

## **Biocartis Reports Results of First Quarter of 2023: 16% Growth of Oncology Cartridge Revenues Gross Margin on Products of 37% and EBITDA of EUR -8.4m**

**Mechelen, Belgium, 20 April 2023** – Biocartis Group NV (the "Company" or "Biocartis"), an innovative molecular diagnostics company (Euronext Brussels: BCART), today provides a business update for the first quarter of 2023 and the outlook for the full year 2023.

**Commenting on the Q1 2023 results, Herman Verrelst, Chief Executive Officer of Biocartis, said:** *"The start of 2023 was broadly in line with our expectations, with 16% growth of cartridge revenues in our core oncology business and a 35% gross margin. While we still expect to grow such product related revenues by 25-30% for the entire year, we saw Q1 2023 revenues were affected by the impact of the price increases we implemented end of 2022 that led customers to place anticipative orders, particularly so in the US. Furthermore, the macroeconomic environment continued to slow down investments in the development and the commercialization of certain partner products, affecting both cartridge as well as instrument sales. Despite these effects, which we believe to be temporary and short-term, we again took critical steps in securing future growth that will be driven by continued menu - and geographical expansion. Our Idylla™ MSI Test received 510(k) clearance<sup>1</sup> by the US FDA, marking the start of the commercialization of our in-vitro diagnostic solution for clinical use and paving the way to unlock significant growth potential in the US. Launching the Idylla™ IDH1-2 Mutation Assay Kit (RUO<sup>2</sup>) among selected customers was a breakthrough for our new Idylla™ FLEX technology that we expect will allow us to bring new assays to the market faster and to further tap into the vast market of liquid biopsy-based monitoring. We also welcomed APIS Assay Technologies as a new collaboration partner and look forward to adding their novel Breast Cancer Subtyping test to our broad oncology menu on Idylla™. Finally, we implemented management changes to enhance our focus on the US market. Bryan Dechairo was appointed to the board of directors and in my new role of executive chairman of the board of directors, I look forward to partnering with Roger Moody, Biocartis' new CEO who brings a wealth of experience in the US diagnostic industry to our executive leadership team. We are more confident than ever about our ability to sustain future growth to profitability and, save for further impact of the current economic climate on ongoing collaborations, we reiterate our expectations for the year."*

### **Q1 2023 HIGHLIGHTS**

- Product related revenue of EUR 10.8m, up 2% year-on-year and including EUR 8.5m cartridge revenue from 75k cartridges sold and EUR 2.3m from instrument sales, rentals and servicing:
  - Oncology cartridge revenue of EUR 8m (+16% year-on-year)
  - Revenue contribution from Idylla™ SARS-CoV-2 product sales down by 53%, from EUR 1.1m in Q1 2022 to EUR 0.5m in Q1 2023
  - Cartridge Average Sales Price (ASP) of EUR 120 in oncology and EUR 113 overall vs EUR 114 and EUR 101 in Q1 2022, respectively
  - EUR 2.2m revenue from instruments. 57 net new instruments placed year-to-date, total installed base of 2,142 instruments end of Q1 2023
- Gross profit on product sales<sup>3</sup> of EUR 3.8m (Q1 2022: EUR 3.5m), reflecting a gross margin of 37% (34% for the full year 2022). Q1 2023 was the last quarter that included cartridge production on the old manufacturing line ML1, which is now no longer in use for commercial cartridge production. Continued scaling of the more automated high-throughput manufacturing line ML2 is expected to further reduce cartridge production cost and contribute to a gross margin on products of 40-45% for the full year 2023
- EBITDA<sup>4</sup> of EUR -8.4m, an improvement of EUR 1.1m or 12% year-on-year. The cash position end Q1 2023 amounts to EUR 43.9m
- Idylla™ test menu & partnerships:
  - Announcement [9 February 2023](#): Launch among selected customers of the Idylla™ IDH1-2 Mutation Assay Kit (RUO), the first test developed with the new Idylla™ FLEX technology that separates the generic components of an Idylla™ test from the test-specific components
  - Announcement [2 March 2023](#): 510(k) clearance by the U.S. Food and Drug Administration (FDA) for the Idylla™ MSI Test
  - Post the reporting period, announcement [4 April 2023](#): New partnership agreement with [APIS Assay Technologies](#) Ltd. for development of APIS' [Breast Cancer Subtyping assay](#) on the Idylla™ platform. This

1 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). 510(k) (premarket notification) to FDA is required at least 90 days before marketing unless the device is exempt from 510(k) requirements. Source: <https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances>, last consulted on 17 April 2023

2 RUO = Research Use Only, not for use in diagnostic procedures

3 Excluding instrument servicing

4 Earnings before interest, taxes, depreciation and amortization

assay, already available for in vitro diagnostic use<sup>5</sup> in centralized expert laboratories in the UK, will be commercialized<sup>6</sup> by Biocartis ahead of the Idylla™ version of the assay

- Organizational news:
  - *Recapitalization* – Announcement on [16 January 2023](#) on the completion of the final steps of the comprehensive recapitalization transactions
  - *Strengthening US market positioning* - During Q1 2023 and shortly after, the Company undertook several actions to strengthen its orientation towards the US market:
    - Announcement on [22 February 2023](#): Resignation of Mr. Roald Borré as Director and appointment of Mr. Bryan Dechairo as a new independent board member and member of the Audit Committee of the Company
    - Announcement post the reporting period, on [11 April 2023](#): Appointment of Roger Moody to the position of Chief Executive Officer effective 24 April 2023<sup>7</sup>. Herman Verrelst, who has been the Company's Chief Executive Officer since August 2017, will move into the new position of Executive Chairman of the board of directors. Christian Reinaudo, who has served as Chairman of the board since May 2018, will assume the role of Lead Independent Director to act as principal liaison between the non-executive members of the board and the executive leadership team

## 2023 OUTLOOK

Biocartis reconfirms its 2023 guidance:

- Product related revenues<sup>8</sup> of between EUR 55m and EUR 60m, reflecting growth of 25%-35% when excluding sales of SARS-CoV-2 tests that are expected to further decrease
- A gross margin on product sales<sup>9</sup> of between 40% and 45%
- EBITDA of between EUR -25m and EUR -28m, an improvement of between EUR 8.5m to EUR 11.5m

These projections are based on foreign currency exchange rates applicable on 23 February 2023, the date on which the 2022 results and 2023 outlook were published.

## IDYLLA™ TEST MENU OUTLOOK

After having obtained US FDA 510(k) clearance for the Idylla™ MSI Test in Q1 2023, Biocartis expects to achieve the following regulatory milestones and to launch the assays listed below. The timing of the planned launch of partner tests remains subject to changes imposed by the relevant partners:

- *SeptiCyte® RAPID on Idylla™ EDTA* – submission of 510(k) to the US FDA by Immunexpress
- *Idylla™ IDH1-2 Mutation Assay Kit (RUO)* – Global availability to all customers
- *Idylla™ PIK3CA-AKT1 Mutation Assay* – RUO product development in collaboration with LifeArc
- *Idylla™ Merlin CP-GEP Assay* – RUO launch in collaboration with SkylineDx
- *Idylla™ ThyroidPrint Assay* – RUO launch in collaboration with GeneproDx

## FINANCIAL CALENDAR

- 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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## More information:

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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, liver and breast 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.

<sup>5</sup> Registered as IVD in the UK, submission for IVDR CE marking pending

<sup>6</sup> In the European Union and selected export markets

<sup>7</sup> Mr Moody will also become a member of the Board of Directors, subject to the approval by the Company's general shareholders' meeting

<sup>8</sup> Including revenue from instrument servicing

<sup>9</sup> Excluding revenue from instrument servicing

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**Forward-looking statements**

*Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.*