



PRESS RELEASE

INSIDE INFORMATION / REGULATED INFORMATION

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## **Biocartis Reports Results of Third Quarter of 2022: Full-year guidance raised for product gross margin, despite expected lower product revenues Improving operating cash burn guidance**

**Mechelen, Belgium, 21 October 2022** – Biocartis Group NV (the "Company" or "Biocartis"), an innovative molecular diagnostics company (Euronext Brussels: BCART), today provides a business update for the third quarter of 2022 and the outlook for the full year 2022.

*In view of the ongoing implementation of the comprehensive recapitalization transaction, the Company deemed it appropriate to publish the Q3 2022 results earlier.*

**Commenting on the Q3 2022 results, Herman Verrelst, Chief Executive Officer of Biocartis, said:** "Our operating performance in Q3 2022 remained strong and fully in line with expectations. We continued to grow cartridge revenue in our core oncology business by 36%, significantly improved the gross margin on products to 32% and reduced the year-on-year operating cash burn by EUR 15.2 million. The current economic climate and the looming recession are nevertheless expected to affect product sales in Q4 2022, which may result in lower-than-expected product revenues for 2022. In particular, certain of our collaboration partners revert to cash preserving measures and delay investments such as planned clinical trials until 2023. We also continue to attract and onboard new customers, but they make increasing use of the possibility to adopt Idylla™ through our free-of-charge Idylla™ instrument evaluation programs<sup>1</sup> before purchasing or renting new systems. Despite this temporary impact, we increase our expectation for gross margin on products to at least 30% and we expect to reduce the operating burn rate beyond initial expectations. Despite the significant impact of rising inflation, we are reducing expenses, this year and next year, and remain committed to our ambition to become profitable."

### **Q3 2022 HIGHLIGHTS**

- Product revenue of EUR 30.5m, up 14% year-on-year and including EUR 25.2m cartridge revenue and EUR 5.3m from instrument sales and rentals:
  - Continued strong growth of oncology cartridge revenue to EUR 22m (+36% year-on-year)
  - EUR 3.2m contribution from infectious diseases, of which EUR 2.5m from Idylla™ SARS-CoV-2 product sales, which represents 8% of product revenue
  - Continued increase of commercial Average Sales Price (ASP) to EUR 116 in oncology and EUR 106 ASP overall (+3% versus H1 2022)
  - EUR 5.3m revenue from instruments. 189 new instruments<sup>2</sup> placed year-to-date, total installed base of 2,029 instruments end of Q3 2022
- Gross profit on product sales of EUR 9.7m (Q3 2021: EUR 2.3m), reflecting a gross margin of 32% (8% in Q3 2021)
- Operating cash burn of EUR 30.6m, a reduction of EUR 15.2m year-on-year. The cash position end Q3 2022 amounts to EUR 12.6m and includes EUR 7.5m drawn on total available credit facilities of EUR 15m from KBC Bank, awaiting the completion of the recapitalization transaction in a gross amount of EUR 66m which was announced on [1 September 2022](#)
- Partnerships:
  - SkylineDx: On [1 September 2022](#), Biocartis announced the start of the commercialization in Europe of SkylineDx's innovative [Merlin Assay](#) as a CE-IVD marked manual kit<sup>3</sup>
  - Ophiomics: On [10 October 2022](#), Biocartis announced the start of the commercialization in Europe of Ophiomics' [HepatoPredict](#) test as a CE-IVD marked manual kit<sup>4</sup>
- China: On 16 September 2022, Biocartis obtained regulatory approval for its Idylla™ Instrument by the regulatory authorities NMPA in China, an important step ahead of the further regulatory approval and commercialization of Idylla™ assays in China.

<sup>1</sup> Under these programs, customers can make use of the instruments while only paying for the cartridge consumption. Revenues from the sale or the rental of these instruments are therefore delayed by an average of six months, subject to the satisfactory outcome of the evaluation

<sup>2</sup> 117 net new instruments year-to-date

<sup>3</sup> The test, developed by SkylineDx together with the Mayo Clinic (US), aims to predict a melanoma patient's risk of nodal metastasis and may help safely forgo an invasive surgery, which is now often performed to determine metastatic spread of the cancer for staging purposes

<sup>4</sup> The test is a prognostic diagnostic test that supports the decision of liver transplantation in patients with Hepatocellular Carcinoma (HCC)

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- 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 to commercially launch the Idylla™ MSI Test in Japan in Q4 2022.

## **REFINANCING**

On [1 September 2022](#), Biocartis announced a comprehensive recapitalization intended to provide the Company with a gross amount of new cash of approximately EUR 66m to help manage liquidity until the Company reaches operating breakeven. As part of this recapitalization, certain amendments<sup>5</sup> to the existing 4.00% convertible bonds due in 2024 ("Existing Convertible Bonds") were approved by the required majority of holders of the Existing Convertible Bonds, as announced on [11 October 2022](#), and as such have become effective. Holders of the Existing Convertible Bonds were also offered the right to exchange their Existing Convertible Bonds into new second lien secured convertible bonds (the "New Convertible Bonds"), subject to their commitment to participate pro-rata in a fully backstopped EUR 25m investment into additional New Convertible Bonds. The deadline for the exchange offer for holders of the Existing Convertible Bonds is 24 October 2022.

On [19 October 2022](#), approximately EUR 18m of the overall EUR 30m of new senior secured term loan ("New Convertible Term Loans") has been drawn following the approval of the amendment of the terms and conditions of the Existing Convertible Bonds announced on [11 October 2022](#). From the amount drawn, approximately EUR 14 million was used to repurchase and cancel more than EUR 16 million of principal amount of Existing Convertible Bonds from certain holders thereof. The drawdown of the remaining portion of the New Convertible Term Loans is conditional on the exchange of Existing Convertible Bonds, certain shareholder approvals, and the Company's contemplated rights offering.

An extraordinary shareholders' meeting (EGM) will take place on Thursday [27 October 2022](#) at 2:00 p.m. CEST at the offices of the Company at Generaal de Wittelaan 11B, 2800 Mechelen, Belgium to fully effect the comprehensive recapitalization transaction, subject to the fulfilment of the attendance quorum requirement of at least 50% of the outstanding shares for the majority of the items on the agenda of the EGM. The convening notice and other documents relating to the EGM can be consulted on the [website](#) of the Company.

## **OUTLOOK**

Product revenues are expected to be impacted in Q4 2022 as a direct result of the current economic environment. Planned and often committed product sales are deferred in light of postponed investment decisions by certain collaboration partners and new customers. In particular, certain content partners decided to postpone clinical trials that were projected to start in 2022, involving the placement of a significant number of Idylla™ instruments, and would now shift into 2023. Furthermore, an increasing number of new customers onboard Idylla™ through a free-of-charge Idylla™ instrument evaluation program. Under this program, customers can make use of the instruments while only paying for the cartridge consumption. Revenues from the sale or the rental of these instruments are therefore delayed by an average of six months, subject to the satisfactory outcome of the evaluation. Generally, both partners and customers recently became more cautious and hold less cartridge stock.

The expected product revenue for 2022 is now projected to be around EUR 45m. More importantly however, the profitability continues to improve, and the product gross margin for the year is expected to be at least 30% versus the previous expectation of 25%-30%. Similarly, the operating cash burn is expected to improve to between EUR 41m-EUR 43m, versus the previously stated range of EUR 43m-EUR47m. Full year guidance is now summarized as follows:

- Increase product revenues to be around EUR 45m (versus around EUR 50m previously)
- Increase gross margins on product sales to at least 30% (from 25% - 30% previously)
- Reduce the operating cash burn (EBITDA plus capital expenditure) by around EUR 13.5-15.5m, to approximately EUR 41m - 43m for full year 2022 (vs EUR 43m - 47m previously)

In spite of rising inflation and its significant impact on costs, we remain committed to reduce our operating cash burn and are implementing various measures to further improve the profitability. Amongst others cartridge manufacturing will be further streamlined and, starting 2023, more than 90% of commercial cartridge production will have been transferred to the highly automated second manufacturing line 'ML2', allowing to further grow the gross margin. Furthermore, operating costs have been reduced across the business, while maintaining the focus on continued menu expansion and achieving global commercial success. More detailed guidance on expected performance in 2023 will be provided when announcing the full year 2022 results on 23 February 2023.

For the time being, due to the ongoing replanning, the Company does not provide an outlook on timing of product launches and registrations.

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<sup>5</sup> Such as the partial equitization equal to 10% of notional amounts outstanding, a maturity extension by 3.5 years to November 2027 and remaining coupons to be paid as Payment-In-Kind (via capitalization of coupons) to preserve cash

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## FINANCIAL CALENDAR

- 27 October 2022 Extraordinary Shareholders' Meeting Biocartis Group NV
- 23 February 2023 2022 full year results
- 30 March 2023 Publication 2022 annual report
- 20 April 2023 Q1 2023 Business Update
- 12 May 2023 Annual Shareholders' Meeting Biocartis Group NV
- 31 August 2023 H1 2023 results
- 9 November 2023 Q3 2023 Business Update

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## About Biocartis

With its revolutionary and proprietary Idylla™ platform, Biocartis (Euronext Brussels: BCART) aspires to enable personalized medicine for patients around the world through universal access to molecular testing, by making molecular testing actionable, convenient, fast and suitable for any lab. The Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) based system designed to offer in-house access to accurate molecular information in a minimum amount of time for faster, informed treatment decisions. Biocartis' continuously expanding menu of molecular diagnostic tests addresses key unmet clinical needs, with a focus in oncology. This is the fastest growing segment of the molecular diagnostics market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal, lung and liver cancer, as well as for COVID-19, Flu, RSV and sepsis. For more information, visit [www.biocartis.com](http://www.biocartis.com) or follow Biocartis on Twitter @Biocartis\_, Facebook or LinkedIn.

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## Forward-looking statements

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