%3A%2F%2Fwww.goldjournal.net%2Farticle%2FS0090-4295(19)30001-9%2Ffulltext&a=Urology, last consulted on 5 February 2019.
[10] All study abstracts can be found in the AMP Abstract Book available on https://amp18.amp.org/abstracts-posters/.
[11] The MSI Biomarkers were identified by Prof. Diether Lambrechts' laboratory and exclusively licensed to Biocartis from the Flemish Institute for Biotechnology (VIB) in 2013.
[12] On 17 May 2018, Biocartis announced that two studies conducted in cooperation with VIB regarding the performance of its exclusively licensed novel set of biomarkers for microsatellite instability (MSI) that are included in the Idylla™ MSI Assay (the 'MSI Biomarkers'), have been selected for publication at the ASCO. B. De Craene et al., "Detection of microsatellite instability (MSI) in colorectal cancer samples with a novel set of highly sensitive markers by means of the Idylla™ MSI Assay prototype", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, US; H. Zhao et al., "A novel set of 7 homopolymer indels for detection of MSI is associated with tumor mutation burden and total indel load in endometrial and colorectal cancers", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, US. The methodology used for detection of the seven biomarkers, TMB (tumor mutation burden,) and indel load, was whole-exome sequencing.

- Studies[13] on the Idylla™ MSI Assay (RUO) and the Idylla™ RAS liquid biopsy tests[14] were presented at the European Society for Medical Oncology (ESMO) congress, 19-23 October 2018 in Munich, Germany.
- A study[15] published on 14 June 2018 in the Journal of Clinical Pathology reviewing 2,500 performed Idylla™ tests across 18 performance studies showed the generation of valid results in 98.1% of the cases and outperformance over currently used reference methods. The 1.9% invalid results generated with Idylla™ is approx. 40% lower than the results of the included reference methods, which showed invalid results in 3.1% of the cases.
- Other studies included a study abstract[16] on the performance of the Idylla™ ctRAS liquid biopsy tests which was selected for oral presentation at the 2018 American Association for Cancer Research (AACR) Annual Meeting taking place between 14-18 April 2018 in Chicago (US); a study demonstrating the ability of the Idylla™ EGFR Mutation Test (CE-IVD) to produce a result in 80% of failed Next Generation Sequencing Lung Cancer Tests was published in the Journal of Clinical Pathology on 24 May 2018[17]; and a study abstract on the performance of the Idylla™ RAS tests[18] was selected for oral presentation at the 70th AACC Annual Scientific Meeting in Chicago, IL (US) on 31 July 2018.

**Organizational and operational highlights**

- *New board composition* – Following the annual general shareholders' meeting (AGM) held on 11 May 2018, five new independent board members[19] were appointed and three board members whose mandate expired at the closing of the AGM, were re-appointed[20]. The new board composition allows for a transition towards a board of directors consisting predominantly of independent directors and consists of: CRBA Management BVBA (represented by Christian Reinaudo), chairman of the board, Ann-Christine Sundell, Scientia II LLC (represented by Harry Glorikian), CLSCO BVBA (represented by Leo Steenbergen), Luc Gijsens BVBA (represented by Luc Gijsens), Peter Piot, Hilde Windels BVBA (represented by Hilde Windels), Roald Borré and Herman Verrelst (CEO of Biocartis).
- *US R&D center* - On 1 March 2018, Biocartis announced to have established an R&D center in the US as the result of a transfer of R&D staff members and Idylla™ related assay development assets and tests of Janssen Diagnostics (a division of Janssen Pharmaceuticals, Inc.). With the establishment of this US R&D center, Biocartis supports the execution of its strategy to accelerate test menu expansion on the Idylla™ platform through predominantly companion diagnostics collaborations and assay content partnerships.
- *Cartridge manufacturing* – During 2018, Biocartis completed the construction and validation of its second cartridge manufacturing line that should provide for an additional annual cartridge capacity of over 1 million Idylla™ cartridges. Currently, Biocartis is in the process of transferring the commercial production of its high volume tests to this new cartridge manufacturing line.
- *Contract terminations* – During H2 2018, a review of infectious disease oriented collaborations and license agreements was conducted, which resulted in the termination of certain collaborations that were no longer of strategic importance to Biocartis. As part of this review, the agreement with Koninklijke Philips N.V., under which Biocartis had gained access to certain patent rights and know-how, in relation to an ancillary platform for selective enrichment of pathogen DNA for use with bloodstream infection tests, has been terminated. The underlying patent rights are being returned to Philips and the related book value has been fully impaired, resulting in EUR 3.2m non-cash impairment.

[13] It concerns two studies, one treatment outcome study on the Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests (CE-IVD) and one on the performance of the prototype Idylla™ MSI test. Montagut et al., "Clinical impact of circulating tumor RAS and BRAF mutation dynamics in metastatic colorectal cancer patients treated with first-line chemotherapy plus anti-EGFR therapy: Combined analysis of two prospective clinical trials", presented at ESMO, 19-23 October 2018, Münich, Germany, and published in the ESMO 2018 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology; Decraene et al., "Detection of microsatellite instability (MSI) with a novel set of 7 Idylla™ biomarkers on colorectal cancer samples in a multi-center study", presented at ESMO, 19-23 October 2018, Münich, Germany, and published in the ESMO 2018 Congress Abstract Book, a supplement to the official ESMO journal Annals of Oncology.

[14] The Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests (CE-IVD).

[15] The performance review study was performed by Dr. Arnaud Uguen (MD, PhD, Department of Pathology of the Brest University Hospital, Brest, France) and Dr. Giancarlo Troncone (MD, PhD, Professor of Anatomic Pathology, University of Naples Federico II, Naples, Italy) and was published in the Journal of Clinical Pathology on 14 June 2018.

[16] B Jacobs, B Claes, P Laurent-Puig, JP Bachet, S Tejpar, G Maertens, E Sablon, "Analytical and clinical validation of the Idylla™ ctKRAS and ctNRAS-BRAF Liquid biopsy tests", first presented at the 2018 AACR Annual Meeting in Chicago, US, 14-18 April 2018.

[17] De Luca et al, University of Naples Federico II, "The Idylla™ Assay and Next Generation Sequencing: an integrated EGFR mutational testing algorithm", Journal of Clinical Pathology, to consult online on http://jcp.bmj.com/content/jclinpath/early/2018/05/24/jclinpath-2018-205197.full.pdf?ijkey=V8eBoaMDpKZ7t9N&keytype=ref, 24 May 2018.

[18] The Idylla™ KRAS and NRAS-BRAF-EGFR492 Mutation Assays (RUO, not for use in diagnostic procedures). M. Rabie Al-Turkmani et al., "Rapid Somatic Mutation Testing in Colorectal Cancer Using a Fully Automated System and Single-Use Cartridge: A Comparison with Next-Generation Sequencing", first presented at 70th AACC Annual Scientific Meeting in Chicago, IL (US).

[19] CRBA Management BVBA, represented by Christian Reinaudo (chairman of the board), Ann-Christine Sundell, Harry Glorikian, CLSCO BVBA, represented by Leo Steenbergen, and Luc Gijsens BVBA, represented by Luc Gijsens.

[20] Peter Piot (independent director), Hilde Windels BVBA, represented by Hilde Windels (non-executive director) and Roald Borré (non-executive director).

**Financial highlights**

- *Product sales revenues* – Total product sales increased year-over-year with 46% to EUR 18.8m in 2018 (EUR 12.9m in 2017), as the consequence of higher Idylla™ cartridge sales (year-over-year growth of 76%) due to increased cartridge volumes partially offset by lower Idylla™ platform sales (year-over-year decline of 9%) as more instruments are now being placed under reagent rental contracts.
- *Total operating income* – Total operating income amounted to EUR 28.7m in 2018, representing a year-over-year growth of 24% due to higher Idylla™ product sales, collaboration revenues and service revenues partially offset by lower grant income.
- *OPEX* – Total operating expenses (including cost of sales) amounted to EUR 75.5m, a year-over-year increase of 13% due to higher cost of sales, sales and marketing expenses and general and administrative expenses partially offset by lower research and development expenses.
- *Operational cash flow* – Total operational cash flow amounted to minus EUR 42.0m in 2018 versus minus EUR 41.4m in 2017.
- *Cash position* - Biocartis' cash position as per 31 December 2018 amounted to EUR 63.5m compared to EUR 112.8m as per 31 December 2017. Please see the paragraph post-period events on the equity raise completed in January 2019.
- *Additional details* – see 'key figures for 2018' below for more details on the 2018 financials.

**Post-period events**

- *Japan commercialization* – On 7 January 2019, Biocartis announced to have signed an agreement with Nichirei Bioscience, a leading supplier of biological and diagnostics products in Japan, for the product registrations and distribution of the Idylla™ platform in Japan. Upon successful registration, Nichirei Bioscience's sales force will commercialize the Idylla™ platform across its network of some 2,000 pathology laboratories.
- *Achievement 2018 key business objectives* – On 7 January 2019, Biocartis announced to have achieved its key business objectives for 2018.
- *Equity raise* – On 23 January 2019, Biocartis raised an amount of EUR 55.5m in gross proceeds by means of a private placement via an accelerated bookbuild offering of 5,000,000 new shares (being approximately 9.73% of the Company's outstanding shares). Consequently, Biocartis' cash position per end January 2019 amounted to over EUR 110m (unaudited figure). In addition, the Company has EUR 27.5m of multiple purpose credit lines at its disposal on which no drawdowns were made as per end of January 2019.
- *Strengthening management team* – Biocartis is pleased to announce that it's strengthening its management team in light of further international growth, expansion of its partner network and associated scaling of its organization with the appointment of Piet Houwen as Chief Operating Officer (effective as of April 2019). With more than 25 years in various operational and general management roles, Piet Houwen has a strong track record in manufacturing, process engineering, project and people management. Piet Houwen has gained broad operational experience in dynamic international environments, including in fast moving consumer goods, food manufacturing, bio-pharmaceuticals and consulting. Prior to joining Biocartis, Piet Houwen was Chief Operations Officer at Ablynx and prior to that, he held global roles for Sanofi/Genzyme and Janssen Pharmaceutica (part of Johnson & Johnson family of companies) where he was active in pharmaceutical manufacturing of large and small molecules, stent coating and medical devices. Piet Houwen holds a Master's Degree in Mechanical Engineering from the Delft University of Technology (The Netherlands).

**Summary long term Idylla™ test menu strategy[21]**

The oncology MDx market that Biocartis operates in, is growing rapidly and is continuously evolving according to the ever-increasing pace of scientific and technological progress. Biocartis therefore continuously monitors the trends affecting its core markets with the aim to strengthen Idylla™'s competitive position and to identify new segments where the platform has unique value. During today's Capital Markets Day, Biocartis will provide an update on its long-term Idylla™ test menu strategy as a response to several important market trends that are believed to have a potential favorable impact the Company's business. With respect to Biocartis' internally developed Idylla™ assay menu, the focus going forward is on three key strategic building blocks: targeted therapies (assays focused on cancer specific therapies as well as pan-cancer applications), immunotherapy (assays focused on immune checkpoint inhibitors and cell-based therapies) and liquid-biopsy based monitoring applications (assays focused on on-therapy and post-therapy monitoring). Furthermore, Biocartis is envisioning additional collaborations with partners who own validated, proprietary, high-value oncology gene signatures that can be ported onto the Idylla™ platform. This is expected to result in the addition of cancer franchises for Idylla™, and the expansion of the platform into new customer segments within the oncology MDx market.

[21] The Biocartis Idylla™ menu strategy is indicative and subject to change driven by amongst others commercial, partnering, financial and operational considerations.

More details on the long term Idylla™ test menu strategy can be found in Biocartis' corporate presentation available on www.biocartis.com under 'investors'.

**Outlook 2019**

- *Installed base* –Targeting an installed base growth in 2019 of 350 new instrument placements, bringing the total installed base to over 1,300 Idylla™ instruments by year-end.
- *Commercial cartridge consumption* - Targeting a commercial volume of 210k-225k Idylla™ cartridges in 2019, representing a year-over-year increase of around 60%-70%.
- *Menu expansion:*
  - Colorectal cancer menu - CE-IVD marking of the Idylla™ MSI Assay expected in Q1 2019 and US FDA 510(k) submission of the Idylla™ MSI Assay is expected in 2020. Submission of Idylla™ RAS PMA[22] documentation with the US FDA, subject to further feedback from US FDA interactions is expected in 2020;
  - Lung cancer menu – Launch of a liquid biopsy version of the Idylla™ EGFR Mutation Assay (RUO) expected mid-2019. Further development of the Idylla™ GeneFusion Panel towards expected launch in 2020;
  - Breast cancer menu – Start of the European validation studies of the Idylla™ Oncotype DXi IVD Breast Recurrence Score™ test in H2 2019 to target expected launch in 2020.
- *Cash position:* Targeted cash position in the range of EUR 55m – EUR 65m by 2019 year end, excluding drawdowns on the Company's multiple purpose credit facility.

**Key figures for 2018**

The tables below show an overview of the key figures and a breakdown of operating income for 2018. A consolidated income statement, balance sheet, cash flow statement and statement of changes in equity of Biocartis Group NV is presented in the paragraph 'Financial information' at the end of this press release.

| Key figures *(EUR 1,000)* | 2018 | 2017 | % Change |
|---|---|---|---|
| **Total operating income** | **28,651** | **23,110** | **24%** |
| Cost of sales | -15,349 | -8,673 | 77% |
| Research and development expenses | -36,842 | -39,594 | -7% |
| Sales andmarketing expenses | -15,349 | -11,600 | 32% |
| General and administrative expenses | -7,971 | -6,832 | 17% |
| **Operating expenses** | **-75,511** | **-66,699** | **13%** |
| **Operational result** | **-46,860** | **-43,589** | **8%** |
| Net financial result | -1,402 | -1,736 | -19% |
| Income tax | 109 | 3,365 | -97% |
| **Net result** | **-48,153** | **-41,960** | **15%** |
| Cash flow from operating activities | -41,993 | -41,405 | 2% |
| Cash flow from investing activities | -5,820 | -4,320 | 30% |
| Cash flow from financing activities | -1,508 | 75,256 | -102% |
| **Net cash flow** | **-49,320** | **29,531** | **-267%** |
| **Cash and cash equivalents**[1] | **63,539** | **112,765** | **-44%** |
| Financial debt | 35,335 | 35,388 | 0% |

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

[22] PMA = Pre-Market Approval.

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

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

***Income statement***

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

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

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

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

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

R&D expenses amounted to EUR 36.8m in 2018 versus EUR 39.6m in 2017 which represents a year-over-year decrease of approx. 7%. This was predominantly driven by lower platform and cartridge prototype costs, subcontracting expenses (i.e. outsourced R&D activities) and allocated depreciation and amortization expenses which was partially offset by an one-off (non-cash) impairment expense related to patent rights that are being returned to Philips (see the paragraph 'Organizational and operational highlights' above) as well as higher employee benefit expenses and consultancy costs. Sales and marketing expenses amounted to EUR 15.3m in 2018 compared to EUR 11.6m in 2017, a year-over year increase of 32%. This increase is predominantly a consequence of increased additional operational expenses incurred in relation to the expansion of the Company's sales and marketing team,

mainly in the US, and higher allocated depreciation and amortization expenses. G&A expenses amounted to EUR 8.0m in 2018 compared to EUR 6.8m in 2017 being a year-over-year increase of approx. 17% as a result of higher costs for staffing (including non-cash share based payment expenses), human resources and external advice.

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

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

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

***Balance sheet***

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

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

Inventory amounted to EUR 11.9m as per end 2018 compared to EUR 9.1m as per end 2017. This year-over-year increase was driven by higher inventory levels of finished products and raw materials. Trade receivables increased to EUR 9.7m as per year-end 2018 (EUR 9.9m end of 2017) as a consequence of higher overall commercial volumes as well as amongst others invoicing to strategic partners in Q4 in light of collaboration activities.

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

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

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

Trade payables end of 2018 amounted to EUR 8.0m, representing an increase of EUR 2.4m compared to the EUR 5.6m that was outstanding end of 2017. Deferred income increased in 2018 to EUR 3.0m (EUR 2.8m end of 2017) as a consequence of payments received from collaboration partners, partially offset by the revenue recognition of received grant payments.

***Cash flow statement***

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

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

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

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

**Financial calendar 2019**

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

**Webcast and presentation**

Biocartis will host a conference call with live webcast, during which the 2018 results will be presented, followed by a Q&A session. This event will be held today, 28 February 2019 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)844 571 88 92 (standard international), followed by the confirmation code 1775755. 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 4 April 2019. The statutory auditor, Deloitte Bedrijfsrevisoren /Réviseurs 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 Income Statement**

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

**Consolidated Balance Sheet**

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

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

**Consolidated cash flow statement**

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

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

## Consolidated Statement of Changes in Shareholder Equity

| | Attributable to owners of the Company | | | | | | |
|---|---|---|---|---|---|---|---|
| In EUR 000 | **Share capital** | **Share premium** | **Share based payment reserve** | **Gains and losses on defined benefit plans** | **Accumulated deficit** | **Total equity attributable to the owners of the Company** | **Total equity** |
| **Balance as at 1 January 2017** | **-220,786** | **554,065** | **1,716** | **-19** | **-238,088** | **96,889** | **96,889** |
| Loss for the period | | | | | -41,960 | -41,960 | -41,960 |
| Other comprehensive loss | | | | -26 | 0 | -25 | -25 |
| ***Total comprehensive loss*** | | | | ***-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** | **-220,722** | **630,670** | **2,381** | **-45** | **-280,046** | **132,240** | **132,240** |
| **Balance as at 1 January 2018** | **-220,722** | **630,670** | **2,381** | **-45** | **-280,046** | **132,240** | **132,240** |
| Loss for the period | | | | | -48,153 | -48,153 | -48,153 |
| Re-measurement gains and losses on defined benefit plan | | | | -23 | | -23 | -23 |
| Consolidation translation difference | | | | | 123 | 123 | 123 |
| ***Total comprehensive loss*** | | | | ***-23*** | ***-48,030*** | ***-48,053*** | ***-48,053*** |
| Share-based payment expense | | | 1,064 | | | 1,064 | 1,064 |
| Share issue - exercise of stock options on 5 April 2018 | 2 | 1,807 | | | | 1,809 | 1,809 |
| Share issue - exercise of stock options on 4 October 2018 | 1 | 239 | | | | 240 | 240 |
| Share issue - exercise of stock options on 20 December 2018 | 1 | 53 | | | | 53 | 53 |
| Other | | | | | -2 | -2 | -2 |
| **Balance as at 31 December 2018** | **-220,718** | **632,769** | **3,445** | **-67** | **-328,078** | **87,351** | **87,351** |

**--- END ---**

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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 is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology. This area represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @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.*