PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS ANNOUNCES 2020 RESULTS AND 2021 OUTLOOK

Mechelen, Belgium, 25 February 2021 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its operational highlights and financial results for 2020, prepared in accordance with IFRS as adopted by the European Union as well as selected post period events and its outlook for 2021.

Commenting on the 2020 results and 2021 guidance, Herman Verrelst, Chief Executive Officer of Biocartis, said:

"*2020 was an extraordinary year, to say the least. The pandemic deprioritized and disrupted cancer care globally. Patient access to hospitals was significantly restricted throughout almost the entire year and customer prospection was severely hampered. Nevertheless, we showed resilience and delivered on our pre-pandemic outlook. Oncology volumes continued to grow, mostly in the US, but also in Europe, and the versatility of Idylla™ allowed the rapid rollout of a pandemic response test menu that alleviated the pressure on oncology testing volumes. Furthermore, we continued to expand our global Idylla™ ecosystem, attracted new partners and made significant operational progress on our path towards continued growth.*

We look ahead with confidence and start 2021 with a better than expected cash position that we plan to put at work to accelerate test menu expansion and diversification in a year that will again be marked by continued impact of the pandemic. We are determined to serve and build on the undebated need for rapid response testing in an overburdened healthcare system, convinced that we are very well equipped to deliver on our customers' needs in oncology as well as in infectious diseases."

KEY MESSAGES 2020 RESULTS

- **Total operating income:**
  - Total operating income increased year-over-year by 47% to EUR 55.6m;
  - Product sales revenues amounted to EUR 31.9m (year-over-year increase of 32%).
- **Commercial cartridge volume**:
  - Growth of the commercial cartridge volume by 31% to 230k cartridges;
  - Moderate year-over-year growth in oncology complemented by strong demand for the Idylla™ SARS-CoV-2 Test[1].
- **Installed base:**
  - Biocartis placed 335 new Idylla™ instruments in 2020;
  - Biocartis' installed base as per 31 December 2020 increased to 1,581 Idylla™ instruments[2].
- **Expansion partnerships:**
  - Strengthening of the oncology business through the expansion of the partnerships with AstraZeneca (LON: AZN) and Bristol-Myers Squibb Company (NYSE: BMY) and new partnerships with GeneproDx[3] in the thyroid cancer domain;
  - Partner funded expansion of the Idylla™ infectious diseases test menu, together with Immunexpress, LifeArc and Endpoint Health[4].
- **Idylla™ test menu:**
  - Oncology test menu progress with the EUR 1.2m grant from VLAIO[5] for the development of the highly innovative Idylla™ GeneFusion Assay (RUO[6]);
  - Infectious diseases strategy sparked by the launch of the first pandemic Idylla™ test menu, consisting of the market release of the SeptiCyte® RAPID test on Idylla™ (CE-IVD)[7], followed by the CE-IVD launch of the Idylla™ SARS-CoV-2 Test[1];
  - US FDA 510(k) submission, led by Immunexpress, of the SeptiCyte® RAPID test on Idylla™ completed in December 2020.

1 In the US, distribution of the Idylla™ SARS-CoV-2 Test was initiated in Q3 2020 per US FDA Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), May 2020, Section IV.C. Commercial Manufacturer Development and Distribution of Diagnostic Tests Prior to EUA Submission
2 Including 64 Idylla™ instruments returned by Exact Sciences in accordance with the termination agreement announced on 29 October 2020
3 A molecular diagnostics company based in Santiago, Chile
4 A Palo Alto, CA (USA) based company developing personalized care solutions and targeted therapies for critically ill patients. Under the terms of the agreement, Endpoint Health will lead the development and registration of the Idylla™ Endpoint CDx test in interventional trials across a range of interventions including targeted immunotherapy and coagulation therapy indications. The parties intend to collaborate on the commercialization of the Idylla™ Endpoint CDx test, building on the growing worldwide commercial infrastructure of Idylla™ instruments
5 The Flanders Organization for Innovation & Entrepreneurship. The grant is intended to support the development of the GeneFusion Assay on the Idylla™ platform, and to support related research studies on different sample and tumor tissue types, including on lung cancer tissue. The Idylla™ GeneFusion Assay will include a highly multiplexed panel of established and emerging biomarkers, and will be the first FFPE (Formalin fixed, paraffin embedded) RNA based assay (= RNA or Ribonucleic Acid is one of the three major biological macromolecules that are essential for all known forms of life along with DNA and proteins) on the Idylla™ platform. The Idylla™ GeneFusion Assay is expected to bring results in approx. 3 hours, with less than 2 minutes hands-on time
6 RUO = Research Use Only, not for use in diagnostic procedures
7 Developed in collaboration with Immunexpress, a Seattle-based (WA, US) molecular diagnostic company

- **China commercialization:**
  - Compliance testing of the Idylla™ Instrument and Console with the China NMPA[8] successfully completed in January 2021.
- **Cash position:**
  - EUR 16m reduction of cash used in operating and investing activities to EUR 43.3m in 2020 compared to EUR 59.7m in 2019;
  - Cash and cash equivalents amounted to EUR 124m as at 31 December 2020.

COVID-19 IMPACT AND 2021 OUTLOOK

The year 2021 will again be marked by continued impact of the pandemic. The visibility on normalization of timing of global cancer care is limited. It is equally difficult to reliably predict how the further need for SARS-CoV-2 testing will develop as vaccination progresses throughout the year at varying paces across different countries. Having a broad Idylla™ menu of tests in oncology and an attractive Idylla™ pandemic response menu, Biocartis nevertheless believes it can accelerate its growth and achieve the following objectives:

- **Commercial cartridge volume**: Targeting a year-over-year growth of 40%-60% or commercial cartridge volumes in the range of 320k-370k. The high-end of the range will only be delivered in case of consistent strong demand for the Idylla™ SARS-CoV-2 Test at attractive average selling prices throughout 2021;
- **Installed base**: Targeting 300-350 new Idylla™ instrument placements;
- **Cash position**: Targeting at least EUR 50m cash position at year-end, including potential investments in upgrading and expanding the infectious diseases menu.

Biocartis will host a conference call with live webcast presentation today at 14:30 CET / 13:30 BST (UK) / 08:30 EDT (US) to discuss the 2020 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 8444819752 (standard international), followed by the confirmation code 5349189. The conference call and webcast will be conducted in English. A replay of the webcast will be available on the Biocartis investors' website shortly after.

COMMERCIAL HIGHLIGHTS

- *Global* – Despite the global pandemic, the number of commercial cartridges sold in 2020 grew by 31% to 230k, from 175k in 2019. After a strong first quarter of 2020, commercial cartridge volumes in oncology were significantly impacted by the disruption and de-prioritization of global cancer care. Restricted access to hospitals also hampered new customer prospection and slowed down new Idylla™ instrument placements in the first half of the year. Testing volumes in oncology started to recover towards the end of Q2, but the global surge of COVID-19 cases in Q4 ultimately tempered the year-over-year growth in oncology. To bridge the shortfall in oncology and to respond to its customers' need for COVID-19 testing, Biocartis developed the Idylla™ SARS-CoV-2 Test[1]. Strong demand for this test in Q4, especially in the US, enabled the Company to meet its pre-pandemic guidance with 31% growth in commercial cartridge volumes and the placement of 335 new Idylla™ instruments. As per year-end, the total Idylla™ installed base amounted to 1,581 Idylla™ instruments[2].
- *Europe* – Sales in Europe proved to be very resilient throughout 2020. After the slow-down in Q2 2020, both cartridge volumes and instrument sales were rapidly tracking pre-pandemic expectations. When growth slowed down again in Q4 as a direct result of renewed lock-down measures across large parts of Europe, lagging sales in oncology were supplemented by demand for the Idylla™ SARS-CoV-2 Test, CE-IVD marked since 10 November 2020. Together with SeptiCyte® RAPID[7] on Idylla™, released as CE-IVD in European markets on 6 October 2020, the Idylla™ SARS-CoV-2 Test is ideally positioned to alleviate the pressure on intensive care units (ICUs) and is expected to drive further growth in 2021.
- *US* – After strong growth in Q1 2020, demonstrating the continued success of the direct US sales strategy, sales in the US slowed down due to the global pandemic. Cartridge volumes in oncology nevertheless grew by 20% year-over-year. Thanks to additional strong demand for the Idylla™ SARS-CoV-2 Test, US commercial cartridge volumes tripled compared to 2019. New Idylla™ instrument placements in the US also increased year-over-year and accounted for one third of total placements.
- *Distributor markets*[9] – In 2020, several countries that are served through distributors were hit specifically hard by the pandemic, often compounded by a significant weakening of local currency versus the Euro. As a result, declining volumes in amongst others Latin-America, India, Pakistan and Turkey outweighed continued growth in other parts of the world. New market authorizations were obtained for the Idylla™ MSI Test in Colombia, Canada, Malaysia and Singapore, and for the Idylla™ EGFR Mutation Test in Argentina during H1 2020. End of October 2020, medical device registration certificates were issued for the Idylla™ platform and the Idylla™ EGFR Mutation Test by the Taiwan FDA. Post the reporting period, in February 2021, the Idylla™ platform, the Idylla™ BRAF Mutation Test (CE-IVD) and the Idylla™ EGFR Mutation Test (CE-IVD) completed registration in Russia, as such expanding the distribution network for Biocartis' IVD medical devices.
- *China commercialization* – In 2020, Wondfo-Cartis, the joint venture with Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, took further steps towards establishing

8 China NMPA requires local type testing for the market approval of Class II and Class III medical device/IVD products. China local type testing is a mandatory step for registration and must be completed before the initiation of local clinical studies if needed. Testing was conducted by a testing lab authorized by the NMPA

9 Defined as the world excluding European direct markets, US, China and Japan

local manufacturing capabilities. Concerning the registration of products, a CDx[10] partnership was announced on 5 March 2020 with Bristol Myers Squibb Company (BMS), aimed at pursuing the registration in China of the Idylla™ MSI Test as a CDx test in metastatic colorectal cancer (mCRC). First product registrations in China are to be expected earliest by 2022. Compliance testing of the Idylla™ Instrument and Console with the China NMPA[8] was successfully completed in January 2021.

- *Japan commercialization* – Continued progress in the in vitro diagnostic ('IVD') registration preparations for the Idylla™ assays, paving the way to commercialization with Nichirei Biosciences in Japan. First Idylla™ assays registrations in Japan are expected in the course of 2022.

TEST MENU AND PARTNERSHIP HIGHLIGHTS

- *Oncology:* In 2020, Biocartis further strengthened its footprint in oncology activities through progress in its test menu and the launch of several new and expanded partnerships:
  - Partnership AstraZeneca – On 22 January 2020, Biocartis announced a master collaboration agreement with lung cancer targeted therapy leader AstraZeneca aimed at rapid and easy testing and expanded its partnership to, amongst others, the area of liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay.
  - Partnership Bristol-Myers Squibb in China – On 5 March 2020, Biocartis announced the expansion of its partnership with Bristol-Myers Squibb Company, to now also pursue, after the US, the registration of the Idylla™ MSI test as a CDx test in mCRC[11] in China.
  - Idylla™ GeneFusion Assay – Biocartis made progress in its oncology test menu, more specifically in the lung cancer domain with the development of the Idylla™ GeneFusion Assay, for which a EUR 1.2m grant from VLAIO was announced on 30 September 2020.
  - Partnership Exact Sciences – On 29 October 2020, Biocartis and Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation) announced to have agreed to terminate their collaboration[12]. As part of a termination settlement, Genomic Health, Inc. agreed to pay USD 12m to Biocartis and licensed certain rights and transferred certain assets to Biocartis.
  - Partnership GeneproDx – On 3 November 2020, Biocartis announced to have signed a license, development and commercialization agreement with GeneproDx, a molecular diagnostics company based in Santiago, Chile, for the development of GeneproDx's novel genomic test ThyroidPrint® on the Idylla™ platform. Under the terms of the agreement, GeneproDx will take the lead in the development of the Idylla™ ThyroidPrint® test, whereas Biocartis will be responsible for the distribution of the ThyroidPrint® on Idylla™ through its growing commercial infrastructure of Idylla™ instruments across the globe[13].
  - Partnership Amgen – Motivated by a strong demand from partners and customers, Biocartis gave priority to the development of the Idylla™ SARS-CoV-2 Test and re-allocated resources accordingly. Consequently, Biocartis delayed the US FDA submission of the PMA (Pre-Market Approval) application for the Idylla™ RAS tests. More info under 'Outlook' below.
- *Infectious diseases:* Against the backdrop of the pandemic, in 2020 Biocartis paved the way to the gradual build-out of its infectious disease test menu on Idylla™:
  - Partnership Immunexpress – In March 2020, the agreement with Immunexpress[7] was expanded with a co-commercialization agreement for the SeptiCyte® RAPID test for use on the Idylla™ platform. End of December 2020, the 510(k) submission with the US FDA of the SeptiCyte® RAPID on Idylla™, led by Immunexpress, was completed.
  - Idylla™ SARS-CoV-2 Test – In August 2020, Biocartis submitted a notification of intent to distribute and request for 'Emergency Use Authorization' (EUA) from the US FDA for the Idylla™ SARS-CoV-2 Test[1].
  - Partnership LifeArc – In September 2020, Biocartis announced that the agreement with LifeArc[14] was expanded to now also include the development of highly innovative prototype assays in the field of infectious and immune related diseases on the Idylla™ platform.
  - COVID-19 Testing Industry Consortium – In October 2020, Biocartis announced to have joined the COVID-19 Testing Industry Consortium, led by Bristol-Myers Squibb Company which is aimed at improving, innovating and accelerating all aspects of COVID-19 testing[15]. A first Whitepaper on 'COVID-19 Back-to-Work' was published by the COVID-19 Testing Industry Consortium in January 2021.

10 A companion diagnostic (CDx) test is a test used as a companion to a therapeutic drug, that helps predict if a patient is likely to respond to a treatment or not
11 Metastatic colorectal cancer
12 The collaboration was focused on the development of the Oncotype DX Breast Recurrence Score® Test and the Oncotype DX Genomic Prostate Score® (GPS™) Test on the Idylla™ platform. As a result of COVID-19, the project had been suspended earlier during 2020, with the project plan and timing under evaluation. The decision to terminate the agreement was driven by the uncertain timing of a product market release because of the pandemic and a decision by Exact Sciences to shift priorities to other initiatives
13 ThyroidPrint® is a qRT-PCR (Quantitative Reverse Transcription PCR) based mRNA-expression classifier test (based on RTqPCR analysis, combined with an advanced machine learning algorithm) that helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant (this means that the probability of the nodule being malignant drops from 25% to less than 5%, allowing follow-up to be recommended as an alternative to surgery. Info and source: https://thyroidprint.com/en/home-us/, last consulted on 13 January 2021). A benign test result (NPV or Negative Predictive Value > 95%) allows physicians to recommend watchful waiting as an alternative to diagnostic surgery. This reduces exposing patients to surgical risks and permanent thyroid hormone supplementation. Moreover, it significantly reduces health costs associated with unnecessary surgery. PCR or Polymerase chain reaction is an efficient and cost-effective way to copy (amplify) small segments of DNA or RNA. As such, millions of copies of a section of DNA are made in just a few hours, allowing further analysis for clinicians to diagnose and monitor diseases using a minimal amount of sample, such as blood or tissue. Source: www.genome.gov, last consulted on 13 January 2021
14 LifeArc, formerly known as the Medical Research Council Technology (MRC Technology, MRCT) is a London (UK) based life science medical research charity
15 Including research, regulatory oversight, clinical implications, reliability and access

- SeptiCyte® RAPID on Idylla™ – Also in October 2020, Biocartis announced the market release of the SeptiCyte® RAPID test on Idylla™ (CE-IVD)[7].
- Idylla™ SARS-CoV-2 Test – In November 2020, Biocartis announced the CE-IVD launch of its Idylla™ SARS-CoV-2 Test[1].
- Partnership Endpoint Health – Also in November 2020, Biocartis announced the signing of a new partnership with Endpoint Health aimed at the development and commercialization of a novel CDx test on Idylla™ for critical illnesses.

- *Idylla™ performance data:* During 2020, 29 new Idylla™ papers were published, bringing the total number of Idylla™ papers end of 2020 to 84. Next to the Idylla™ papers, also several dozens of abstracts and posters were published in 2020 at large scientific conferences, including ASCO, AMP, ESMO and ECP[16]. Some highlights:
  - In June 2020, Biocartis announced the publication of a new US multicenter study[17] published in the 'American Journal of Clinical Pathology' which showed that, compared to current standard-of-care testing methods, the Idylla™ platform can substantially improve turnaround time of the results of mutation testing, independent of the size of the laboratory. The study was one of the largest studies performed involving Idylla™, with 20 laboratories of different types and sizes included throughout the US and Puerto Rico, and data from almost 800 colorectal cancer samples.
  - In August 2020, during the virtual annual ASCO, five Idylla™ abstracts and posters were published by key oncology opinion leaders, including first Idylla™ data from China where amongst others the Idylla™ EGFR Mutation Assay (RUO) showed excellent concordance with other methods.
  - In September 2020, the FACILITATE[18] study, launched as part of the agreement between Biocartis and AstraZeneca, was selected for presentation at the renowned European Society for Medical Oncology ('ESMO') Virtual Congress. The study concluded that Idylla™ reduced turnaround time by more than a week versus reference methods, allowing earlier patient management decisions;
  - In November 2020, at the annual meeting of the 'Association for Molecular Pathology' (AMP), ten Idylla™ studies were published which highlighted the strengths of the Idylla™ platform and assays[19] in terms of performance, ease of use and turnaround time, as well as Idylla™'s capacity to overcome the obstacles of working with small amounts of sample[20].
  - Also in November 2020, a global multi-center real world study[21] with the Idylla™ MSI Assay was published and demonstrated excellent performance of the Idylla™ MSI Assay (RUO)[6] with a very low failure rate. The study was the largest so far published for Biocartis.

ORGANIZATIONAL AND OPERATIONAL HIGHLIGHTS

- *Management team* – Following the departure of former CFO Ewoud Welten as announced on 27 January 2020, Biocartis announced on 23 April 2020 the appointment of Jean-Marc Roelandt, a senior executive with an established track record of more than 25 years as CFO in globally active publicly listed companies, as the new CFO of the Company.
- *Cartridge manufacturing* – In 2020, further progress was made in the transfer of Idylla™ assays to the second cartridge manufacturing line ('ML2'). After the transfer of the Idylla™ KRAS Mutation Test (CE-IVD) during H1 2020, the Idylla™ NRAS-BRAF Mutation Test (CE-IVD) and the Idylla™ MSI Test (CE-IVD) were successfully transferred to ML2. The transfer of the Idylla™ EGFR Mutation Test (CE-IVD) is near completion. Transferring the production of key Idylla™ assays to this line is driving cost optimizations within the Company's cartridge manufacturing activities.
- *Ordinary and Extraordinary General Shareholders' Meeting* – During the ordinary shareholders' meeting held on 8 May 2020, the shareholders of the Company approved all agenda items, including the re-appointment of Ann-Christine Sundell, Luc Gijsens BV, represented by Luc Gijsens, and Roald Borré, as independent directors of the Company. Christine Kuslich, PhD was appointed as new independent director of the Company. During the extraordinary general shareholders' meeting held on 25 September 2020, the shareholders of the Company approved all agenda items, including the renewal of the authorization to the Board of Directors to increase the share capital of the Company by up to 20% of the then current amount of the share capital, during a period of one year.

16 ASCO = American Society of Clinical Oncology, AMP = Association for Molecular Pathology, ESMO = European Society for Medical Oncology, ECP = European Congress of Pathology

17 Led by researchers from Dartmouth's and Dartmouth-Hitchcock's Norris Cotton Cancer Center (Lebanon, New Hampshire, US). Tsongalis et al., "Comparison of Tissue Molecular Biomarker Testing Turnaround Times and Concordance Between Standard of Care and the Biocartis Idylla Platform in Patients With Colorectal Cancer", Am J Clin Pathol. 2020 Jun 11;aqaa044. doi: 10.1093/ajcp/aqaa044. Online ahead of print

18 Hummel M. et al, "*FACILITATE: a real-world multicenter prospective study investigating the utility of a rapid, fully automated RT-PCR assay vs reference methods (RM) for detecting epidermal growth factor receptor mutations (EGFRm) in NSCLC*", ESMO Virtual Congress 2020 (19-21 September 2020), first published online on 14 September 2020. A large, prospective, study across 16 European sites in Belgium, France, Germany and Italy. The study aimed to prospectively test 100 paraffin-embedded biopsy or cytology tissue samples with ≥10% neoplastic cells per site, from patients with advanced NSCLC (non-small cell lung cancer)

19 All studies were performed with Idylla™ RUO assays, research use only, not for use in diagnostic procedures. Three studies also discussed new Biocartis assays in the area of infectious disease: the Idylla™ SARS-CoV-2 Assay and the SeptiCyte® RAPID on Idylla™

20 This represents a major challenge for many current molecular testing methods in a variety of different cancer types

21 A. Velasco et al., Multi-center real-world comparison of the fully automated Idylla™ microsatellite instability assay with routine molecular methods and immunohistochemistry on formalin-fixed paraffin-embedded tissue of colorectal cancer, Virchows Archiv, https://doi.org/10.1007/s00428-020-02962-x, November 2020

- *Convertible bonds* – On 7 December 2020, Biocartis announced its agreement with a holder of part of its outstanding EUR 150m 4% Senior Unsecured Convertible Bonds due 2024 (the 'Bonds') regarding the exercise of conversion rights in relation to EUR 15m aggregate principal amount of Bonds[22]. Biocartis agreed to this incentivized conversion of the Bonds, as it allowed to reduce its debt at attractive market conditions while strengthening the Company's shareholders' equity at a premium to the then current share price.

FINANCIAL HIGHLIGHTS

- *Product sales revenues* – Total product sales increased year-over-year by 32% to EUR 31.9m in 2020 from EUR 24.2m in 2019.
  - Income from cartridge sales of EUR 24.8m grew 38% year-over-year for total cartridge volume of 243k cartridges, of which 230k were commercial cartridges and 13k R&D cartridges. In addition to 31% growth of commercial cartridge volumes, good progress was made on the average selling price ('ASP') of commercial cartridges, which increased by 7% in 2020.
  - Idylla™ platform sales increased by 14% for a similar level of new Idylla™ instrument placements as in 2019 (335 in 2020, compared to 337 in 2019).
- *Total operating income* – Total operating income amounted to EUR 55.6m in 2020, representing a year-over-year growth of 47% and included a settlement payment of EUR 10.3m (USD 12m) received in connection with the termination of the collaboration with Genomic Health, Inc. for the development of the Oncotype DX Breast Recurrence Score® test on Idylla™.
- *Cost of goods sold* – Cost of goods sold increased to EUR 26.3m, 23% higher than in 2019 on the back of 31% higher commercial cartridge volumes and leading to an improved gross margin on products of 18% (2019: 12%).
- *OPEX* – Total operating expenses (excluding cost of sales) amounted to EUR 76.1m, an increase of 6% compared to EUR 72m in 2019. Cautious cost management triggered by the pandemic and prioritizing the development of the Idylla™ SARS-CoV-2 Test, led to the delay and carry-over of certain projects to 2021.
- *Operational cash flow* – Revenue growth, gross margin improvement and lower than planned operating expenses reduced the total cash flow used in operating and investing activities from EUR 59.7m in 2019 to EUR 43.3m in 2020.
- *Convertible bond* – Biocartis' debt was reduced by EUR 13.6m following the incentivized conversion of 10% of total outstanding Bonds. Biocartis paid a cash incentive of EUR 4.3m to the relevant bondholder as part of the transaction.
- *Cash position* - Biocartis' cash position as per 31 December 2020 amounted to EUR 123.7m compared to EUR 178.7m as per 31 December 2019.
- *Additional details* – See key figures 2020 below for more details on the 2020 financials.

POST-PERIOD EVENTS

- *Achievement 2020 key business objectives* – On 11 January 2021, Biocartis announced to have achieved its most recent key business objectives for 2020.

OUTLOOK

- *Commercial cartridge volume, Idylla™ installed base and cash position outlook:* see above.
- *Idylla™ test menu outlook:*

  1. ONCOLOGY MENU:
     - Colorectal cancer menu: US FDA submissions:
       - Subject to further feedback from US FDA interaction, the US FDA 510(k) submission of the Idylla™ MSI Test is expected in Q2 2021;
       - Motivated by a strong demand from partners and customers, Biocartis gave priority to the development of the Idylla™ SARS-CoV-2 Test and re-allocated resources accordingly. Consequently, Biocartis delayed the US FDA submission of the PMA (Pre-Market Approval) application for the Idylla™ RAS tests, which is now expected in Q4 2021.
     - Lung cancer menu:
       - RUO launch of the Idylla™ GeneFusion Assay is expected in Q1 2021;
       - RUO launch of the Idylla™ EGFR-BRAF+ Assay is expected in the course of 2022.
     - Breast cancer:
       - RUO launch of the Idylla™ ABC (Advanced Breast Cancer) Assay in collaboration with LifeArc is expected in H2 2022.

[22] As a result, an aggregate principal amount of EUR 15m of the Bonds was converted, and 1,163,575 new Ordinary Shares were issued by the Company

2. INFECTIOUS DISEASE PARTNER MENU:
   - Emergency Use Authorization ('EUA') with the US FDA of the Idylla™ SARS-CoV-2 Test is pending;
   - The Idylla™ SARS-CoV-2 Panel is in development and is expected in H1 2021 (CE-IVD);
   - 510(k) clearance with the US FDA of the SeptiCyte® RAPID on Idylla™ (Immunexpress) is pending.

Key figures 2020

The tables below show an overview of the key figures and a breakdown of operating income for 2020. A consolidated income statement, balance sheet, cash flow statement and statement of changes in shareholder equity of Biocartis Group NV is presented in the paragraph 'Financial information' at the end of this press release.

Key figures *(EUR 1,000)*	2020	2019	% Change
Total operating income	**55,559**	**37,732**	**47%**
Cost of sales	-26,284	-21,328	23%
Research and development expenses	-45,783	-39,844	15%
Sales and marketing expenses	-15,736	-18,011	-13%
General and administrative expenses	-14,618	-14,151	3%
Operating expenses	**-102,421**	**-93,334**	**10%**
Operational result	**-46,862**	**-55,602**	**-16%**
Net financial result	-15,768	-7,934	99%
Share in the result of associated companies	-532	-631	-16%
Income tax	228	99	130%
Net result	**-62,934**	**-64,068**	**-2%**
Cash flow from operating activities	-39,267	-54,254	-28%
Cash flow from investing activities	-4,007	-5,496	-27%
Cash flow from financing activities	-11,523	175,023	-107%
Net cash flow	**-54,797**	**115,273**	**-148%**
Cash and cash equivalents[1]	**123,668**	**178,725**	**-31%**
Financial debt	150,558	166,578	-10%

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

Operating income *(EUR 1,000)*	2020	2019	% Change
Collaboration revenue	**9,989**	**12,451**	**-20%**
Idylla™ system sales	7,085	6,220	14%
Idylla™ cartridge sales	24,808	18,004	38%
Product sales revenue	**31,893**	**24,224**	**32%**
Service revenue	1,246	769	62%
Total revenue	**43,128**	**37,444**	15%
Grants and other income	12,431	288	4216%
Total operating income	**55,559**	**37,732**	47%

Product sales revenue *(EUR 1,000)*	2020	2019	% Change
Commercial revenue	30,709	22,862	34%
Research & Development revenue	1,184	1,362	-13%
Total product sales revenue	**31,893**	**24,224**	**32%**

Income statement

Total operating income increased by EUR 17.8m or 47% to EUR 55.6m in 2020. Collaboration revenue amounted to EUR 10m, a decrease of 20% from 2019. R&D service revenue decreased by EUR 0.9m, license fees by EUR 0.7m and milestone revenue by EUR 0.9m. The collaboration with Genomic Health, Inc., a subsidiary of Exact Sciences Corporation, for the development of the Oncotype DX Breast Recurrence Score® test on Idylla™ was initially delayed and ultimately terminated because of the pandemic and a decision by Exact Sciences Corporation to shift priorities to other initiatives. Genomic Health, Inc. paid a settlement fee of EUR 10.3m, which is recorded as other income.

Revenue from product sales increased by 32% from EUR 24.2m in 2019 to EUR 31.9m in 2020, and included Idylla™ cartridge sales of EUR 24.8m (EUR 18.0m in 2019) and Idylla™ system revenues of EUR 7.1m (EUR 6.2m in 2019). Idylla™ cartridge sales included revenue from the sale of 230k commercial cartridges and of 13k R&D cartridges.

Services revenue amounted to EUR 1.2m in 2020 versus EUR 0.8m in 2019. Grant income increased to EUR 1.2m and related to the recognition of subsidies awarded in relation to the establishment of a second cartridge manufacturing line, and to the development of the Idylla™ SARS-CoV-2 Test and the Idylla™ GeneFusion Assay (RUO). In addition to the aforementioned settlement fee paid by Genomic Health, Inc., other income included the proceeds of a USD 1.0m loan received under the US Paycheck Protection Program ('PPP'), established as part of the Coronavirus Aid, Relief and Economic Security Act ('CARES Act'). On 29 October 2020 Biocartis submitted a loan forgiveness application for the full amount of the loan plus applicable interest to its lender. The lender approved the forgiveness application and recommended full forgiveness to the Small Business Administration ("SBA"). While no response has yet been received from the SBA, the Company believes its use of the loan proceeds met the conditions for forgiveness of the loan.

Total operating expenses amounted to EUR 102.4m in 2020, compared to EUR 93.3m in 2019. The increase was primarily driven by the cost of goods sold that increased by EUR 5m or 23% to EUR 26.3m. The increased cost of goods sold reflected the increase in commercial cartridge volume of 31%, partly offset by a reduction in the cartridge manufacturing cost, leading to an improvement of the gross margin on products to 18% (2019: 12%).

Total operating expenses, excluding the cost of goods sold, amounted to EUR 76.1m in 2020, compared to EUR 72.0m in 2019. The increase of EUR 4.1m resulted from increased R&D expenses, offset by lower spending in sales and marketing. The increase in R&D expenses was largely driven by the development of the Idylla™ SARS-CoV-2 Test. Sales and marketing expenses decreased by EUR 2.3m, in part because the pandemic significantly hampered normal commercial activities for a good part of the year. Travel was restricted and numerous conferences and events were cancelled due to global lockdown measures.

The operating loss for 2020 amounted to EUR 46.9m, an improvement of EUR 8.7m or 16% compared to 2019.

Net financial expenses amounted to EUR 15.8m in 2020 compared to EUR 7.9m, and included expenses associated with the Company's convertible bond, and commitment fees for the multiple purpose credit. In 2020, the interest expense on the convertible bond increased to EUR 6.0m compared to EUR 3.0m in 2019. The bond was issued in May 2019 and last year therefore only included one coupon. Similarly, the debt appreciation expense amounted to EUR 2.7m, compared to EUR 2.2m in 2019. The financial expenses also included a cash payment of EUR 4.3m in connection with the incentivized exercise of conversion rights in relation to EUR 15 million aggregate principal amount of Bonds (see details in the section balance sheet).

Balance sheet

In 2020, total assets reduced from EUR 268.3m in 2019 to EUR 210.5m. Non-current assets amounted to EUR 50.5m compared to EUR 53.7m, mostly because of the depreciation of intangible assets and property, plant and equipment (EUR 9.7m) and an impairment charge of EUR 1.6m, offset by investments of EUR 3.0m in new equipment. Financial assets amounted to EUR 2.9m (2019: EUR 2,4m) and included the investment in the China joint venture Wondfo-Cartis. In 2020, the Company invested an additional EUR 1.0m in the joint venture and recorded its share of EUR 0.5m in Wondfo-Cartis' net loss for the year.

End 2020, current assets amounted to EUR 160.0m, or EUR 54.4m less than in 2019. Cash and cash equivalents of EUR 123.7m reduced by EUR 55.1m. Accounts receivable increased by EUR 2.8m as a direct result of higher levels of cartridge sales towards the end of the year. Inventory increased by EUR 1.6m, mostly finished cartridges in order

to meet increased demand. Other receivables decreased by EUR 4.7m from EUR 8.6m in 2019, to EUR 4.0m in 2020, following the collection of a tax credit on research and development. Other current assets increased by EUR 0.7m.

End 2020, total financial debt amounted to EUR 150.6m compared to EUR 166.6m end of 2019. The reduction resulted from the incentivized conversion (EUR 13.6m) of part of the convertible bond and the net reduction of EUR 5.1m of lease obligations, offset by the appreciation of EUR 2.7m of the convertible bond. The incentivized conversion resulted from an agreement with a holder of part of the Company's EUR 150m 4% senior unsecured convertible Bonds regarding the exercise of conversion rights in relation to EUR 15 million aggregate principal amount of Bonds. The Company agreed to the incentivized conversion of the Bonds, as it allowed the Company to reduce the reported debt at attractive market conditions and to strengthen the shareholders' equity at a premium to the share price. The amount of the debt reduction in exchange for the new ordinary shares amounts to EUR 9.3m or EUR 8 per share, 70% higher than the closing price on 4 December 2020. The total debt reduction amounts to EUR 13.6m and was recorded as a credit to the share premium in the equity attributable to the owners of the Company.

Current liabilities end of 2020 amounted to EUR 29.4m, compared to EUR 23.2m end of 2019. Trade accounts payable increased by EUR 4.8m to EUR 13.9m. Other current liabilities included payroll related provisions and amounted to EUR 7.6m, representing an increase of EUR 1.5m compared to end 2019.

Cash flow statement

The cash flow from operating activities in 2020 amounted to EUR -39.3m, a decrease of EUR 15m from EUR -54.3m in 2019. The improvement resulted from reduced operating losses and a net reduction in working capital, partly offset by increased financial expenses.
The cash flow from investing activities in 2020 amounted to EUR –4.0m, EUR 1.5m less than in 2019, and included the capital contribution made to the China joint venture, capitalized Idylla™ systems as well as investments in laboratory and manufacturing equipment.
Financing activities used EUR 11.5m cash for the incentivized conversion of part of the convertible bond (EUR 4.3m), interest on the convertible bond (EUR 6.0m) and the scheduled repayment of lease and other obligations.

The total cash flow for 2020 amounted to EUR -54.8m compared to EUR 115.3m in 2019, which included EUR 198.8m net proceeds from the issuance of new ordinary shares (EUR 53.4m) and the convertible bond (EUR 145.5m).

Financial calendar 2021

- 1 April 2021 Publication 2020 annual report
- 22 April 2021 Q1 2021 Business Update
- 14 May 2021 AGM Biocartis Group NV
- 2 September 2021 H1 2021 results
- 10 November 2021 Q3 2021 Business Update

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 1 April 2021. The statutory auditor, Deloitte Bedrijfsrevisoren /Réviseurs d'Entreprises, represented by Nico Houthaeve, 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 2020	2019
Revenue		
Collaboration revenue	9,989	12,451
Product sales revenue	31,893	24,224
Service revenue	1,246	769
	43,128	**37,444**
Other operating income		
Grants and other income	12,431	288
Total operating income	**55,559**	**37,732**
Operating expenses		
Cost of sales	-26,284	-21,328
Research and development expenses	-45,783	-39,844
Sales and marketing expenses	-15,736	-18,011
General and administrative expenses	-14,618	-14,151
	-102,421	**-93,334**
Operating loss for the year	**-46,862**	**-55,602**
Financial expense	-14,569	-8,008
Other financial results	-1,199	74
Financial result, net	**-15,768**	**-7,934**
Share in the results of associates	-532	-631
Loss for the year before taxes	**-63,162**	**-64,167**
Income taxes	228	99
Loss for the year after taxes	**-62,934**	**-64,068**
Attributable to owners of the Company	-62,934	-64,068
Attributable to non-controlling interest		
Earnings per share		
Basic and diluted loss per share	-1.11	-1.14

Consolidated Balance Sheet

In EUR 000	As of 31 December 2020	2019
Assets		
Non-current assets		
Intangible assets	5,645	6,294
Property plant and equipment	40,098	43,421
Investment joint ventures	2,893	2,358
Other non-current receivables	426	13
Deferred tax assets	1,472	1,609
	50,534	**53,695**
Current assets		
Inventories	15,712	14,161
Trade receivables	13,488	10,695
Other receivables	3,960	8,640
Other current assets	3,155	2,407
Cash and cash equivalents*	123,668	178,725
	159,983	**214,628**
Total assets	**210,517**	**268,323**
Equity and liabilities		
Capital and reserves		
Share capital	-220,657	-220,668
Share premium	711,874	698,027
Share based payment reserve	6,102	4,670
Accumulated deficit	-455,343	-392,259
Other comprehensive income	-5,152	-5,291
Total equity attributable to owners of the Company	**36,824**	**84,479**
Non-current liabilities		
Provisions	0	49
Borrowings and lease liabilities	18,625	24,000
Convertible debt	125,260	136,158
Deferred income	363	461
	144,248	**160,668**
Current liabilities		
Borrowings and lease liabilities	6,673	6,420
Trade payables	13,907	9,070
Deferred income	1,278	1,595
Other current liabilities	7,587	6,091
	29,445	**23,176**
Total equity and liabilities	**210,517**	**268,323**

***** Cash and cash equivalents for 31 December 2020 include EUR 1.2 million restricted cash related to KBC Lease financing

Consolidated cash flow statement

	Years ended 31 December	
In EUR 000	**2020**	**2019**
Operating activities		
Loss for the year	**-62,934**	**-64,068**
Adjustments for		
Depreciation and amortization	9,748	9,719
Impairment losses	1,698	476
Income taxes in profit and loss	-228	-99
Financial result, net	15,768	7,934
Unrealized exchange gains/ losses	-1,030	0
Net movement in defined benefit obligation	-323	-150
Share of net profit of associate and a joint venture	532	631
Share based payment expense	1,432	1,225
Other	-80	37
Changes in working capital		
Net movement in inventories	-4,042	-3,858
Net movement in trade and other receivables and other current assets	1,449	-1,182
Net movement in trade payables & other current liabilities	6,333	1,507
Net movement in deferred income	-415	-960
	-32,092	**-48,788**
Interests paid	-7,172	-5,288
Taxes paid	-3	-178
Cash flow used in operating activities	**-39,267**	**-54,254**
Investing activities		
Interests received	13	8
Acquisition of property, plant & equipment	-3,005	-2,121
Acquisition of intangible assets	-15	-394
Acquisition of investment in a joint venture	-1,000	-2,989
Cash flow used in investing activities	**-4,007**	**-5,496**
Financing activities		
Proceeds from the issue of a convertible bond	0	145,438
Convertible bond – incentivized conversion	-4,306	0
Net proceeds from the issue of common shares, net of transaction costs	0	53,360
Repayment of borrowings	-7,167	-23,738
Bank charges	-50	-37
Cash flow from financing activities	**-11,523**	**175,023**
Net increase / (decrease) in cash and cash equivalents	**-54,797**	**115,273**
Cash and cash equivalents at the beginning of the year	178,725	63,539
Effects of exchange rate changes on the balance of cash held in foreign currencies	-260	-87
Cash and cash equivalents at the end of the year*	**123,668**	**178,725**

* Including EUR 1.2m 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 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 loss				***-5,223***	***-64,181***	***-69,404***	***-69,404***
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**
Balance as at 1 January 2020	**-220,668**	**698,027**	**4,670**	**-5,291**	**-392,259**	**84,480**	**84,480**
Loss for the period					-62,934	-62,934	-62,934
Re-measurement gains and losses on defined benefit plan				139		139	139
Consolidation translation difference					-150	-150	-150
Total comprehensive income				***139***	***-63,084***	***-62,945***	***-62,945***
Share-based payment expense			1,432			1,432	1,432
Convertible bond - incentivized conversion	11	13,847				13,857	13,857
Other						0	0
Balance as at 31 December 2020	**-220,657**	**711,875**	**6,102**	**-5,152**	**-455,343**	**36,824**	**36,824**

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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, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as for SARS-CoV-2 and sepsis. 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.