PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS ANNOUNCES 2021 RESULTS AND 2022 OUTLOOK

Mechelen, Belgium, 24 February 2022 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its operational highlights and financial results for 2021, prepared in accordance with IFRS as adopted by the European Union as well as selected post period events and its outlook for 2022.

Commenting on the 2021 results and 2022 guidance, Herman Verrelst, Chief Executive Officer of Biocartis, said: "*2021 has proven to be an eventful year. A fire and a shortage of raw cartridge materials significantly troubled our cartridge manufacturing, but our teams managed through the situation extremely well and minimized impact to our loyal customers. We were undeniably held back in our ambition to grow much faster. Nonetheless, we were able to deliver a robust 40% volume growth in commercial cartridges for the full year and built out an installed base of close to 2,000 Idylla™ instruments, while exceeding EUR 50m in revenue from core activities. Simultaneously, 2021 was a year of menu expansion: we launched two new tests and signed new partnerships, including the partnership in melanoma with SkylineDx for high-value test content on Idylla™. We also made important progress in the US, where we submitted our first oncology assay with the US FDA and our partner Immunexpress obtained US FDA 510(k) clearance for SeptiCyte® RAPID on Idylla™. Finally, the continued positive feedback from our customers and new studies re-confirmed the value of Idylla™ to patients. These growth drivers are all important as we pursue our mission to bring more, better and faster molecular diagnostics to patients across the globe, through the offering of tests across the entire spectrum of cancer care, from prognosis to surveillance, and in infectious diseases. Looking ahead at 2022, we will continue to grow revenues and lay a solid foundation for profitable growth as we scale our manufacturing capabilities and significantly reduce the cash burn while developing, together with partners, new high value tests on Idylla™.*"

KEY MESSAGES 2021 RESULTS

Total operating income:

- Revenue from product sales and Idylla™ system services amounted to EUR 42.2m, a year-over-year increase of 27%
- Total revenue of EUR 48.3m, up 12% from 2020
- Total operating income of EUR 54.9m compared to EUR 55.6m in 2020

Commercial cartridges:

- Growth of the commercial cartridge volume by 40% to 323k cartridges
- Strong growth in oncology of 25% year-on-year, particularly in European and distributor markets[1]. US volumes were stable as COVID-19 testing volumes declined, while a strong increase of the Average Sales Price (ASP) led to double-digit growth of oncology revenue
- Consistent demand for the Idylla™ SARS-CoV-2 testing products[2], shifting from the US to Europe compared to 2020

Installed base:

- 331 net new Idylla™ instruments placed in 2021
- Global installed base of 1,912 Idylla™ instruments as at 31 December 2021

Partnerships:

- New partnership agreement with SkylineDx for the development of the Merlin Assay on Idylla™, aimed at predicting a patient's risk of nodal metastasis in melanoma
- Expanded partnership with AstraZeneca to improve access to rapid and easy-to-use Idylla™ EGFR testing products at selected hospital sites in European and global distributor markets
- Post the reporting period, on 8 February 2022, Biocartis announced the signing of an agreement with Ophiomics which will initially focus on the commercialization of HepatoPredict™, a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation.

1 Defined as the world excluding European direct markets, US, China and Japan
2 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

Idylla™ test menu:

- Launch of the Idylla™ GeneFusion Assay (RUO[3]) as a rapid lab workflow solution for gene fusion testing of ALK, ROS1, RET, NTRK 1/2/3, as well as MET exon 14 skipping which is increasingly used in research related to multiple cancer types including lung cancer, thyroid cancer and others
- First oncology assay US FDA submission with the 510(k) submission[4] of the Idylla™ MSI Test[5]
- Launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD) which detects, in one single cartridge, SARS-CoV-2, Flu A/B and RSV[6] nucleic acids, with results in approximately 90 minutes
- Received US FDA 510(k) clearance for SeptiCyte® RAPID[7] on Idylla™[8] (CE-IVD, US FDA 510(k)), developed under the partnership with Immunexpress[9]

China & Japan commercialization:

- In China, submission of the Idylla™ Instrument and Console with the China NMPA[10] completed and initial feedback received from the NMPA regulatory agency
- In Japan, Nichirei Biosciences submitted in Q4 2021 the registration applications of the Idylla™ MSI Test, the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test with the PMDA regulatory agency

Cash position:

- 2021 was a year of exceptional investment, including the upgrade of the menu to comply with the new IVDR (In Vitro Diagnostics Regulation[11]) and various initiatives to expand and diversify the test menu and to further improve our technological capabilities. The cash burn for the year amounted to EUR 70.1m and was in line with expectations, except for the insurance claim for fire damages of EUR 4.6m, of which EUR 3.8m is yet to be collected
- Cash and cash equivalents amounted to EUR 53.5m at 31 December 2021. The cash position included EUR 6.0m drawn on short-term credit facilities

2022 OUTLOOK

In 2022, the Company will continue to focus on driving profitable growth and expects to:

- Grow product revenue by 24-36% to between EUR 50m and EUR 55m
- Achieve a gross margin on product sales of between 25% and 30%
- Reduce the operating cash burn (EBITDA plus capital expenditure) with EUR 9.5m-EUR 13.5m to between EUR 47m-EUR 43m

Biocartis will host a conference call with live webcast presentation today at 14:30 CET / 13:30 BST (UK) / 08:30 EST (US) to discuss the full year 2021 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, followed by the confirmation code 9959967. 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* – The number of commercial cartridges sold in 2021 grew by 40% to 323k from 230k in 2020. Oncology volumes were driven by a strong customer demand in all regions, resulting in +96% growth in the first half of 2021. Cartridge volumes also included a continued contribution from the Idylla™ SARS-CoV-2 Test that was comparable to the second half of 2020. Nevertheless, the global supply of reagents was already disrupted in the first half of 2021, and the fire at one of the Biocartis facilities at the end of July 2021 only added to a constrained production capacity on the Company's high-throughput manufacturing line (ML2). The production on the ML2 line had to be halted for two months and the replenishment of raw materials restrained the growth of the commercial cartridge volume for the full year to 40% as customer demand could only be partly met. The pace at which new Idylla™ instruments were installed equally slowed down because of insufficient cartridge supply needed to onboard new customers. Net new placements of 331 instrument were nevertheless in line with the stated objective for the year and strengthened the global installed base to 1,912 Idylla™ instruments. The ASP of commercial cartridges in 2021 amounted to EUR 96. As expected, the ASP for Idylla™ oncology assays of EUR 105 was diluted by lower

3 Research Use Only, not for use in diagnostic procedures
4 A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). A 510(k) or Premarket Notification (PMN) with the US FDA is required when introducing a device into commercial distribution for the first time. Source: https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances, last consulted on 4 January 2022
5 For use as an in vitro diagnostic device intended for the identification of microsatellite instability (MSI) status in colorectal (colon) cancer (CRC) to aid in the differentiation between sporadic CRC and potential Lynch syndrome
6 Respiratory Syncytial Virus
7 SeptiCyte® RAPID is developed by Immunexpress Inc in collaboration with Biocartis. Biocartis has the exclusive distribution rights for the EU. The test is not available in all countries. Availability to be checked with a local Biocartis representative
8 The Idylla™ Instrument and Idylla™ Console have been exempted by the US FDA since 12 July 2017 and as such are not subject to 510(k) notification requirements prior to being placed on the US market for in vitro diagnostic use with US FDA approved or cleared assays
9 Immunexpress Pty Ltd ('Immunexpress') is a Seattle-based molecular diagnostic company focused on improving outcomes for suspected sepsis patients
10 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
11 Replacing the current Directive 98/79/EC on in vitro diagnostic medical devices from 26 May 2022

prices for the Idylla™ SARS-CoV-2 Test as compared to 2020. Sales related to the Idylla™ SARS-CoV-2 products amounted to 14% of total revenues in 2021.

- *Europe* – Sales in Europe exceeded expectations with a year-over-year overall growth of 69%, driven by continued high growth in oncology as well as a strong sale of the Idylla™ SARS-CoV-2 tests to new, large customers in Norway, the UK and Italy.
- *US* – In the US, the commercialization of Idylla™ products to new customers has not entirely normalized across the country. The Company took the opportunity to restructure its US commercial operations, putting in place new sales leadership to reorientate, expand and retrain its commercial staff. This restructuring, in combination with the overall market environment, temporarily paused new Idylla™ instrument placements and cartridge volumes in oncology stabilized. However, the ASP significantly increased, leading to robust double-digit growth of oncology cartridge revenue. As expected, demand for the Idylla™ SARS-CoV-2 Test reduced from the strong demand in the fourth quarter of 2020 which was characterized by a capacity constrained testing market.
- *Distributor markets* – Of all geographies, in oncology, the distributor markets grew the fastest 2021. Except for a few smaller countries, demand bounced back strongly from 2020, including in Latin-America that was hit hard by the pandemic. Initial commercial sales were accomplished in Russia and Taiwan, following product registrations in these markets in Q1 2021[12]. Additionally, further to new UK regulations, market authorizations for the Idylla™ platform and oncology assays have been granted by the UK MHRA regulatory agency in December 2021. Furthermore, in November 2021, the Idylla™ SARS-CoV-2 Test was submitted with the UK CTDA and the registration is expected in Q1 2022. Finally, in December 2021, Kazakhstan granted the registration of the Idylla™ platform and oncology assays.
- *Japan commercialization* – After successfully completing the clinical performance evaluation studies in Japan, Biocartis' partner Nichirei Biosciences submitted in Q4 2021 the registration applications of the Idylla™ MSI Test, the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test with the Japanese PMDA agency. Initial Idylla™ assay registrations in Japan are expected earliest end of 2022.
- *China commercialization* – Following the submission of the Idylla™ Instrument and Console with the China NMPA early 2021, Biocartis received initial feedback. The set-up of local manufacturing capability is nearing completion. Initial Idylla™ assays registrations in China are however not expected before late 2023 due to changed regulatory requirements regarding clinical validation.

TEST MENU AND PARTNERSHIP HIGHLIGHTS

- Oncology*:* In 2021, Biocartis progressed both in its test menu and partnerships:
  - *Idylla™ GeneFusion Assay* – In March 2021, Biocartis launched the Idylla™ GeneFusion Assay (RUO) as a rapid lab workflow solution for gene fusion testing of ALK, ROS1, RET, NTRK 1/2/3, as well as MET exon 14 skipping which is increasingly used in research related to multiple cancer types including lung cancer, thyroid cancer and others. A CE-IVD launch of the Idylla™ GeneFusion Assay is expected in 2022 (see 'menu outlook');
  - *510(k) submission Idylla™ MSI Test* – In April 2021, Biocartis announced its first US FDA submission of an oncology assay with the 510(k) submission of its Idylla™ MSI Test for use as an in vitro diagnostic device intended for the identification of microsatellite instability (MSI) status in colorectal (colon) cancer (CRC) to aid in the differentiation between sporadic CRC and potential Lynch syndrome;
  - *Partnership SkylineDx* – Also in April 2021, Biocartis announced the signing of a partnership agreement with SkylineDx which targets the development of their novel proprietary test, the Merlin Assay, on the Idylla™™ platform, which is aimed at predicting a patient's risk of nodal metastasis in melanoma. The CE-IVD launch of the manual kit of the Merlin Assay in collaboration with SkylineDx for commercialization in Europe by Biocartis is expected this year (see 'outlook' below);
  - *Partnership AstraZeneca* – In May 2021, Biocartis announced its expanded partnership with AstraZeneca to improve access to rapid and easy-to-use Idylla™ EGFR testing products at selected hospital sites in European and global distributor markets;
  - *VLAIO grant* – Also in May 2021, Biocartis announced the EUR 1.4 million grant it received from VLAIO, the Flanders organization for Innovation & Entrepreneurship, for the ongoing development of a highly innovative technology to be deployed on the Idylla™ platform aimed at enabling the off-line customization of the Idylla™ cartridge;
  - *Partnership Ophiomics* – Post the reporting period, on 8 February 2022, Biocartis announced it had signed an agreement with Ophiomics, a Lisbon (Portugal) based biotech company developing a precision medicine portfolio focused on liver cancer. The collaboration will initially focus on the commercialization of HepatoPredict™, a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation. HepatoPredict™ will be distributed by Biocartis in

12 During Q1 2021, the Idylla™ platform, the Idylla™ BRAF Mutation Test (CE-IVD) and the Idylla™ EGFR Mutation Test (CE-IVD) completed registration in Russia, and the Idylla™ MSI Test (CE-IVD) completed registration in Taiwan, as such expanding the commercial footprint for Biocartis' IVD medical devices. Post the reporting period, additional registrations were also completed in Taiwan

Europe as a manual kit mainly addressing centralized expert laboratories, and the test may later be translated into a version on the Idylla™ platform;
  - *Partnership GeneproDx* – RUO launch of the ThyroidPrint© on Idylla™ in collaboration with GeneproDx is expected in 2022 (see 'outlook' below);
  - *Partnership LifeArc* – RUO launch of the Idylla™™ ABC (Advanced Breast Cancer) Assay in collaboration with LifeArc is expected in 2022 (see 'outlook' below).
- Infectious diseases: In 2021 Biocartis further strengthened its infectious disease menu:
  - *Launch Idylla™ SARS-CoV2/Flu/RSV Panel* – In September 2021, Biocartis announced the launch of its Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD) which detects, in one single cartridge, SARS-CoV-2, Flu A/B and RSV nucleic acids, with results in approximately 90 minutes;
  - *510(k) clearance for SeptiCyte® RAPID* – In November 2021, Biocartis announced the US FDA granted 510(k) clearance for SeptiCyte® RAPID (CE-IVD, US FDA 510(k)) which runs on the Idylla™ platform[13] and was developed under the partnership with Immunexpress. The SeptiCyte® RAPID is a fully automated, rapid host-response test[14] that distinguishes sepsis from infection negative systemic inflammation in patients suspected of sepsis, providing actionable results in approximately 1 hour, enabling physicians to optimize patient management decisions. In 2022, SeptiCyte® RAPID PLUS, an assay based on SeptiCyte® RAPID that can also distinguish between bacterial and viral infections, is expected to be launched as a CE-IVD (see 'outlook' below).

- Idylla™ performance data*:* During 2021, 34 new Idylla™ papers were published, bringing the total number of Idylla™ papers published end of 2021 to 123. Idylla™'s excellence along with the performance of Idylla™'s EGFR[15] testing solutions was emphasized through several studies and abstracts:
  - In February 2021, Biocartis announced the publication of two studies[16] by Memorial Sloan Kettering Cancer Center ('MSKCC', New York, US) on the use of Biocartis' Idylla™ EGFR Mutation Assay (RUO) as a rapid first-line testing method before using next-generation sequencing (NGS). Both studies concluded that Idylla™ EGFR testing enables rapid assessment of the most common EGFR mutations with low sample input, even on different sample types, without compromising subsequent more comprehensive NGS testing[17];
  - In November 2021, Biocartis announced the publication of a study[18] which concluded that the Idylla™ platform contributes to improving patient management decisions for patients with non-small cell lung cancer (NSCLC) through the faster screening of EGFR mutations.

ORGANIZATIONAL AND OPERATIONAL HIGHLIGHTS

- *Fire incident* – During the night of 30 July 2021, a fire broke out at one of the warehouse facilities in Mechelen (Belgium), causing the loss of finished products and raw materials as well as the temporary unavailability of the high-throughput ML2 manufacturing line. Cartridge manufacturing was suspended on the ML2 line for nearly two months and the time needed to replenish available stocks of raw materials caused order backlogs across a variety of Idylla™ assays in the second half of the year.
- *Cartridge manufacturing* – Transfer of the Idylla™ EGFR Mutation Test (CE-IVD) to the ML2 line was completed during H1 2021, as such concluding the transfer of Biocartis' main oncology assays to the fully automated ML2 line. This is a key driver of cost optimizations within the Company's cartridge manufacturing activities and was demonstrated by a 33% gross margin on assays produced on the ML2 line, despite lower-than-expected production volumes on this line throughout 2021. The Idylla™ SARS-CoV-2 Test and Idylla™ SARS-CoV-2/Flu/RSV Panel are being transferred to the ML2 line in the first half of 2022 and this is expected to further contribute to absorbing fixed manufacturing costs awaiting full capacity utilization of the ML2 line that can produce up to 1m tests annually.
- *Ordinary and Extraordinary General Shareholders' Meetings* – During the ordinary shareholders' meeting held on 14 May 2021, the shareholders of the Company approved all items on the agenda of the annual shareholders' meeting including the approval of the remuneration policy and report, the re-appointment of Herman Verrelst, Chief Executive Officer of the Company, as director of the Company for a term of four years, and the re-appointment of Christian Reinaudo as independent director of the Company for a term of three years. Since there was no deliberation and voting on the items on the agenda of the extraordinary shareholders' meeting because the attendance quorum for such meeting was not reached, Biocartis convened a second extraordinary shareholders' meeting with the same agenda items, for which no attendance quorum applied. During this extraordinary general shareholders' meeting held on 4 June 2021, the shareholders of the Company approved all agenda items, including the renewal of the

13 The Idylla™ Instrument and Idylla™ Console have been exempted by the US FDA since 12 July 2017 and as such are not subject to 510(k) notification requirements prior to being placed on the US market for in vitro diagnostic use with US FDA approved or cleared assays
14 Host-response based tests focus on measuring biomarkers that are indicative of the response of a patient's immune system to an infection rather than measuring pathogens that are the cause of the infection
15 EGFR or 'Epidermal growth factor receptor' mutations are the second most common oncogenic driver in non-small cell lung cancer (NSCLC)
16 Arcila ME, Yang S-R, Momeni A, Mata DA, Salazar P, Chan R, Elezovic D, Benayed R, Zehir A, Buonocore DJ, Rekhtman N, Lin O, Ladanyi M, Nafa K, Ultra-Rapid EGFR Mutation Screening Followed by Comprehensive Next-Generation Sequencing: A Feasible, Informative Approach for Lung Carcinoma Cytology Specimens with a High Success Rate., JTO Clinical and Research Reports (2020), doi: https://doi.org/10.1016/j.jtocrr.2020.100077., available online 18 July 2020; Arcila ME et al., Rapid EGFR Mutation Detection Using the Single-Institution Experience of 1200 Cases Analyzed by an In-House Developed Pipeline and Comparison with Concurrent Next-Generation Sequencing Results Idylla™ Platform, J Mol Diagn 2020, Published on 23 December 2020, 1-12; https://doi.org/10.1016/j.jmoldx.2020.11.009
17 Which can be useful in cases where EGFR mutation results were negative and further testing is needed
18 Petiteau, C.; Robinet-Zimmermann, G.; Riot, A.; Dorbeau,M.; Richard, N.; Blanc-Fournier, C.; Bibeau, F.; Deshayes, S.; Bergot, E.; Gervais, R.; et al. Contribution of the Idylla™ System to Improving the Therapeutic Care of Patients with NSCLC through Early Screening of EGFR Mutations. Curr. Oncol. 2021, 28, 4432–4445. https://doi.org/10.3390/curroncol28060376, published 3 November 2021

authorization to the Board of Directors to increase the share capital of the Company by up to 75% of the then current amount of the share capital, during a period of five years.

FINANCIAL HIGHLIGHTS

- *Product sales revenues* – Total product sales increased to EUR 40.5m in 2021, a 27% increase from EUR 31.9m in 2020.
  - Income from cartridge sales amounted to EUR 31.6m and grew 27% year-over-year. Total cartridge volume of 326k cartridges (+34%) included 323k commercial cartridges (+40%) and 4k R&D cartridges (-69%). As expected, the commercial ASP of EUR 105 in oncology was diluted by the lower pricing of the Idylla™ SARS-CoV-2 Test, resulting in an overall commercial ASP of EUR 96 compared to EUR 102 in 2020. Revenue generated by sales of the Idylla™ SARS-CoV-2 products represented 14% of total revenue.
  - The 331 net new installations of the Idylla™ platform was relatively consistent with 2020 (335), but the revenue increased by 25% to EUR 8.9m. The increase was primarily driven by a higher ASP while the proportion of capital sales in total placements of 51% remained comparable (2020: 49.5%).
- *Total operating income* – Total operating income amounted to EUR 54.9m in 2021 compared to EUR 55.6m in 2020. In addition to grant income of EUR 2.0m, other income included the insurance claim of EUR 4.6m for damages caused by the fire, including the impact of lost revenue. 2020 included a one-off settlement payment of EUR 10.3m (USD 12.0m) 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™. The continued growth of the installed base led to a 39% increase in income from system servicing (2021: EUR 1.7m; 2020: EUR 1.2m). Income from collaborations decreased from EUR 10.0m in 2020 to EUR 6.1m in 2021, in the absence of licensing fees (2020: EUR 1.8m) and because of lower R&D services provided to partners. Despite a growing number of collaborations, the recognition of revenue is strongly depending on and varying with the specific stage of the various development projects.
- *Cost of goods sold* – Cost of goods sold increased to EUR 33.9m, 29% higher than in 2020, driven by 40% higher commercial cartridge volumes. Despite higher cartridge volumes, the gross margin on product sales amounted to 16% in 2021 compared to 18% in 2020. The utilization of the high-throughput automated manufacturing line ML2 was significantly lower than planned as a direct result of the fire and constrained supply of certain reagents. During the forced two-month production stop of the ML2 line, the production of certain assays was transferred to the ML1 line to preserve customer supply as much as possible. The manufacturing capacity on the ML1 line is however significantly lower and the manufacturing cost significantly higher than on the ML2 line. However, even with low production volumes on the ML2 line throughout 2021, the gross margin on assays produced on the ML2 line already reached 33%, clearly demonstrating the Company's ability to scale with unhindered and increasing production on the ML2 line. Additionally, the gross margin also slightly decreased because of lower pricing of the Idylla™ SARS-CoV-2 test products in 2021. Both tests are being transferred to the ML2 line in the first half of 2022 and will generate a contribution to the absorption of fixed manufacturing costs awaiting full capacity utilization of the ML2 line that can produce up to 1m tests annually.
- *OPEX* – Total operating expenses (excluding cost of sales) amounted to EUR 83.6m included a write-off of EUR 3.2m on raw materials and cartridges lost in the fire. Excluding the impact of the fire, operating expenses increased by EUR 4.2m or 6% from EUR 76.1m in 2020. As announced at the beginning of 2021, the Company allowed for exceptional investment in menu expansion and diversification. The pandemic and prioritizing the development of the Idylla™ SARS-CoV-2 Test in 2020 also led to the delay and carry-over of certain projects into 2021.
- *Operational cash flow* – Lower total operating income, higher operating expenses and the outstanding collection of most of the fire insurance claim caused the total cash flow used in operating and investing activities to increase from EUR 43.3m in 2020 to EUR 69.5m in 2021.
- *Cash position* - Biocartis' cash position as per 31 December 2021 amounted to EUR 53.5m and included EUR 6.0m drawn-down on short-term credit facilities. Biocartis intends to significantly reduce its cash burn in 2022 and is investigating multiple options to strengthen its cash position in the course of 2022.
- *Additional details* – See key figures 2021 below for more details on the 2021 financials.

POST-PERIOD EVENTS

- *Achievement 2021 key business objectives* – On 10 January 2022, Biocartis announced it had achieved its most recent key business objectives for 2021.
- *Large UK study EGFR testing* – On 25 January 2022, Biocartis announced the publication of a large new study[19] comparing the difference in turnaround time between in-house automated rapid PCR[20]-based EGFR analysis and Next-Generation Sequencing (NGS) by an external laboratory, with a focus on patient health outcome. The study concluded that a dual PCR and NGS testing strategy for stage IV non-squamous, non-small cell lung cancer (NSCLC)

19 A. Finall et al., J Clin Pathol . 2022 Jan 18;jclinpath-2021-207987. doi: 10.1136/jclinpath-2021-207987. Online ahead of print
20 Polymerase Chain Reaction or PCR is a fast and inexpensive technique used to amplify or copy small segments of DNA and used to detect genetic material such as biomarkers that drive cancer

patients has the potential to improve care and survival outcomes by providing access to the right test at the right time.

- *Partnership with Ophiomics* – On 8 February 2022, Biocartis announced it had signed an agreement with Ophiomics, a Lisbon (Portugal) based biotech company developing a precision medicine portfolio focused on liver cancer. The collaboration will initially focus on the commercialization of HepatoPredict™, a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation. HepatoPredict™ will be distributed by Biocartis in Europe as a manual kit mainly addressing centralized expert laboratories, and the test may later be translated into a version on the Idylla™ platform.

OUTLOOK

- *Commercial cartridge volume, Idylla™ installed base and cash position outlook:* see above.
- *Idylla™ test menu outlook:* In 2022, Biocartis expects to launch the following assays and regulatory milestones:
  1. ONCOLOGY MENU:
     - Subject to further feedback from US FDA interaction, US FDA 510(k) clearance of the Idylla™ MSI Test
     - CE-IVD launch of the Idylla™ GeneFusion Assay
     - RUO launch of the Idylla™ ABC (Advanced Breast Cancer) Assay in collaboration with LifeArc
     - CE-IVD launch of the manual kit of the Merlin Assay in collaboration with SkylineDx for commercialization in Europe by Biocartis
     - RUO launch of the ThyroidPrint© on Idylla™ in collaboration with GeneproDx
  2. INFECTIOUS DISEASE PARTNER MENU:
     - CE-IVD launch of the SeptiCyte® RAPID PLUS, an assay based on SeptiCyte® RAPID that can also distinguish between bacterial and viral infections

Key figures 2021

The tables below show an overview of the key figures and a breakdown of operating income for 2021. 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)*	2021	2020	% Change
Total operating income	**54,898**	**55,559**	**-1%**
Cost of sales	-33,922	-26,284	29%
Research and development expenses	-48,054	-45,783	5%
Sales and marketing expenses	-16,763	-15,736	7%
General and administrative expenses	-15,560	-14,618	6%
Other expenses	**-3,244**	**-**	
Operating expenses	**-117,543**	**102,421**	**15%**
Operational result	**-62,645**	**-46,862**	**34%**
Net financial result	-8,411	-15,768	-47%
Share in the result of associated companies	-659	-532	24%
Income tax	243	228	7%
Net result	**-71,472**	**-62,934**	**14%**
Cash flow from operating activities	-65,716	-39,267	64%
Cash flow from investing activities	-3,748	-4,007	22%
Cash flow from financing activities	-1,204	-11,523	-90%
Net cash flow	**-70,668**	**-54,797**	**29%**
Cash and cash equivalents[1]	**53,522**	**123,668**	**-57%**
Financial debt	154,162	150,558	2%

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

Operating income *(EUR 1,000)*	2021	2020	% Change
Collaboration revenue	**6,053**	**9,989**	**-39%**
Idylla™ system sales	8,868	7,085	25%
Idylla™ cartridge sales	31,618	24,808	27%
Product sales revenue	**40,486**	**31,893**	**27%**
Service revenue	1,730	1,246	39%
Total revenue	**48,269**	**43,128**	12%
Grants and other income	6,629	12,431	-47%
Total operating income	**54,898**	**55,559**	-1%

Product sales revenue *(EUR 1,000)*	2021	2020	% Change
Commercial revenue	40,351	30,709	31%
Research & development revenue	135	1,184	-89%
Total product sales revenue	**40,486**	**31,893**	**27%**

Income statement

Total operating income decreased by EUR 0.7m to EUR 54.9m in 2021. Collaboration revenue amounted to EUR 6.0m, a decrease of 39% from 2020. License fees amounted to EUR 0.2m compared to EUR 1.8m in 2020, while R&D service revenue decreased by EUR 2.3m from EUR 8.2m in 2020 to EUR 5.9m in 2021.

Revenue from product sales increased with EUR 8.6m or 27% from EUR 31.9m in 2020 to EUR 40.5m in 2021. Both Idylla™ cartridge sales and Idylla™ system revenues increased to EUR 31.6m and EUR 8.9m, respectively (2020: EUR 24.8m and EUR 7.1m). Idylla™ cartridge sales included revenue from the sale of 323k commercial cartridges and of 4k R&D cartridges. Services revenue amounted to EUR 1.7m in 2021 versus EUR 1.2m in 2020, a 39% increase in line with the growing installed base of Idylla™ systems.

Grant income increased to EUR 2.0m in 2021, an increase of EUR 0.9m compared to EUR 1.2m in 2020, and related to the recognition of subsidies awarded in relation to the establishment of a second cartridge manufacturing line, to the development of the Idylla™ SARS-CoV-2 Test and the Idylla™ GeneFusion Assay (RUO), as well as the highly innovative technology to be deployed on the Idylla™ platform aimed at enabling the off-line customization of the Idylla™ cartridge. Other income included a EUR 4.6m insurance claim for damages caused by the fire on 30 July 2021. In 2020, other income included a settlement fee of EUR 10.3m paid by Genomic Health (Exact Sciences) following the termination of the development of the Oncotype DX Breast Recurrence Score® test on Idylla™, and the proceeds of a USD 1.0m loan received under the US Paycheck Protection Program ('PPP'), that was entirely forgiven.

Total operating expenses amounted to EUR 117.5m in 2021, compared to EUR 102.4m in 2020. Within operating expenses, the cost of goods sold increased by EUR 7.6m from EUR 26.3m in 2020 to EUR 33.9m in 2021 as commercial cartridge volumes increased by 40%. The resulting gross margin on product sales amounted to 16% compared to 18% in 2020. The decrease of the gross margin resulted from a lower ASP on the Idylla™ SARS-CoV-2 Test compared to 2020. Prices for COVID-19 testing reduced as expected because the testing capacity was expanded. The lower than planned utilization of the high-throughput automated manufacturing line ML2 also caused gross margin on cartridges to be lower than expected. Production on the ML2 line was constrained because of the shortage of reagents during the first half of the year and because of the forced 2-month production stop after the fire on 30 July 2021. The production of certain assays was transferred to the ML1 line to preserve customer supply as much as possible, but the manufacturing capacity on the ML1 line is significantly lower and the manufacturing cost significantly higher than on the ML2 line.

Total operating expenses, excluding the cost of goods sold, increased by EUR 7.5m from EUR 76.1m in 2020 to EUR 83.6m in 2021 (including EUR 3.2m inventory write-off from the fire). R&D expenses amounted to EUR 48.1m, an increase of EUR 2.3m compared to 2020. In 2020, several projects were delayed and carried over to 2021. Furthermore, the Company invested in further menu expansion and diversification. These investments included the preparatory work to apply for conformity of our CE-IVD assays under the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) that establishes a new regulatory framework for in vitro diagnostic medical devices. In addition to ongoing

projects to broaden the core oncology test menu on Idylla™ and upgrading the functionality of the Idylla™ platform, the Company also developed and launched its Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD) which detects, in one single cartridge, SARS-CoV-2, Flu A/B and RSV nucleic acids. Finally, R&D included the continued investment in the transfer of assays from the ML1 line to the ML2 line as well as continuous improvement projects with a view to optimize the manufacturing output. S&M and G&A expenses increased by EUR 1.0m and EUR 0.9m, respectively, reflecting inflation, the restructuring of the US commercial team and increased facility costs. Other expenses of EUR 3.2m entirely related to the write-off of materials and finished products lost in the fire.

The operating loss for 2021 amounted to EUR 62.6m compared to EUR 46.9m in 2020. Excluding the impact of the settlement fee of EUR 10.3m paid by Exact Sciences in 2020, the increase of EUR 5.5m resulted from higher and exceptional investment in various development projects and the build-out of the commercial and organizational infrastructure.

Net financial expenses in 2021 amounted to EUR 8.4m of which EUR 8.3m related to the outstanding balance of EUR 135m on the convertible bond. In 2020, net financial expenses amounted to EUR 15.8m, which included EUR 9.0m interest and debt appreciation expense and 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 the convertible bonds.

Balance sheet

On 31 December 2021, total assets amounted to EUR 142.5m, compared to EUR 210.5m at the end of 2020. Non-current assets amounted to EUR 47.4m, compared to EUR 50.5m, mostly because of the net reduction of intangible assets and property, plant, and equipment (EUR 3.5m) and an impairment charge of EUR 1.4m, offset by an investment in a convertible note issued by GeneproDx in lieu of payment for the technology access fee due under the collaboration agreement. Financial assets amounting to EUR 2.3m (2020: EUR 2.9m) included the investment in the China joint venture Wondfo-Cartis, which was adjusted by EUR 0.7m for our share in the loss for the year.

End 2021, current assets amounted to EUR 95.1m, a decrease of EUR 64.9m from EUR 160.0m in 2020, mainly because of the reduction in cash and cash equivalents of EUR 70.1m. Trade receivables increased by EUR 2.7m, an increase of 20% year-on-year which mainly resulted from the 27% increase in product revenues compared to 2020. Inventory only increased by EUR 0.4m. Stock levels of finished cartridges and raw materials decreased as a result of the fire and the insufficient supply of reagents to deliver all open customer orders. On the other hand, the inventory of Idylla™ instruments increased awaiting the availability of sufficient cartridges to onboard new customers. Other receivables increased by EUR 2.7m from EUR 4.0m in 2020 to EUR 6.6m in 2021 and included EUR 3.8m of uncollected insurance claims for fire damages. Other current assets decreased by EUR 0.4m.

On 31 December 2021, total financial debt amounted to EUR 154.2 compared to EUR 150.6m end of 2020. The increase resulted from the appreciation of the convertible bond by EUR 2.9m and a EUR 6.0m draw-down on working capital facilities, offset by the scheduled repayment of leasing obligations of EUR 5.2m.

Trade payables decreased by EUR 2.3m to EUR 11.6m in 2021. Other current liabilities increased by EUR 0.9m to EUR 8.4m, partly related to VAT payable as a result of Brexit and increased payroll related provisions as the number of employees (FTE or Full Time Equivalent) increased from 366 in 2020 to 407 in 2021.

Cash flow statement

The cash flow from operating activities in 2021 increased by EUR 26.4m to EUR 65.7m compared to EUR 39.3m in 2020. Apart from the collection of the EUR 10.3m settlement fee paid by Exact Sciences, 2020 was characterized by more cautious spending because of the pandemic and several projects being carried over to 2021, causing the operating loss to increase by EUR 15.8m to EUR 62.6m in 2021. Investments in working capital amounted to EUR 9.6m, a year-on-year increase of EUR 13m, in line with the expansion of our commercial activity and a significantly higher amount of trade payables at the end of last year. Furthermore, EUR 3.8m of losses caused by the fire were not yet collected from the insurance carriers on 31 December 2021. Interest expense was EUR 0.9m lower than in 2020 following the decrease of the convertible bond by EUR 15.0m in 2020.

The cash flow from investing activities in 2021 amounted to EUR -3.7m, compared to EUR -4.0m in 2020. Investments in property, plant and equipment amounted to EUR 3.7m in 2021, an increase of EUR 0.7m compared to 2020 and including capitalized Idylla™ systems as well as investments in laboratory and manufacturing equipment.

The cash flow from financing amounted to EUR -1.2m as a result of the scheduled repayment of lease and other obligations offset by the drawdown of EUR 6.0m on existing working capital facilities.

The total cash flow for 2021 amounted to EUR 70.7m compared to EUR -54.8m in 2020.

Financial calendar 2022

- 31 March 2022 — Publication 2021 annual report
- To be determined — Q1 2022 Business Update
- 13 May 2022 — AGM Biocartis Group NV
- 1 September 2022 — H1 2022 results
- To be determined — Q3 2022 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 31 March 2022. The financial information in this press release was not audited by the statutory auditor.

Consolidated income statement

	Years ended 31 December		
In EUR 000	**2021**		**2020**
Revenue			
Collaboration revenue	6,053		9,989
Product sales revenue	40,486		31,893
Service revenue	1,730		1,246
	48,269		**43,128**
Other operating income			
Grants and other income	6,629		12,431
Total operating income	**54,898**		**55,559**
Operating expenses			
Cost of sales	-33,922		-26,284
Research and development expenses	-48,054		-45,783
Sales and marketing expenses	-16,763		-15,736
General and administrative expenses	-15,560		-14,618
Other expenses	-3,244		
	-117,543		**-102,421**
Operating loss for the year	**-62,645**		**-46,862**
Financial expense	-9,488		-14,569
Other financial results	1,077		-1,199
Financial result, net	**-8,411**		**-15,768**
Share in the results of associates	-659		-532
Loss for the year before taxes	**-71,715**		**-63,162**
Income taxes	243		228
Loss for the year after taxes	**-71,472**		**-62,934**
Attributable to owners of the Company	-71,472		-62,934
Attributable to non-controlling interest			
Earnings per share			
Basic and diluted loss per share	-1.26		-1.11

Consolidated balance sheet

In EUR 000	As of 31 December, 2021	2020
Assets		
Non-current assets		
Intangible assets	5,067	5,645
Property plant and equipment	37,192	40,098
Financial assets	1,140	0
Investment joint ventures	2,344	2,893
Other non-current receivables	16	426
Deferred tax assets	1,595	1,472
	47,354	**50,534**
Current assets		
Inventories	16,106	15,712
Trade receivables	16,206	13,488
Other receivables	6,556	3,960
Other current assets	2,736	3,155
Cash and cash equivalents*	53,522	123,668
	95,126	**159,983**
Total assets	**142,480**	**210,517**
Equity and liabilities		
Capital and reserves		
Share capital	-220,657	-220,657
Share premium	711,874	711,874
Share based payment reserve	6,862	6,102
Accumulated deficit	-526,405	-455,343
Other comprehensive income	-5,571	-5,152
Total equity attributable to owners of the Company	**-33,897**	**36,824**
Non-current liabilities		
Provisions	75	0
Borrowings and lease liabilities	14,133	18,625
Convertible debt	128,151	125,260
Deferred income	313	363
	142,672	**144,248**
Current liabilities		
Borrowings and lease liabilities	11,878	6,673
Trade payables	11,560	13,907
Deferred income	1,822	1,278
Other current liabilities	8,445	7,587
	33,705	**29,445**
Total equity and liabilities	**142,480**	**268,323**

***** Cash and cash equivalents for 31 December 2020 and 2021 include EUR 1.2 million restricted cash related to KBC Lease financing

Consolidated cash flow statement

	Years ended 31 December	
In EUR 000	**2021**	**2020**
Operating activities		
Loss for the year	**-71,472**	**-62,934**
Adjustments for		
Depreciation and amortization	9,845	9,748
Impairment losses	1,362	1,698
Income taxes in profit and loss	-243	-228
Financial result, net	8,411	15,768
Unrealized exchange gains/ losses	1,134	-1,030
Net movement in defined benefit obligation	69	-323
Share of net profit of associate and a joint venture	659	532
Share based payment expense	760	1,432
Other	-162	-80
Changes in working capital		
Net movement in inventories	-2,737	-4,042
Net movement in trade and other receivables and other current assets	-5,916	1,449
Net movement in trade payables & other current liabilities	-1,489	6,333
Net movement in deferred income	494	-415
	-59,285	**-32,092**
Interests paid	-6,429	-7,172
Taxes paid	-2	-3
Cash flow used in operating activities	**-65,716**	**-39,267**
Investing activities		
Interests received	7	13
Acquisition of property, plant & equipment	-3,686	-3,005
Acquisition of intangible assets	-69	-15
Acquisition of investment in a joint venture	0	-1,000
Investment convertible note		
Cash flow used in investing activities	**-3,748**	**-4,007**
Financing activities		
Proceeds from borrowings	6,000	0
Convertible bond – incentivized conversion	0	-4,306
Net proceeds from the issue of common shares, net of transaction costs	0	0
Repayment of borrowings	-7,089	-7,167
Bank charges	-115	-50
Cash flow from financing activities	**-1,204**	**-11,523**
Net increase / (decrease) in cash and cash equivalents	**-70,668**	**-54,797**
Cash and cash equivalents at the beginning of the year	123,668	178,725
Effects of exchange rate changes on the balance of cash held in foreign currencies	522	-260
Cash and cash equivalents at the end of the year*	**53,522**	**123,668**

* Including EUR 1,2m restricted cash related to KBC Lease financing

Consolidated statement of changes in shareholder equity

	Attributable to owners of the Group						
In EUR 000	**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 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**
Balance as at 1 January 2021	**-220,657**	**711,875**	**6,102**	**-5,152**	**-455,343**	**36,824**	**36,824**
Loss for the period					-71,472	-71,472	-71,472
Re-measurement gains and losses on defined benefit plan				-419		-419	-419
Consolidation translation difference					410	410	410
Total comprehensive income				***-419***	***-71,062***	***-71,481***	***-71,481***
Share-based payment expense			760				
Convertible bond - incentivized conversion						760	760
Other							
Balance as at 31 December 2021	**-220,657**	**711,875**	**6,102**	**-5,571**	**-526,405**	**-33,897**	**-33,897**

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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 COVID-19, flu, RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

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