PRESS RELEASE

REGULATED INFORMATION

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BIOCARTIS ANNOUNCES 2019 RESULTS AND 2020 OUTLOOK

Mechelen, Belgium, **5 March 2020 –** Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its operational highlights and financial results for 2019, prepared in accordance with IFRS as adopted by the European Union as well as selected post period events and its outlook for 2020.

Key messages 2019 results

- **Total operating income:** Total operating income increased year-over-year with 32% to EUR 37.7m. Product sales revenues amounted to EUR 24.2m (year-over-year increase of 29%).
- **Cartridge volume:** Commercial cartridge volume amounted to 175k Idylla™ cartridges, representing a year-over-year increase of approx. 32%.
- **Installed base:** In total 337 Idylla™ instruments were added to the installed base, bringing the total to 1,310 as per year-end.
- **US go-to-market strategy:** Successful implementation of new go-to-market strategy for the US market, under which Biocartis' US direct sales team will drive commercialization going forward. The US team realized a strong performance in Q4 2019, further supporting the aforementioned strategic decision.
- **Idylla™ menu:** CE-marking of the Idylla™ MSI Test on 28 February 2019, further strengthening Biocartis' colorectal cancer (CRC) Idylla™ test menu. Launch of the Idylla™ ctEGFR Mutation Assay (RUO[1]) on 25 October 2019, the liquid biopsy version of the solid biopsy Idylla™ EGFR Mutation Test (CE-IVD) for lung cancer.
- **Immuno-oncology partnerships:** Menu expansion into immuno-oncology (IO) through new partnerships with Bristol-Myers Squibb Company (NYSE: BMY), aimed at the registration of the Idylla™ MSI test as a companion diagnostic[2] (CDx) for immuno-oncology therapies, and with Kite Pharma, Inc. (a Gilead Company), aimed at the development of Idylla™ assays that are supportive to Kite's therapies. Post period, on 5 March 2020, Biocartis announced to have signed a new IO project with Bristol-Myers Squibb Company aimed at the registration of the Idylla™ MSI test in the People's Republic of China.
- **Cash position:** Cash and cash equivalents amounted to EUR 179m as per 31 December 2019.

2020 guidance

- **Impact COVID-19 outbreak**: The guidance for 2020 assumes a moderate impact of the ongoing worldwide COVID-19 outbreak as well as a stabilization of the situation around the April 2020 timeframe.
- **Commercial cartridge volume:** Targeting a year-over-year commercial volume growth in the range of 30%, representing a volume of Idylla™ cartridges in the range of 228k.
- **Installed base:** Targeting an installed base growth in the range of 300-350 new instrument placements.
- **Cash position:** Targeted cash position in the range of EUR 110m by 2020 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 2019 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 8445718892 (standard international), followed by the confirmation code 6194332. 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 2019 results and 2020 guidance, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"The financials that we disclose today show a continued healthy growth in revenues and a cash position that allows us to further execute on our plans for the coming years. More importantly, we today also announce a strong outlook for 2020 in which we expect to see an encouraging growth of our cartridge volumes. Our 2020 outlook is driven by a strong Q4 2019, our sizeable installed base, our new US go-to-market strategy announced in September 2019, a good outlook for Europe and RoW[3] as well as the menu expansion realized in 2019 through the CE-marking of our Idylla™ MSI Test and launch of our Idylla™ ctEGFR Mutation Assay. I am also excited about the new and increasing research use of our Idylla™ assays in exploring pan-tumor settings – pointing*

[1] RUO = Research Use Only, not for use in diagnostic procedures
[2] A companion diagnostic test is a test that provides information that is essential for the safe and effective use of a corresponding therapeutic product
[3] RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan

to a broader applicability of the test menu on the Idylla™ platform. We expect more publications on this topic over the course of 2020. In addition, towards end 2020 we expect to see important new assay launches, by ourselves and our partners, and we expect our first oncology US FDA filing. All of this will fuel growth for 2021 and the years to come, also supported by the progress we are making in our commercial plans for China and Japan, both sizable untapped markets for Biocartis. 2019 was an eventful year, but we finished it in a position of strength. I confidently look forward to 2020 and beyond."

Commercial highlights

- *Commercial cartridge volume* – In 2019, Biocartis realized a commercial volume of approx. 175k Idylla™ cartridges, a year-over-year increase of approx. 32%. The European and RoW markets contributed most to the absolute volume growth. A promising pick-up in US cartridge volume was realized in Q4 2019.
- *Installed base* – The installed base of Idylla™ instruments increased to 1,310 as per year-end as a result of 337 new installations in 2019. Continued installed base growth was realized in European and US markets. RoW markets realized a strong ramp-up in new placements and initial instruments were placed in China.
- *European commercialization* – European direct markets realized a good and consistent performance both in terms of new instrument placements and cartridge volumes in 2019. This was mainly driven by a continued growing use of Idylla™ in first line testing, predominately by larger laboratory customers in Western Europe, and a solid expansion into the medium sized laboratory segment amongst others in Southern Europe.
- *US commercialization* – Biocartis implemented a new go-to-market strategy for the US market, following the joint termination of the distribution collaboration with Fisher Healthcare on 5 September 2019. Under the new go-to-market strategy Biocartis' US direct sales team will drive commercialization going forward with a focus on large tier 1 pathology labs where Idylla™ demonstrates its added value as a rapid and easy testing method complementary to other technologies such as Next Generation Sequencing (NGS). In H2 2019, the Biocartis US direct sales team was strengthened, all customers were successfully transitioned from Fisher Healthcare to Biocartis and actions to address amongst others US market specific operational lessons learned in H1 2019 were implemented. The successes realized in Q4 2019, also including the addition of new high profile US Idylla™ users, support the decision making around the new go-to-market strategy.
- *RoW distribution markets* – In 2019, RoW realized a solid performance in cartridge volume growth and closed the year with a number of new instrument placements exceeding expectations. This performance was driven by the active commercialization in more than 50 countries on the back of a strong network of local distribution partners, and supported by numerous collaborations with pharma partners.
- *China commercialization* – In 2019, Biocartis completed the closing of the joint venture ('China JV') with Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, which resulted in the first capital contribution by both partners and subsequently the payment by the China JV of a license fee to Biocartis. The China JV is aimed at the commercialization of the Idylla™ platform in China with a first focus on the establishment of local manufacturing capabilities and product registrations.
- *Japan commercialization* – On 7 January 2019, Biocartis announced to have signed an agreement with Nichirei Biosciences[4] ('Nichirei Bio') for the product registrations and distribution of the Idylla™ platform in Japan. In October 2019, Nichirei Bio completed the registration of the Idylla™ Instrument and Idylla™ Console with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. With that, Nichirei Bio will now be able to offer the Idylla™ platform in combination with Idylla™ RUO assays to local pathology laboratories in Japan, whilst both partners are further progressing in vitro diagnostic ('IVD') registration preparations for the Idylla™ assays.

Menu and partnership highlights

Colorectal cancer menu

- CE-marking Idylla™ MSI Test – On 28 February 2019, Biocartis announced the CE-marking of its fully automated Idylla™ MSI Test. MSI testing is currently recommended for all colorectal and endometrial cancers[5] but is still underused, mainly because of the high complexity of current methods. The Idylla™ MSI Test has been developed to overcome this drawbacks and its unique features could enable a broader penetration of MSI testing.
- US FDA submission Idylla™ MSI Assay – During 2019, further progress was made in the preparation of the 510(k) notification to the US FDA of the Idylla™ MSI Assay for colorectal cancer, of which the submission is expected end 2020, subject to further feedback from US FDA interactions.
- US FDA submission RAS tests – During 2019, further progress was made in the preparation of the premarket approval (PMA) application for the Idylla™ RAS Tests, of which the submission is expected end 2020, subject to further feedback from US FDA interactions.

[4] Nichirei Biosciences Inc. is a leading supplier of biological and diagnostic products in Japan
[5] Source: ASCO guidelines, www.asco.org/endorsements/HereditaryCRC

Lung cancer menu

- Launch Idylla™ ctEGFR Mutation Assay – On 25 October 2019, the Idylla™ ctEGFR Mutation Assay (RUO), the liquid biopsy version of the Idylla™ EGFR Mutation Test (CE-IVD), was launched. The Idylla™ ctEGFR Mutation Assay allows for the detection of 49 EGFR mutations[6] directly from 2 ml of blood plasma and provides results within approximately 160 minutes.
- Idylla™ GeneFusion Panel (RUO) – During 2019, further progress was made in the development of the Idylla™ GeneFusion Panel. This assay is expected to be launched as RUO end 2020. Together with the Idylla™ EGFR Mutation Test (CE-IVD), the GeneFusion Panel will cover the majority of lung cancer biomarkers recommended by all major international guidelines. As such, a complete set of lung cancer biomarkers could be rapidly tested on Idylla™ following the launch of the Idylla™ GeneFusion Panel.

Immuno-oncology menu

- MSI partnership BMS – On 12 March 2019, Biocartis announced the signing of a collaboration agreement with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company, focused on MSI testing in connection with immuno-oncology therapies. Bristol-Myers Squibb's Opdivo® (nivolumab) plus low-dose Yervoy®[7] (ipilimumab) is the first immuno-oncology combination treatment approved by the US FDA for MSI-High or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with certain chemotherapies[8]. The collaboration agreement allows for joint developments and registrations of the Idylla™ MSI test for use in a variety of indications, commercial settings and geographies. The first focus under the agreement is expected to be the registration in the US of the Idylla™ MSI assay as a CDx device in mCRC.
- Cell therapy monitoring partnership Kite/Gilead – On 1 June 2019, Biocartis announced a master development and commercialization agreement with Kite Pharma, Inc., a Gilead Company (NASDAQ: GILD), a pharmaceutical company engaged in the development of innovative cancer cell therapies. The collaboration aims at the development of molecular-based assays on the Idylla™ platform that are supportive to Kite's therapies. The speed and ease-of-use of the Idylla™ platform could enable regular and rapid monitoring of patients under such cancer cell therapies in a near patient setting, which is expected to help optimize patient management.

Breast cancer menu

- Idylla™ Oncotype DX Breast Recurrence Score® test (Exact Sciences[9]) - During 2019, Exact Sciences Corporate (NASDAQ: EXAS) progressed the development of an Idylla™ IVD version of the Oncotype DX Breast Recurrence Score® test. Idylla™ instruments were placed in Q4 2019 at early access sites in Europe, beginning with France and Germany, as a preparation for the start of the validation studies which are expected to start in 2020. Furthermore, on 20 June 2019, Genomic Health announced that the German Federal Joint Committee (G-BA) issued a positive reimbursement decision for the Oncotype DX Breast Recurrence Score® Test.
- Idylla™ ABC Panel (RUO) – Because of the emerging pipeline of drugs that target molecular biomarkers in advanced breast cancer ('ABC'), Biocartis and LifeArc[10] decided to strengthen the positioning of this assay. Going forward, it will be referred to as the Idylla™ Advanced Breast Cancer Panel and is positioned to target a multi-gene panel of predictive and resistance-inducing mutations based on an FFPE[11] sample type.

Pan tumor testing potential

Therapy selection is increasingly driven by the genetic make-up of the tumor rather than its tissue of origin within the body. This could allow for a pan-tumor application of targeted therapies, which in turn increases the demand for molecular tests. Consequently, Idylla™ assays are increasingly being assessed for pan-tumor testing, as such potentially expanding the applicability of the current Idylla™ test menu. Examples of research into new applications include:

1. KRAS mutations detected in FFPE lung samples[12];
2. KRAS mutations detected in pancreatic cyst fluid samples[13];
3. NRAS and BRAF mutations detected in FFPE melanoma samples[14]; and
4. NRAS and BRAF mutations detected in thyroid Fine Needle-Aspirates (FNA) samples[15].

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[6] Including insertions and deletions in exon 18, 19, 20 and 21 in the EGFR gene

[7] See product labelling on https://www.yervoy.com/

[8] Treatment with fluoropyrimidine, oxaliplatin and irinotecan

[9] Genomic Health was acquired by Exact Sciences Corp. (NASDAQ: EXAS) on 8 November 2019

[10] In June 2017, Biocartis announced a partnership with LifeArc to develop selected molecular diagnostic tests for use on the Idylla™ platform. 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. More info on www.biocartis.com/partners

[11] Formalin fixed, paraffin embedded

[12] Huang et al. J Mol Diagn. 2019 Sept

[13] The use of the Idylla™ ctKRAS Mutation Assay directly on pancreatic cyst fluid was researched as a solution for direct, rapid KRAS mutation testing, which is especially helpful in cases where cellular content and fluid volume of pancreatic cysts are suboptimal for other routine testing (Al-Turkmani M et al., Pancreatic cyst fluid harboring a KRAS mutation. Cold Spring Harb Mol Case Study 5.(2) Apr 2019. Available online on https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6549572/)

[14] Huang et al. J Mol Diagn. 2019 Sept

[15] The Idylla™ BRAF Assay and the Idylla™ NRAS-BRAF Assay (RUO) were used to research the direct use of thyroid FNA samples as a Rapid On site Molecular Evaluation (ROME) solution for the rapid and easy detection of NRAS and BRAF mutations without having to send out the samples to specialized, centralized labs (De Luca C et al. Rapid On-site Molecular Evaluation in thyroid cytopathology: A same-day cytological and molecular diagnosis. Diagn Cytopathol. 6 January 2020, doi: 10.1002/dc.24378. Epub ahead of print. Available online on https://www.ncbi.nlm.nih.gov/m/pubmed/31904908/)

Additionally, various efforts are ongoing to demonstrate the feasibility of the Idylla™ MSI Test in multiple cancer types. Worldwide, more than 30 Idylla™ MSI studies[16] were initiated in 2019. Many of these demonstrate the importance of pan-tumor MSI testing in non-colorectal cancer types such as endometrial, gastric, ovarian, pancreatic and other cancers in the context of Lynch Syndrome and immunotherapy use[17].

Idylla™ performance data

In 2019, the performance of Idylla™ was the subject of over 26 publications[18] and multiple study abstracts, of which several were selected for publication at large scientific conferences such as ESMO[19] (European Society for Medical Oncology), ASCO[20] (American Society of Clinical Oncology) and AMP[21] (Association of Molecular Pathology).

- Europe - 19 new Idylla ™ performance publications in Europe, of which five Idylla™ study abstracts were selected for publication at the renowned ESMO congress and multiple study abstracts were selected for national conferences. All Idylla™ studies published at ESMO demonstrated excellent performance of Idylla™ compared to other methods, in combination with the ease of use and fast turnaround time of the Idylla™ platform. The studies included, amongst others, the Idylla ™ MSI Assay (RUO) and a prototype of the Idylla™ ctEGFR Mutation Assay (RUO).
- US – Five new Idylla™ publications in the US and six study abstracts were selected for publication at the USCAP congress, one study abstract was selected for the ASCO congress and five study abstracts were selected for the AMP[22] congress. All studies published at AMP showed a strong performance of Idylla™ assays (RUO) compared to other methods including IHC[22] and NGS[23] in terms of concordance[24], ease of use, workflow automation and turnaround times. Some studies researched Idylla™'s capability to analyze different sample types[25] and smaller sample quantities.

Organizational and operational highlights

- *Management team* – In light of the Company's further international growth, expansion of its partner network and associated scaling of the organization, several changes to the Company's management team were effectuated in 2019:
  - Appointment Chief Operating Officer – Piet Houwen joined Biocartis as its Chief Operating Officer in April 2019.
  - Appointment Global Head Pharma Collaborations and Partnering – Dirk Zimmermann joined Biocartis in May 2019 as Global Head of Pharma Collaborations and Partnering.
  - Changes in the Chief Commercial Officer role – Biocartis and Hilde Eylenbosch, the Company's Chief Commercial Officer, agreed to terminate their collaboration as per the end of April 2019. The tasks of the CCO have been reallocated to the Company's CEO and senior commercial management.
- *Cartridge manufacturing* – In 2019, progress was made in the production transfer to the new cartridge manufacturing line and commercial manufacturing of the Idylla™ KRAS Mutation Test was started on this line. Additional assays are to be transferred to the new cartridge manufacturing line over the course of 2020, driving costs optimizations within the Company's cartridge manufacturing activities.

Financial highlights

- *Product sales revenues* – Total product sales increased year-over-year with 29% to EUR 24.2m in 2019 (EUR 18.8m in 2018), as a consequence of higher Idylla™ cartridge sales (year-over-year growth of 23%) as well as Idylla™ platform sales (year-over-year growth of 49%).
- *Total operating income* – Total operating income amounted to EUR 37.7m in 2019, representing a year-over-year growth of 32% as a result of higher Idylla™ product sales, collaboration revenues (49% year-over year growth) and service revenues, partially offset by lower grant income.
- *OPEX* – Total operating expenses (including cost of sales) amounted to EUR 93.3m, a year-over-year increase of 24% due to higher cost of sales and operational expenses.
- *Operational cash flow* – Total cash flow used in operating activities amounted to minus EUR 54.3m in 2019 versus minus EUR 42.0m in 2018.

[16] See list of publications on www.biocartis.com/publications
[17] The Idylla™ MSI Test is intended for the qualitative detection of a novel panel of seven monomorphic homopolymer biomarkers for identification of colorectal cancers (CRC) with microsatellite instability (MSI)
[18] Two of which the epub version was published in 2019, ahead of the print version in 2020
[19] The European Society for Medical Oncology ('ESMO') congress that took place between 27 September and 1 October 2019 in Barcelona (Spain)
[20] The American Society of Clinical Oncology ('ASCO') Annual Meeting took place between 30 May and 4 June 2019 in Chicago (IL), US
[21] The Association for Molecular Pathology ('AMP') conference took place between 7 and 9 November 2019 in Baltimore, Maryland, US
[22] Immuno-histochemistry is often used to assess the MSI status. MSI is useful for screening patients for Lynch syndrome, and has become a predictive marker for response to immunotherapy
[23] Next-Generation Sequencing or NGS is a technology for determining the sequence of DNA or RNA to study for example specific genetic alterations in patients with cancer. Source: NCBI, Jan-Dec 2018, last consulted on 21 October 2019
[24] We refer to the abstracts for more details on https://doi.org/10.1016/S1525-1578(19)30391-5
[25] Incl. (un)extracted FFPE tissue, cytologic material, blood, bone marrow, aspirate smears and touch preparation tissue samples as well as NGS pre-capture libraries

- *Equity raise* – On 28 January 2019, Biocartis raised an amount of EUR 55.5m in gross proceeds by means of a private placement via an accelerated bookbuild offering.
- *Convertible bonds issue* – On 2 May 2019, Biocartis issued EUR 150 million senior unsecured convertible bonds due 9 May 2024. The convertible bonds were admitted to trading and listing on the regulated market of Euronext Brussels on 15 November 2019.
- *Cash position* - Biocartis' cash position as per 31 December 2019 amounted to EUR 178.7m compared to EUR 63.5m as per 31 December 2018.
- *Additional details* – See 'key figures for 2019' below for more details on the 2019 financials.

Post-period events
- *Achievement 2019 key business objectives* – On 9 January 2020, Biocartis announced to have achieved its latest key business objectives for 2019.
- *Partnership AstraZeneca* – On 22 January 2020, Biocartis announced that it entered into a master collaboration agreement with AstraZeneca, a global science-led biopharmaceutical company (LON/STO/NYSE: AZN). The scope of the new master collaboration agreement enables collaborative development and commercialization projects between Biocartis and AstraZeneca, such as but not limited to, CDx development projects that may cover any type of indication or biomarker. The first project to be initiated in that context is a study focused on evaluating if liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay (RUO) could provide further benefits to tissue-based EGFR molecular testing.
- *CFO resignation* – On 27 January 2020, Biocartis announced that Ewoud Welten, the Company's Chief Financial Officer ('CFO'), has decided to resign from Biocartis and to pursue an opportunity in the Netherlands, closer to his home and family. Biocartis has initiated a selection process to recruit a new CFO.
- *Limitation of the Executive Committee* – It has been decided that going forward the Company's executive management will be composed of the Chief Executive Officer (CEO), the Chief Financial Officer (CFO) and the Chief Operational Officer (COO).
- *New project under BMS IO collaboration* – On 5 March 2020, Biocartis announced a new project under its existing immuno-oncology collaboration with Bristol-Myers Squibb Company (see above in section 'menu and partnership highlights'). The new project pursues the registration of the Idylla™ MSI test as a companion diagnostic test in metastatic colorectal cancer in the People's Republic of China. Biocartis' joint venture Wondfo-Cartis will commercialize the Idylla™ MSI test in the People's Republic of China upon obtaining regulatory approval.

Outlook
- *Commercial cartridge volume:* Targeting a year-over-year commercial volume growth in the range of 30%, representing a volume of Idylla™ cartridges in the range of 228k.
- *Installed base:* Targeting an installed base growth in the range of 300-350 new instrument placements.
- *Menu outlook:*
  - Colorectal cancer menu – Subject to further feedback from US FDA interaction, US FDA 510(k) submission of the Idylla™ MSI Test is expected by end 2020 and US FDA submission of PMA[26] application for the Idylla™ RAS tests is now expected by Q1 2021;
  - Lung cancer menu – Further development of the Idylla™ GeneFusion Panel towards expected RUO launch by end 2020; and
  - Breast cancer menu – Start of the clinical validation studies of the Idylla™ IVD Oncotype DX Breast Recurrence Score® test in France and Germany is expected in 2020.
- *Cash position:* Targeted cash position in the range of EUR 110m by 2020 year-end.

Key figures for 2019
The tables below show an overview of the key figures and a breakdown of operating income for 2019. 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.

[26] PMA = Pre-Market Approval

Key figures *(EUR 1,000)*	2019	2018	% Change
Total operating income	**37,732**	**28,651**	**32%**
Cost of sales	-21,328	-15,349	39%
Research and development expenses	-39,844	-36,842	8%
Sales and marketing expenses	-18,011	-15,349	17%
General and administrative expenses	-14,151	-7,971	78%
Operating expenses	**-93,334**	**-75,511**	**24%**
Operational result	**-55,602**	**-46,860**	**19%**
Net financial result	-7,934	-1,402	466%
Share in the result of associated companies	-631	0	na
Income tax	99	109	-9%
Net result	**-64,068**	**-48,153**	**33%**
Cash flow from operating activities	-54,254	-41,993	29%
Cash flow from investing activities	-5,496	-5,820	-6%
Cash flow from financing activities	175,023	-1,508	-11714%
Net cash flow	**115,273**	**-49,320**	**-334%**
Cash and cash equivalents[1]	**178,725**	**63,539**	**181%**
Financial debt	166,578	35,335	371%

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

Operating income *(EUR 1,000)*	2019	2018	% Change
Collaboration revenue	**12,451**	**8,329**	**49%**
Idylla™ system sales	6,220	4,185	49%
Idylla™ cartridge sales	18,004	14,658	23%
Product sales revenue	**24,224**	**18,843**	**29%**
Service revenue	769	639	**20%**
Total revenue	**37,444**	**27,811**	**35%**
Grants and other income	288	840	-66%
Total operating income	**37,732**	**28,651**	**32%**

Product sales revenue by type *(EUR 1,000)*	2019	2018	% Change
Commercial revenue	22,862	17,843	28%
Research & Development revenue	1,362	1,000	36%
Total product sales revenue	**24,224**	**18,843**	**29%**

Income statement

Collaboration revenue increased year-over-year with 49% to EUR 12.5m in 2019 driven by proceeds from R&D services that increased with 108% to EUR 9.0m and increased milestone revenues (EUR 0.9m, 9% year-over-year increase) which was partially offset by lower license fees (EUR 2.5m, 20% year-over-year decrease).

Total product sales amounted to EUR 24.2m in 2019 (EUR 18.8m in 2018), representing a year-over-year growth of 29%, and included Idylla™ cartridge sales of EUR 18.0m (EUR 14.7m in 2018) and Idylla™ system revenues of EUR 6.2m (EUR 4.2m in 2018).

Service revenue amounted to EUR 0.8m in 2019 versus EUR 0.6m in 2018. Recognized grants and other income amounted to EUR 0.3m in 2019 (EUR 0.8m in 2018) and consisted of R&D project support grants and training

subsidies related to the establishment of a second cartridge manufacturing line. Driven by the aforementioned Biocartis' total operating income in 2019 amounted to EUR 37.7m versus 28.7m in 2018, representing an increase of 32%.

Total operating expenses in 2019 amounted to EUR 93.3m versus EUR 75.7m in 2018, an increase of 24%. This included cost of sales of EUR 21.3m in 2019 compared to EUR 15.3m in 2018 as the consequence of an overall increase in product volumes as well as higher operational costs for cartridge manufacturing due to expanded night and weekend shifts in order to meet volume demand. Operating expenses excluding cost of sales amounted to EUR 72.0m in 2019 versus EUR 60.2m in 2018 (year-over-year increase of 20%) as the result of an overall increase in research and development ('R&D'), sales and marketing ('S&M') and general and administrative expenses ('G&A'). As of the first of January 2019, Biocartis has adopted the new IFRS 16 standard for lease accounting (the modified retrospective approach was applied, i.e. comparatives will not be restated) as described below in the balance sheet section. The year-over-year net impact of this adoption on operating expenses is estimated to be an increase of around EUR 3.0m, of which the majority are non-cash depreciation expenses.

R&D expenses amounted to EUR 39.8m in 2019 versus EUR 36.8m in 2018 which represents a year-over-year increase of approx. 8%. This was predominantly driven by increased depreciation and amortization charges, employee benefit expenses and laboratory & cartridge costs which was partially offset by decreased facilities, office and other costs as well as the EUR 3.2m one-off impairment charge on certain patents in 2018. Sales and marketing expenses amounted to EUR 18.0m in 2019 compared to EUR 15.3m in 2018, a year-over year increase of 17%. 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 and related consultancy and subcontracting expenses. G&A expenses increased year-over-year with 78% due to overall organizational growth as well as a general cost allocation that is shifting more towards a commercial stage organizational structure.

The above resulted in an operational result for the period of EUR -55.6m, compared to EUR -46.9m in 2018, a year-over-year change of approx. 19%.

Net financial expenses amounted to EUR 7.9m in 2019 compared to EUR 1.4m in 2018 and included financial expenses in relation to the Company's convertible bond (see details in section balance sheet) of EUR 5.2m (consisting of EUR 3.0m coupon payment and EUR 2.2m of debt appreciation), the Company's subordinated loan of EUR 1.1m as well as commitment fees for the multiple purpose credit.

As the Company had no taxable income in 2019, income tax expenses consists of recognized research and development tax credits in Belgium.

As a result of the foregoing, the net result for the year 2019 amounted to EUR –64.1m compared to EUR -48.2m in 2018.

Balance sheet

As required, Biocartis has adopted the new IFRS 16 standard for lease accounting with date of initial application on 1 January 2019. This standard introduces a single lessee accounting model and requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, eliminating the distinction between operating and finance leases. The first time adoption of IFRS 16 has an impact on the Group's balance sheet as well as results in a reclassification of operational expenses in the Group's income statement. Concretely, as of 1 January 2019, Biocartis also recognizes its operational leasing contracts (i.e. for buildings, company cars and office furniture) on its balance sheet in addition to the Group's financial leasing contracts (i.e. for manufacturing equipment). This resulted in a one-off increase in property, plant and equipment of EUR 14.3m and lease liabilities of EUR 15.8m on 1 January 2019. Furthermore, as property, plant and equipment is depreciated over time, the income statement recognizes deprecation charges and financing expenses for all the recognized leases versus previously the recognition of lease payments as e.g. building rent or facility & office expenses.

During 2019, property plant & equipment increased with EUR 13.0m to EUR 43.4m. This increase was driven by a EUR 14.1m net impact of IFRS 16, EUR 4.3m of actual capital expenditures (mainly related to capitalization of instrumentation placed at clients under leasing or rental contracts and investments in cartridge manufacturing equipment) and a depreciation charge of around EUR 6.1m.

Financial assets amounted to EUR 0.0m as per the end of 2019 versus EUR 5.0m end of 2018. This decrease was driven by a full impairment of the Company's participation in MyCartis NV as the consequence of changed activities of MyCartis NV and realized valuation levels of related recent capital increases. Investments in associates and joint ventures was added to the balance sheet in 2019 in relation to the formal closing of the China joint venture and amounted to EUR 2.4m as per end of 2019.

Deferred tax assets per 31 December 2019 amounted to EUR 1.6m versus EUR 6.6m end of 2018 and relate to tax credits for research and development in Belgium. This decrease is driven by the re-allocation of the short-term portion of these tax credits (EUR 5.2m) to the line item other receivables under current assets on the Company's balance sheet.

Inventory amounted to EUR 14.1m as per end 2019 compared to 11.9m as per end 2018. This year-over-year increase was driven by higher inventory levels of finished products and raw materials, partially offset by lower inventory levels for semi-finished products. Trade receivables increased to EUR 10.7m as per year-end 2019 (EUR 9.7m end of 2018) as a consequence of higher overall commercial volumes and the change in go-to-market strategy for the US market. Other receivables increased from EUR 3.8m in 2018 to EUR 8.6m in 2019 as the consequence of the allocated short-term portion of tax credits, partially offset with lower VAT receivables.

The Company's cash and cash equivalents end of 2019 amounted to EUR 178.7m compared to EUR 63.5m end of 2018.

Total financial debt end of 2019 amounted to EUR 166.6m, representing an increase of EUR 131.2m compared to end of 2018. This was the result of the issuance of the Company's convertible bond, an increase in lease liabilities due to amongst others the first time adoption of IFRS 16 and the early repayment of the Company's subordinated loan. The IFRS accounting treatment of the Company's convertible bond has resulted in an allocation of the EUR 150m nominal amount to financial debt of EUR 133.5m and equity of EUR 12m (as adjusted for related transaction costs) as per the end of 2019. The repaid subordinated loan had a nominal amount of EUR 15m, carried a 7% interest rate, had an initial duration of 5 years and was due September 2021. The cash out related to the early repayment of this loan amounted to EUR 17.5m based on the nominal amount of the loan and capitalized interest.

Deferred income decreased in 2019 to EUR 2.0m (EUR 3.0m end of 2018) as a consequence of net revenue recognition from pending and new collaboration agreements.

Trade payables end of 2019 amounted to EUR 9.1m, representing an increase of EUR 1.1m compared to the EUR 8.0m that was outstanding end of 2018. Other current liabilities increased in 2019 with EUR 1.9m to EUR 6.1m and consisted predominantly of provisions for vacation pay and for variable compensation schemes.

Cash flow statement

The cash flow from operating activities in 2019 amounted to EUR –54.3m compared to EUR –42.0m in 2018, a change of EUR 12.3m. This increase is the result of a higher operating loss and higher investments in working capital for the period that was partially offset by increased non-cash adjustments (mainly driven by a higher depreciation charge and higher non-cash elements in the net financial result).

The cash flow from investing activities in 2019 amounted to EUR –5.5m (compared to EUR –5.8m in 2018) and consisted of the initial capital contribution made to the China joint venture, capitalized Idylla™ systems as well as investments in laboratory and manufacturing equipment.

The cash flow from financing activities in 2019 amounted to EUR 175.0m (compared to EUR -1.5m in 2018) which was driven by the issuance of the convertible bonds (net proceeds of EUR 145.5m) and by the capital raise (net proceeds of EUR 53.4m), partially offset by the repayments of borrowings (predominantly the Company's subordinated loan) of EUR 23.7m.

Driven by the aforementioned, the total net cash flow in 2019 amounted to EUR 115.3m compared to EUR -49.3m in 2018.

Financial calendar 2020

- 5 March 2020 Full year results 2019
- 2 April 2020 Publication Annual Report 2019
- 23 April 2020 Q1 2020 Business Update
- 8 May 2020 Annual and Extraordinary General Meeting Biocartis Group NV
- 3 September 2020 H1 2020 results
- 12 November 2020 Q3 2020 Business Update

After the summer of 2020, Biocartis will organize a Capital Markets Day for financial analysts, media & institutional investors to provide an update of its Idylla™ product strategy (date to be confirmed).

Webcast and presentation

Biocartis will host a conference call with live webcast, during which the 2019 results will be presented, followed by a Q&A session. This event will be held today, 5 March 2020 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 8445718892 (standard international), followed by the confirmation code 6194332. 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 2 April 2020. 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, 2019	2018
Revenue		
Collaboration revenue	12,451	8,329
Product sales revenue	24,224	18,843
Service revenue	769	639
	37,444	27,811
Other operating income		
Grants and other income	288	840
Total operating income	**37,732**	**28,651**
Operating expenses		
Cost of sales	-21,328	-15,349
Research and development expenses	-39,844	-36,842
Sales and marketing expenses	-18,011	-15,349
General and administrative expenses	-14,151	-7,971
	-93,334	**-75,511**
Operating loss for the year	**-55,602**	**-46,860**
Financial expense	-8,008	-1,565
Other financial results	74	163
Financial result, net	**-7,934**	**-1,402**
Share in the results of associates	-631	
Loss for the year before taxes	**-64,167**	**-48,262**
Income taxes	99	109
Loss for the year after taxes	**-64,068**	**-48,153**
Attributable to owners of the Company	-64,068	-48,153
Attributable to non-controlling interest		
Earnings per share		
Basic and diluted loss per share	-1.14	-0.94

Consolidated Balance Sheet

In EUR 000	As of 31 December, 2019	2018
Assets		
Non-current assets		
Intangible assets	6,294	6,579
Property plant and equipment	43,421	30,391
Investments in associates	0	5,052
Investment joint ventures	2,358	0
Other non-current receivables	13	11
Deferred tax assets	1,609	6,569
	53,695	48,602
Current assets		
Inventories	14,161	11,919
Trade receivables	10,695	9,744
Other receivables	8,640	3,751
Other current assets	2,407	1,830
Cash and cash equivalents*	178,725	63,539
	214,628	90,783
Total assets	**268,323**	**139,385**
Equity and liabilities		
Capital and reserves		
Share capital	-220,668	-220,718
Share premium	698,027	632,769
Share based payment reserve	4,670	3,445
Accumulated deficit	-397,550	-328,145
Total equity attributable to owners of the Company	84,479	87,351
Non-current liabilities		
Provisions	49	28
Borrowings and lease liabilities	24,000	30,221
Convertible debt	136,158	0
Deferred income	461	6
Accrued charges	0	1,501
	160,668	31,756
Current liabilities		
Borrowings and lease liabilities	6,420	5,114
Trade payables	9,070	7,973
Deferred income	1,595	3,010
Other current liabilities	6,091	4,181
	23,176	20,278
Total equity and liabilities	**268,323**	**139,385**

***** Cash and cash equivalents for 31 December 2019 include EUR 1.2 million restricted cash related to KBC Lease financing

Consolidated cash flow statement

In EUR 000	Years ended 31 December, 2019	2018
Operating activities		
Loss for the year	-64,068	-48,153
Adjustments for		
Depreciation and amortization	9,719	4,273
Impairment losses	476	3,456
Income taxes in profit and loss	-99	109
Financial result, net	7,934	1,402
Net movement in defined benefit obligation	-150	-15
Share of net profit of associate and a joint venture	631	
Share based payment expense	1,225	1,065
Other	37	-19
Changes in working capital		
Net movement in inventories	-3,858	-2,859
Net movement in trade and other receivables and other current assets	-1,182	-4,060
Net movement in trade payables & other current liabilities	1,507	2,893
Net movement in deferred income	-960	229
	-48,788	**-41,679**
Interests paid	-5,288	-215
Taxes paid	-178	-99
Cash flow used in operating activities	**-54,254**	**-41,993**
Investing activities		
Interests received	8	8
Acquisition of property, plant & equipment	-2,121	-5,571
Acquisition of intangible assets	-394	-257
Acquisition of investment in a joint venture	-2,989	0
Cash flow used in investing activities	**-5,496**	**-5,820**
Financing activities		
Proceeds from the issue of a convertible bond	145,438	0
Net proceeds from the issue of common shares, net of transaction costs	53,360	2,102
Repayment of borrowings	-23,738	-3,580
Bank charges	-37	-29
Cash flow from financing activities	**-175,023**	**-1,507**
Net increase / (decrease) in cash and cash equivalents	**115,274**	**-49,320**
Cash and cash equivalents at the beginning of the year	63,539	112,765
Effects of exchange rate changes on the balance of cash held in foreign currencies	-87	94
Cash and cash equivalents at the end of the year*	**178,726**	**63,539**

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

Consolidated Statement of Changes in Shareholder Equity

In EUR 000	Attributable to owners of the Group						
	Share capital	**Share premium**	**Share based payment reserve**	**Other comprehensive income**	**Accumulated deficit**	**Total equity attributable to the owners of the Group**	**Total equity**
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**
Balance as at 1 January 2019	**-220,718**	**632,769**	**3,445**	**-67**	**-328,078**	**87,351**	**87,351**
Loss for the period					-64,068	-64,068	-64,068
Re-measurement gains and losses on defined benefit plan				-171		-171	-171
Consolidation translation difference					-113	-113	-113
Other comprehensive income				-5,052		-5,052	-5,052
Total comprehensive income				***-5,223***	***-64,181***	***-69,404***	***-64,404***
Share-based payment expense			1,225			1,225	1,225
Share issue – private placement on 28 January 2019	50	55,450				55,500	55,500
Costs related to private placement on 28 January 2019		-2,311				-2,311	-2,311
Share issue - exercise of stock options on 4 April 2019	0	171				171	171
Issuance of convertible bond on 9 May 2019		11,948				11,948	11,948
Other						0	0
Balance as at 31 December 2019	**-220,668**	**698,027**	**4,670**	**-5,291**	**-392,259**	**84,480**	**84,480**

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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 continuously expanding test menu addressing key unmet clinical needs in oncology. This 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. 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. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. 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.