PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS ANNOUNCES H1 2022 RESULTS

Affirms 2022 Outlook
35% growth in oncology cartridge revenues
Gross Margin on Products of 32%
Refinancing underway

Company will host a conference call with live webcast presentation today at 14:30 CEST / 13:30 BST (UK) / 08:30 EDT (US) to discuss H1 2022 results

Mechelen, Belgium, 1 September 2022 – 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 2022, prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union.

Commenting on the H1 2022 results and post-reporting period events, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"Our operational performance in H1 2022 marked a pivotal moment on our journey towards profitability: continued strong growth of our core oncology business translated into significantly higher gross margins. Cartridge revenue in our core oncology business grew by 35% year-on-year, and the gross margin on products increased to 32%. Despite the expected decrease of Idylla™ SARS-CoV-2 product sales, we almost quadrupled gross profit to EUR 6.6m during the first half of the year, fueled by increased average selling prices of cartridges in oncology and economies of scale in our cartridge manufacturing. We are on track to deliver on our objectives for the entire year, and also made important progress in securing future growth. We are particularly proud of the extended partnership with AstraZeneca for the development of a companion diagnostic for its blockbuster Tagrisso®. Furthermore, we were very pleased to announce that we entered into several financing arrangements with the support of certain holders of our convertible bonds. These will, upon successful completion, strengthen our cash position with approximately EUR 66m and fundamentally improve our financing structure."*

KEY MESSAGES H1 2022

- **Product revenue** of EUR 20.3m (H1 2021: EUR 18.5m), of which EUR 16.5m from 153k cartridges sold and EUR 3.8m from instrument rentals and sales:
  - EUR 14.4m cartridge revenue in oncology (+35% year-on-year), double-digit growth across all regions, led by the US, both in cartridge volumes as in Average Selling price (ASP)
  - The contribution of COVID-19 testing to cartridge revenues decreased to EUR 1.7m as both volumes and pricing continued to reduce. Revenues are evenly split between Europe and the US
  - ASP per commercial cartridge of EUR 113 in oncology and EUR 103 overall
  - EUR 3.8m revenue from a global Idylla™ installed base of 2,014 instruments, with 102 net new instruments placed
- **Gross profit on product sales** increased by 370% from EUR 1.4m to EUR 6.6m, reflecting a gross margin of 32%, compared to 8% for H1 2021 and 16% for the full year 2021
- **Operating cash burn**[1] of EUR -19.2m, EUR 9.4m lower than in H1 2021; Company cash position of EUR 19.7m (unaudited figure) end of H1 2022. The available credit facilities of EUR 15.0m remained fully undrawn as of 30 June 2022
- New **partnership** with **AstraZeneca** to develop a companion diagnostic[2] (CDx) for use with Tagrisso® (osimertinib), AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment
- Post the reporting period, start of Biocartis' **commercialization in Europe** of **SkylineDx's** Merlin Assay as a CE-IVD marked kit, ahead of the launch of an Idylla™ version of the Assay

REFINANCING

Today the Company announced a comprehensive recapitalization transaction (the 'Transactions') that will provide adequate capital to support the Company's growth for the foreseeable future. The Transactions, which are supported by key existing investors, is a significant milestone for the Company and will provide for the following:

- Deleveraging via a partial equitization of the 4.00% convertible bonds due 2024 ("Existing Convertible Bonds") equal to 10% of notional amounts outstanding, and maturity extension by 3.5 years to

1 EBITDA plus capital expenditure
2 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

November 2027.

- Allow holders of the Existing Convertible Bonds to exchange into new second lien secured convertible bonds ("New Convertible Notes"), subject to their commitment to participate pro-rata in a fully backstopped EUR 25 million investment into additional New Convertible Notes.
- Allow existing shareholders to participate in the growth of the Company by taking part in a fully covered rights issue of EUR 25 million, which is backstopped in full by certain new investors and KBC Securities (subject to a number of customary and transaction specific conditions).
- Certain existing holders of New Convertible Notes will provide a new senior secured term loan ("New Convertible Term Loans") that will provide the Company with approximately EUR 16 million of additional cash liquidity.

More information can be found in the press release here.

2022 OUTLOOK

As a result of a fading demand for COVID-19 testing, the product revenues for 2022 are projected to be around the lower end of the initial EUR 50-55m range, without any impact however on the previously stated expectations for gross margin on product sales and operating cash burn, which are maintained at:

- Increase gross margins on product sales to 25% - 30%
- Reduce the operating cash burn (EBITDA plus capital expenditure) by EUR 9.5m-13.5m, to be between EUR 43m - 47m for FY22

Biocartis will host a conference call with live webcast presentation today at 14:30 CEST / 13:30 BST (UK) / 08:30 EDT (US) to discuss the H1 2022 results. Participants that want to follow the webcast presentation live, are invited to click on this link on the day of the event. Participants that also want to ask a question and/or attend the event over the phone, are required to register here in advance of the conference. After registration, each participant will be provided with dial-in numbers and a personal PIN. 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

- 153k commercial cartridges sold in H1 2022, compared to 156k in H1 2021: oncology cartridge volumes grew by 21% while infectious disease cartridge volumes almost halved as COVID-19 testing continued to reduce
- Double-digit growth of oncology cartridge volumes in all regions combined with pricing discipline, delivered 35% growth in oncology cartridge revenue:
    - Sustained growth across Europe with growing contribution of the Idylla™ GeneFusion that is now increasingly used in clinical routine
    - The US remains the fastest growing market in oncology, fueled by an increasing ASP as the proportion of free-of-charge cartridge volumes for market seeding and the initial validation of assays by customers declines
    - Strong performance of the distributor markets[3] and good traction from the commercial partnership with AstraZeneca
- Total revenue from Idylla™ instruments increased by 4% to EUR 3.8m in H1 2022, including instruments sold to content partners[4]:
    - Revenue generated from instrument placements at end customers increased by 24% year-on-year, against a 12% increase of the installed base of Idylla™ instruments, and evenly split between revenue from capital sales and reagent rentals
    - The US recorded the strongest growth of instrument revenue, driven by a high proportion of capital sales, representing more than 90% of total US instrument revenue and nearly half of total revenue from sold instruments
    - Continued double-digit growth of instrument revenue in Europe, mostly from rental income that accounts for nearly 90% of total instrument rental income

Idylla™ test menu, partnerships & publications

- *Test menu:*
    - Launch of the fully automated, CE-marked IVD Idylla™ GeneFusion Panel on 20 June 2022
    - Launch of new SeptiCyte RAPID® EDTA[5] (CE-IVD) blood compatible cartridges[6] by Biocartis' partner Immunexpress on 23 August 2022, post the reporting period
- *Product registrations:*
    - Russia – Additional registrations have been completed in June 2022 for the Idylla™ NRAS-BRAF Mutation Test, the Idylla™ KRAS Mutation Test and the Idylla™ MSI Test in Russia. More information on the impact of the war in Ukraine and Russia can be found in the disclaimer at the bottom of this press release.

3 Defined as the world excluding European direct markets, US, China and Japan
4 Partners providing test content so as to develop an Idylla™ version of their assay or test on the Idylla™ platform
5 EDTA represents Ethylenediaminetetraacetic acid, which is the anticoagulant used for most hematology procedures (like identifying and counting blood cells, blood typing, etc.). Source: ksmedical.com, last consulted on 24 August 2022
6 In addition to blood samples collected in PAXgene blood RNA tubes (per the manufacturer's instructions), this test is now also able to process undiluted EDTA blood samples which are commonly used for most hematology procedures, with results available in about one hour

- Japan – On 29 August 2022, Nichirei Biosciences, Biocartis' distribution partner in Japan, received approval by the Japanese regulatory authorities (Ministry of Health, Labor and Welfare) for the commercialization of the Idylla™ MSI Test in Japan. Nichirei Biosciences plans the commercial launch of the Idylla™ MSI Test in Japan in November 2022.

- *Partnerships:*
  - Announcement of a new partnership on 8 February 2022 between Biocartis and Ophiomics, a Lisbon (Portugal) based biotech company with an initial focus on the commercialization of HepatoPredict[7].
  - Announcement of a new agreement with AstraZeneca on 22 June 2022 highlighting the development and planned premarket submission to the US FDA of a novel CDx test on the Idylla™ platform for AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment.
  - Announcement of Biocartis' start of the commercialization in Europe of SkylineDx's innovative Merlin Assay as a CE-IVD marked manual kit, ahead of the launch of an Idylla™ version of the Assay, on 1 September 2022 and post the reporting period.
- *Publications* - During H1 2022, excellent data was published from several new Idylla™ studies, including a study (announced 4 May 2022) by Memorial Sloan Kettering Cancer Center (NY, US), in the *Journal of Molecular Diagnostics* on the Idylla™ GeneFusion Assay (RUO[8]).

Organizational and operational highlights

- *Commercial milestones* – Double milestone announced on 15 June 2022 with the selling of the one-millionth commercial Idylla™ cartridge and the placement of the 2,000th Idylla™ instrument since commercial launch.
- *Shareholders' Meetings* – All agenda items were approved during the ordinary shareholders' meeting held 13 May 2022.
- *Cartridge manufacturing* – Transfer of the Idylla™ SARS-CoV-2 Test (CE-IVD) and the Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD) to the second cartridge manufacturing line ('ML2') was completed during H1 2022. Plans are under development to complete all current assay transfers in the course of 2023. The gradual product transfers to the fully automated ML2 line will further unlock economies of scale and reduce manufacturing costs.
- *ISO 27001 certification* – Post the reporting period, ISO 27001 certification achievement announced on 24 August 2022 for Biocartis for the design, development, maintenance, service provision and support of the Idylla™ platform and associated customer-facing software.
- *Management team* – Biocartis aligned its organizational structure to deliver on its strategic priorities and has appointed, effective as from 1 September 2022:
  - Global Head of Partnering: Madhushree (Madhu) Ghosh, PhD, MS, will join Biocartis as Global Head of Partnering. Dr. Ghosh brings a wealth of experience to successful commercial and strategic team leadership in global strategic alliance management, P/L business unit leadership and IVD and CDx product development for in excess of 20 years spent in molecular diagnostics and clinical assay development with a focus on Next Generation Sequencing, real-time PCR, multiplex PCR, oncology and infectious disease diagnostics. Previously, Dr. Ghosh held senior roles at Thermo Fisher Scientific, NeoGenomics Laboratories Inc., QIAGEN, and AltheaDx.
  - Global Head of Sales: David Dejans, previously Head of Sales Europe and Distributor markets, will move into the role of Global Head of Sales.

Financial highlights

- *Total operating income* – Total operating income amounted to EUR 26.8m compared to EUR 23.1m last year. Product revenues increased by 10% from EUR 18.5m in H1 2021 to EUR 20.3m in H1 2022. Within product sales, cartridge sales revenues increased by 11.6%. Excluding the revenue from the sale of Idylla™ SARS-CoV-2 tests[9] that continue to trend downward, cartridge revenues increased 38%. Revenues from Idylla™ instrument sales amounted to EUR 3.8m (H1 2021: EUR 3.7m). The majority of the 102 net new instruments were placed under reagent rental agreements as opposed to H1 2021 during which immediately recognized capital sales accounted for most of the 189 net placements. Collaboration revenues, almost entirely from R&D services provided to partners, increased by EUR 2.6m to EUR 5.1m.
- *Idylla™ cartridge average sales price (ASP)* – During H1 2022, Idylla™ oncology cartridge ASP increased by 8% to EUR 113, resulting from a growing contribution of the Idylla™ GeneFusion Assay[10] (RUO) and from higher sales from the US where pricing is generally higher than in Europe and other parts of the world. The overall ASP in H1 2022 stood at EUR 103, up from EUR 95 in H1 2021 because of the increased ASP in oncology and a lower contribution of lower priced SARS-CoV-2 tests.
- *Gross margin* – Gross margin on products significantly increased, from 8% in H1 2021 to 32% in H1 2022. Last year, the gross margin was impacted by a higher cartridge COGS (Costs of Goods Sold) because production volumes were lower than expected as the pandemic caused a global shortage of reagent supplies. Moreover, the lower revenues from SARS-CoV-2 tests that have a significantly lower ASP than the other assays, also contributes to an improved gross margin. The total gross profit amounted to EUR 6.6m, or EUR 5.2m more than in H1 2021.

7 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 Biocartis' rapid and easy-to-use molecular diagnostics platform Idylla™. HepatoPredict is a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation
8 Research Use Only, not for use in diagnostic procedures
9 The Idylla™ SARS-CoV-2 Test (CE-IVD) and the Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD)
10 The contribution in H1 2022 mainly resulted from Idylla™ GeneFusion Assay (RUO) sales, as the Idylla™ GeneFusion Panel (CE-IVD) was only launched late in H1 2022, on 20 June 2022

- *OPEX* – Total operating expenses (excluding cost of sales) of EUR 37.7m in H1 2022 decreased by EUR 1.4m from EUR 39.1m in H1 2021. EUR 4.1m lower spending in R&D was partly offset by the post-pandemic normalization of commercial activities, the impact of the 2021 restructuring of the US commercial operations and by global inflation.
- *Net cash flow and cash position* – The operating cash burn of EUR 19.2m (H1 2021: EUR 28.8m) was complemented by working capital investments of EUR 0.6m and a scheduled investment of EUR 1.0m to fund the operations of the Chinese joint venture WondfoCartis. Financial cash flows included EUR 3.1m interest payments and the repayment of EUR 8.6m borrowings, including EUR 6.0m drawn on working capital facilities at the end of 2021. The net cash outflow amounted to EUR 35.5m and resulted in a net cash position of EUR 19.7m. EUR 15m of credit facilities were undrawn and remain fully available awaiting the closing of the refinancing.

KEY FIGURES H1 2022

The tables below show an overview of the key figures and a breakdown of operating income for H1 2022 and H1 2021. Consolidated financial statements and accompanying notes are included in Biocartis' half-year 2022 report available here on the Company's website.

Key figures (EUR 1,000)	H1 2022	H1 2021	% Change
Total operating income	**26,771**	**23,057**	**16%**
Cost of goods sold	-13,720	-17,059	-20%
Research and development expenses	-19,251	-23,389	-18%
Sales and marketing expenses	-10,050	-7,740	30%
General and administrative expenses	-8,376	-7,935	6%
Operating expenses	**-51,397**	**-56,132**	**-8%**
Operating result	**-24,626**	**-33,075**	**-26%**
Net financial result	-3,805	-4,249	-10%
Share in the result of associated companies	-432	-101	328%
Income tax	96	149	-36%
Net result	**-28,767**	**-37,276**	**-23%**
Cash flow from operating activities	-24,154	-33,752	-28%
Cash flow from investing activities	-1,594	-2,087	-24%
Cash flow from financing activities	-9,542	-3,518	171%
Net cash flow [1]	**-35,290**	**-39,357**	**-10%**
Cash and cash equivalents[2]	**19,724**	**84,905**	**-77%**
Financial debt	147,166	149,412	-2%

[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 2022 and H1 2021

Operating income (EUR 1,000)	H1 2022	H1 2021	% Change
Collaboration revenue	**5,082**	**2,640**	**93%**
Idylla™ system sales	3,824	3,715	3%
Idylla™ cartridge sales	16,477	14,749	12%
Product sales revenue	**20,301**	**18,463**	**10%**
Service revenue	977	748	31%
Total revenue	**26,360**	**21,851**	**21%**
Grants and other income	411	1,206	-66%
Total operating income	**26,771**	**23,057**	**16%**

Product sales revenue (EUR 1,000)	H1 2022	H1 2021	% Change
Commercial revenue	19,899	18,441	8%
Research & development revenue	401	22	1724%
Total product sales revenue	**20,301**	**18,463**	**10%**

IDYLLA™ TEST MENU OUTLOOK

- *Idylla™ MSI Test US FDA submission* – Biocartis continues to interact with the US FDA on the 510(k) that was previously submitted for its Idylla™ MSI Test.
- *Idylla™ ABC (Advanced Breast Cancer) Assay* (collaboration LifeArc) – The launch of the Idylla™ ABC Assay (RUO) is planned for Q4 2022.
- *Idylla™ Platform registration in China* –Biocartis continues to interact with the Chinese regulatory authority NMPA on the Idylla™ Platform registration that was completed 10 August 2022 after addressing NMPA feedback.

POST-PERIOD EVENTS

- Announcement of Biocartis' obtaining of ISO 27001 certification on 24 August 2022 – see above.
- Announcement of Biocartis' commercialization in Europe of SkylineDx's Merlin Assay as a CE-IVD marked manual kit on 1 September 2022 – see above.
- Announcement of refinancing on 1 September 2022 – see above.

FINANCIAL CALENDAR

- 10 November 2022 Q3 2022 Business Update
- 23 February 2023 2022 full year results
- 30 March 2023 Publication 2022 annual report

AUDITOR STATEMENT

The condensed consolidated interim financial statements for the six-months' period ended 30 June 2022 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 2021. 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 2022 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 COVID-19, Flu, RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

Impact of the war in Ukraine

Biocartis has no sales in Ukraine. In Russia, Biocartis works through a local sales distributor who realized first commercial sales in H1 2021 following completion of first product registrations in Russia in Q1 2021. The impact to expected revenue for 2022 from Russian distributor sales that were projected prior to the start of the war, is not material. Supplier exposure is limited to one indirect supplier for Idylla™ instrument sub-parts who is based in Russia. Based on the current level of inventory on-hand and on various alternative sources of supply that were identified and are currently being assessed, Biocartis does not expect any material adverse impact on the continued supply of instruments.

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

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