PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS ANNOUNCES H1 2021 RESULTS

- **H1 2021 results:** Very strong growth with 156k commercial Idylla™ cartridges sold, almost twice as high as in H1 2020 (+96%) and 189 new Idylla™ placements in H1 2021;
- **Outlook 40% cartridge growth still in reach** following successful mitigation of the fire incident, but still subject to full restart of ML2 line by 2nd half September and timely availability of reagent raw materials for cartridges;
- **Successful CE-IVD launch of Idylla™ SARS-CoV-2/Flu/RSV Panel** after the reporting period;
- **Cartridge manufacturing**: New concept for simplified, cost-efficient cartridge manufacturing under evaluation.

Mechelen, Belgium, 2 September 2021 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its business highlights and financial results for the first half of 2021, prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union.

H1 2021 RESULTS

- **Commercial cartridge volume:**
  - 156k commercial Idylla™ cartridges sold, almost twice as high as in H1 2020 (+96%);
  - Q1 2021 marked by 70% growth, followed by an even stronger +136% in Q2 2021;
  - Robust growth in oncology across all regions; solid contribution from infectious diseases, comparable to the H2 2020 volumes against the backdrop of declining global COVID-19 testing volumes.
- **Installed base:**
  - 189 new Idylla™ placements in H1 2021 (101 in H1 2020) mainly driven by demand in European and distributor[1] markets as well as by content partners;
  - Installed base of 1,770 Idylla™ instruments end of H1 2021;
  - Average annualized cartridge consumption per Idylla™ instrument 209, in part reflecting high utilization for infectious disease testing.
- **Regional performance:**
  - *Europe* – Strong increase in new Idylla™ placements in European markets, leading to continued growth of cartridge volumes in Europe. Strongest growth in oncology, combined with the acquisition of new EU customers needing rapid SARS-CoV-2 testing for safe access to hospitals, events and travel.
  - *US* – Although Idylla™ placements slowed down in the US because of constrained hospital budgets following the pandemic, US commercial cartridge volumes grew by 150%. Growth driven by increased demand for oncology biomarker testing, although the return to pre-pandemic oncology biomarker testing volumes showed to be more disparate across the US. In infectious diseases, demand for SARS-CoV-2 testing in H1 2021 significantly down from 2020 levels.
  - *Distributor markets* – Strong performance in terms of Idylla™ placements. Cartridge volume regained traction in oncology in all regions[2].
  - *China and Japan* – Continued progress was made in China and Japan[3]. Registration of the Idylla™ instrument in China is expected by the end of this year, while Idylla™ assay registrations are expected to follow earliest end of 2022 in both countries. Furthermore, during H1 2021, the progress in the local manufacturing set-up in China was going well, with local manufacturing of first cartridge volumes needed for local registration of the assays expected in H1 2022.
- **Idylla™ test menu, partnerships & publications:**
  - Encouraging first market demand for the Idylla™ GeneFusion Assay (RUO[4]), launched on 22 March 2021. The Assay detects, in one single cartridge, a wide range of biomarkers covering all gene fusions[5] considered to be relevant in cancer research[6].
  - First oncology assay US FDA submission for Biocartis with the 510(k)[7] notification for the Idylla™ MSI Test for the detection of MSI[8] and to aid in the differentiation between sporadic colorectal cancer and potential Lynch Syndrome on 20 April 2021.
  - EUR 1.4m grant from VLAIO[9] announced on 11 May 2021, subject to the development of a new Idylla™ technology.
  - Post the reporting period, successful CE-IVD launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel. The Panel detects SARS-CoV-2, Flu A/B and RSV nucleic acids in one single cartridge within approx. 90 minutes. Timing of the Emergency Use Authorization ('EUA') submission to the US FDA to be decided.
  - New partnership with SkylineDx announced on 22 April 2021 for the development of SkylineDx's novel

1 Defined as the world excluding European direct markets, US, China and Japan
2 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
3 In China, Biocartis established a joint venture ('China JV') with Guangzhou Wondfo Biotech Co., Ltd (SHE: 300482), a fast-growing diagnostics leader in China. In Japan, Biocartis is collaborating with Nichirei Biosciences
4 RUO = Research Use Only, not for use in diagnostic procedures
5 Biomarkers including gene fusions involving ALK1, ROS1, RET, NTRK1-2-3 as well as MET exon 14 skipping
6 Stransky et al. The landscape of kinase fusions in cancer. Nat Commun. 5, 4846, 2014; Mertens et al. The emerging complexity of gene fusions in cancer. Nat Rev Cancer 15, 371-381, 2015
7 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 17 August 2021
8 MSI or Microsatellite Instability is the result of inactivation of the body's so-called DNA mismatch repair (MMR) system, which normally spontaneously corrects errors that occur during DNA replication
9 Flanders government agency for Innovation & Entrepreneurship

proprietary Merlin Assay on Idylla™ aimed at predicting a patient's risk of nodal metastasis in melanoma.
    - Expanded partnership with AstraZeneca announced on 4 May 2021 to improve access to rapid and easy-to-use Idylla™ EGFR testing products at selected hospital sites in European and global distributor markets.
    - 19 new Idylla™ publications, abstracts and posters were published in peer-reviewed journals during H1 2021, including the publication of two studies[10] by Memorial Sloan Kettering Cancer Center ('MSKCC', New York, US) concluding that Idylla™ EGFR testing (RUO) enables rapid assessment of the most common EGFR mutations with low sample input, even on different sample types, without compromising subsequent more comprehensive NGS[11] testing, which can be useful in cases where EGFR mutation results were negative and further testing is needed. One abstract[12] was presented at the ASCO Annual Meeting taking place virtually between 4-8 June 2021. One abstract on the SeptiCyte© RAPID on Idylla™ was presented at the 31st ECCMID (European Congress of Clinical Microbiology & Infectious Diseases) congress (9-12 July 2021).
- **Organizational and operational highlights:**
    - *Shareholders' Meetings* – All agenda items approved during the ordinary shareholders' meeting held on 14 May 2021, including the re-appointment of Herman Verrelst, CEO of the Company, as director of the Company for a term of four years, and the appointment of Christian Reinaudo as independent director of the Company for a term of three years[13]. All agenda items approved during the extraordinary general shareholders' meeting held on 4 June 2021, including the renewal of the 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 (5) years.
    - *Cartridge manufacturing* – Transfer of the Idylla™ EGFR Mutation Test (CE-IVD) to the second cartridge manufacturing line ('ML2') completed during H1 2021. This concluded the transfer of Biocartis' main oncology assays to ML2, which is a key driver of cost optimizations within the Company's cartridge manufacturing activities. The resulting improvement of the gross margin on product sales was however offset by the global shortage of certain reagent supplies caused by the pandemic that forced lower than planned production volumes.
- **Financial highlights:**
    - *Total operating income* – Total operating income amounted to EUR 23.1m compared to EUR 17.6m last year. Product revenues increased by 62% from EUR 11.4m in H1 2020 to EUR 18.5m in H1 2021. Within product sales, cartridge sales revenues increased by 54%. Idylla™ instrument sales revenues of EUR 3.7m doubled on the back of 189 new instrument placements, 88 more than in H1 2020. Collaboration revenues amounted to EUR 2.6m and solely consisted of R&D services provided to partners. The decrease of EUR 2.0m compared to H1 2020 is predominantly driven by the different timing of certain collaboration projects.
    - *Idylla™ cartridge average sales price (ASP)* - Idylla™ oncology cartridge ASP was stable at EUR 104. The ASP of the Idylla™ SARS-CoV-2 Test was lower than last year, in line with expectations and resulting in an overall ASP of EUR 95.
    - *Gross margin* – Gross margin on products of 8%, compared to 18% in H1 2020 as a result of the impact of the lower ASP of the Idylla™ SARS-CoV-2 Test. Furthermore, the gross margin was also temporarily impacted by higher COGS because production volumes were lower than expected as the pandemic caused a global shortage of reagent supplies. COGS also included the effect of hiring additional staff in anticipation of increasing volumes in the second half of the year.
    - *OPEX* – Total operating expenses (excluding cost of sales) of EUR 39.1m in H1 2021 increased from EUR 34.7m in H1 2020, predominantly as a result of the planned acceleration and diversification of the Idylla™ test menu, both in oncology and in infectious diseases.
    - *Net cash flow and cash position* – The net cash outflow from operating and investing activities amounted to EUR 35.8m in H1 2021 compared to EUR 25.6m in H1 2020. The increased outflow is attributable to (a) lower gross margin and (b) higher investment in net working capital and higher capital expenditure resulting from a higher number of Idylla™ instruments placed under reagent rental agreements. The cash and cash equivalents at 30 June 2021 amounted to EUR 85.0m.
    - *Revised credit facility* – During H1 2021, Biocartis entered into a new credit facility with KBC Bank, replacing the facilities with KBC Bank and BNP Paribas Fortis that came to maturity in 2020. This facility consists of a EUR 7.5m straight loan and a EUR 7.5m rollover credit line. To date, the new credit facility remains undrawn.

KEY FIGURES H1 2021

The tables below show an overview of the key figures and a breakdown of operating income for H1 2021 and H1 2020. Consolidated financial statements and accompanying notes are included in Biocartis' half-year 2021 report that is available here on the Company's website.

10 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

11 Next Generation Sequencing

12 Behera et al. Circulating tumor DNA mutation as a prognostic marker in melanoma with brain metastasis. J Clin Oncol 39, 2021 (suppl 15; abstr e21560); Only the abstracts at the virtual AMP Europe congress (Association for Molecular Pathology, virtual congress taking place 14-18 June 2021) and ASCO (American Society of Clinical Oncology) in the US were screened

13 To replace CRBA Management BV, permanently represented by Christian Reinaudo, as independent director of the Company

Key figures (EUR 1,000)	H1 2021	H1 2020	% Change
Total operating income	**23,057**	**17,606**	**31%**
Cost of goods sold	-17,059	-9,233	85%
Research and development expenses	-23,389	-20,303	15%
Sales and marketing expenses	-7,740	-7,931	-2%
General and administrative expenses	-7,935	-6,491	22%
Operating expenses	**-56,132**	**-43,958**	**28%**
Operating result	**-33,075**	**-26,352**	**26%**
Net financial result	-4,249	-5,129	-17%
Share in the result of associated companies	-101	-195	-48%
Income tax	149	118	26%
Net result	**-37,276**	**-31,558**	**18%**
Cash flow from operating activities	-33,752	-24,526	38%
Cash flow from investing activities	-2,087	-1,028	103%
Cash flow from financing activities	-3,518	-3,456	2%
Net cash flow [1]	**-39,357**	**-29,010**	**36%**
Cash and cash equivalents[2]	**84,905**	**149,674**	**-43%**
Financial debt	149,412	165,258	-10%

[1] Excludes the effect of exchange rate differences on the cash balances held in foreign currencies
[2] Including EUR 1.2m of restricted cash in H1 2021 and H1 2020

Operating income (EUR 1,000)	H1 2021	H1 2020	% Change
Collaboration revenue	**2,640**	**4,746**	**-44%**
Idylla™ system sales	3,715	1,837	102%
Idylla™ cartridge sales	14,749	9,584	54%
Product sales revenue	**18,463**	**11,421**	**62%**
Service revenue	748	530	41%
Total revenue	**21,851**	**16,697**	**31%**
Grants and other income	1,206	909	33%
Total operating income	**23,057**	**17,606**	**31%**

Product sales revenue (EUR 1,000)	H1 2021	H1 2020	% Change
Commercial revenue	18,441	10,491	76%
Research & development revenue	22	930	-98%
Total product sales revenue	**18,463**	**11,421**	**62%**

- **Post-period events since 30 June 2021:**
  - *Fire incident* – See below under 'Impact of the fire incident on the 2021 outlook';
  - *Product registrations Taiwan* – Additional registrations for Idylla™ products have been completed in Taiwan;
  - *Launch Idylla™ SARS-CoV-2/Flu/RSV Panel* (CE-IVD) – Successful CE-launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel which detects SARS-CoV-2, Flu A/B and RSV[14] nucleic acids in one single cartridge within approx. 90 minutes. Timing of the Emergency Use Authorization ('EUA') submission to the US FDA to be decided;
  - *Cartridge manufacturing* – New concept of a simplified, cost-efficient cartridge manufacturing under evaluation, aimed at a significantly lower manufacturing cost for infectious disease and select oncology assays.

IMPACT OF THE FIRE INCIDENT ON THE 2021 OUTLOOK

After the fire that broke out at one of the warehouse facilities in Mechelen (Belgium) during the night of 30 July 2021, the Company has taken immediate actions to mitigate the loss of finished products and raw materials as well as the temporary unavailability of the high-throughput ML2 manufacturing line. Aiming to safeguard continued supply to customers as much as possible, actions included (i) the redirection of additional personnel and resources to the unaffected ML1 cartridge manufacturing line to temporarily increase production on this line, (ii) the placement of orders to replenish critical reagents lost in the fire from different suppliers to minimize production delay and (iii) the prioritization of oncology and partner project tests manufacturing. The latter consequently also reduces the Idylla™ SARS-CoV-2 testing volumes.

As a result, Biocartis is able to confirm a 40% cartridge volume growth target for 2021 (see 'Outlook' below), subject to the timely availability of reagent raw materials for Idylla™ cartridges in sufficient quantities and the full restart of the ML2 line, which is now expected by the 2nd half of September. Nevertheless, due to the already known delays in the supply of certain assay-specific reagents, certain products may still be temporarily unavailable to meet the entire customer demand and further mitigating action may be required after production resumes on ML2.

14 Respiratory Syncytial Virus

SIMPLIFIED, COST-EFFICIENT CARTRIDGE CONCEPT

Alongside the ongoing development of a new technology on Idylla™ with the support of VLAIO, aimed at the off-line customization of the Idylla™ cartridge[15] to shorten development lead times for Idylla™ assays, Biocartis is currently also evaluating a new concept for a simplified, cost-efficient Idylla™ cartridge. In the mid to longer term, this should enable an accelerated reduction of the manufacturing cost of Idylla™ cartridges beyond the impact of continued volume growth and the resulting increased utilization of the available manufacturing capacity. The new cartridge concept reduces the complexity of the cartridge, and is ideally suited for infectious disease testing and certain oncology assays. The new concept is expected to run on the existing Idylla™ platform alongside the existing Idylla™ cartridge, which will continue to be used for those assays that are not compatible with the simplified, cost-efficient cartridge.

Post the reporting period, the feasibility of the new Idylla™ cartridge has been externally confirmed by a reputable global contract manufacturing organization. Subject to the successful design and manufacturing, the new Idylla™ cartridge concept is expected to facilitate the development of a highly competitive franchise of multiplex infectious disease assays with partners and may also be applicable to a number of oncology assays. The decision to invest in the development of new and existing Idylla™ assays using the new Idylla™ cartridge concept and in the accompanying manufacturing equipment, is still subject to completion of the concept design. As a result, the Company decided to review (the timing of) ongoing and future investments in the infectious disease and oncology assay menu.

As a reaction on the H1 2021 results and post-reporting period events, Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"After the very strong performance in H1 2021, both in terms of instrument placements as well as commercial cartridge volumes, the fire was obviously an unfortunate set-back. Although we cannot deny the fire has an impact, this event again showed the incredible resilience of our teams who have been working with relentless focus and dedication to limit the fall-out. I am proud to announce that we currently expect a smooth restart of the ML2 line by the second half of September 2021. This is also important considering the recent launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel, the upgrade of our existing Idylla™ SARS-CoV-2 Test (CE-IVD) that now also includes Flu A/B and RSV. Ahead of a delayed flu season, this Panel is well positioned to guide healthcare providers in this complex landscape of respiratory infections in 2022. Furthermore, I am very excited to announce a possible break-through in our cartridge manufacturing with the ongoing evaluation of a new* simplified, cost-efficient *cartridge design which is expected to significantly lower manufacturing costs for a selection of our Idylla™ assays. Together with the ongoing development of a new technology on Idylla™ which aims to personalize Idylla™ assays while reducing development time and cost, this could prove to be a pivotal development towards sustainable growth in the years to come."*

OUTLOOK

- *Commercial cartridge volume, Idylla™ installed base and cash position outlook:* Despite the impact of the fire, Biocartis confirms its 2021 guidance at 40% growth target for cartridge volumes:
    - *Commercial cartridge volume:* Targeting a year-over-year growth of 40%, or commercial cartridge volumes of 320k. This is subject to the timely availability of reagent raw materials for Idylla™ cartridges and the restart of the ML2 line by the 2nd half of September;
    - *Installed base:* Targeting 300-350 new Idylla™ instrument placements;
    - *Cash position:* Targeting at least EUR 50m cash position at year-end, provided timely collection of insurance claims related to the fire incident.
- *Idylla™ test menu outlook:*
    - ONCOLOGY TEST MENU:
        - Lung cancer: Launch of the Idylla™ EGFR-BRAF+ Mutation Assay is being suspended awaiting the completion of the simplified, cost-efficient cartridge concept. Timelines will be communicated at a later stage;
        - Breast cancer: Launch of the Idylla™ ABC (Advanced Breast Cancer) Assay in collaboration with LifeArc is expected in H2 2022.
    - INFECTIOUS DISEASE (PARTNER) TEST MENU:
        - Timing of the Emergency Use Authorization ('EUA') submission to the US FDA for the Idylla™ SARS-CoV-2/Flu/RSV Panel to be decided;
        - 510(k) clearance with the US FDA of the SeptiCyte® RAPID on Idylla™ (Immunexpress) is pending.
    - DEVELOPMENT OF A NEW SIMPLIFIED, COST-EFFICIENT CARTRIDGE CONCEPT: The concept design of the new simplified, cost-efficient cartridge concept is still under evaluation. This will impact the decision to invest in manufacturing equipment and the actual development of new and existing Idylla™ assays based on this concept. Outcomes of the assessment and associated development timelines will be communicated at a later stage.

15 Previously referred to as the Idylla™ 'FLEX' technology, aimed to tap into new market opportunities with customized and personalized products

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 H1 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 +44844481975 (standard international), followed by the confirmation code 4866873. 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.

FINANCIAL CALENDAR

- 10 November 2021 Q3 2021 Business Update
- 24 February 2022 2021 full year results
- 31 March 2022 Publication 2021 annual report

AUDITOR STATEMENT

The condensed consolidated interim financial statements for the six-months' period ended 30 June 2021 have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union. They do not include all the information required for the full annual financial statements and should therefore be read in conjunction with the financial statements for the year ended 31 December 2020. The condensed consolidated interim financial statements are presented in thousands of Euros (unless stated otherwise). The condensed consolidated interim financial statements have been approved for issue by the Board of Directors. The statutory auditor, Deloitte Bedrijfsrevisoren/Reviseurs d'Entreprises, represented by Nico Houthaeve, has performed a review, which did not reveal any significant adjustments to the condensed consolidated interim financial statements. The interim financial report 2021 and the review opinion of the auditor are available on www.biocartis.com.

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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/flu/RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.