

26 September 2023, 07:00 CEST

## **BIOCARTIS ANNOUNCES H1 2023 RESULTS AND PROVIDES AN UPDATE ON THE OPERATIONAL REORGANIZATION AND RECAPITALIZATION**

*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 2023 results*

- *Solid performance with 22% growth of oncology cartridge revenue, a 40% gross margin on product sales and a 20% improvement in EBITDA to EUR -14.5m*
- *Operational reorganization and cost reduction program nearing completion aimed at reaching operating break-even result by the end of 2024*
- *Comprehensive recapitalization and balance sheet restructuring plan by secured creditors announced and expected wind down of listed holding entity*

**Mechelen, Belgium, 26 September 2023** – 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 2023, prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union, and provides an update on the status of its operational reorganization and the recapitalization.

**Commenting on the H1 2023 results and post-reporting period events, Roger Moody, Chief Executive Officer of Biocartis, said:** *"The core business performance remains strong. However, it became evident that difficult market conditions combined with the Company's balance sheet and historic burn rate made outside funding unattainable. Given this reality, the recapitalization and balance sheet restructuring plan by the secured creditors that we announced today, while disappointing to shareholders and unsecured bondholders, is necessary to fund operations and clear up most of the debt and provide long-term stability for the Biocartis business entities. The recapitalization and balance sheet restructuring plan will safeguard the interests of our customers, suppliers, partners, and employees and allows the operational Biocartis companies to continue their mission to enable universal access to personalized medicine for patients around the world by making molecular testing convenient, fast, and suitable for any lab.*

*The operational performance of the Biocartis business in H1 2023 underpins the strong fundamentals of the business. A solid 22% growth of core cartridge revenue in oncology and a 40% gross margin on product sales were complemented by a consistent contribution of collaboration revenues from our growing network of strategic partners.*

*I am convinced that, under the new, recapitalized holding company and in combination with the operational reorganization and cost reduction program that are now being completed, we will now accelerate the path to becoming a financially healthy and sustainable business."*

### **Recapitalization and Balance Sheet Restructuring Plan**

The Company today announced an agreement by its secured creditors on a comprehensive corporate restructuring and recapitalization transaction (the "**Transaction**"). The Transaction will safeguard the interests of customers, suppliers, partners, and employees of Biocartis, and help to continue and execute the growth strategy towards profitability of its operations and will provide for the following:

- The Company's secured creditors will take ownership of the Biocartis operating subsidiaries through enforcement. Following enforcement, Biocartis Group NV is expected to be wound down in an orderly fashion.
- A new entity will be incorporated ("**New Biocartis**"), owned by the secured creditors, to which substantially all the Company's assets will be transferred upon an anticipated security enforcement by the secured creditors over the Company's assets that were pledged to such creditors.
- Lenders under the Company's first lien convertible term loan facility and KBC have agreed to roll over their first lien debt into New Biocartis (or its wholly owned subsidiaries) and release claims against Biocartis Group NV. KBC have agreed to extend their financing to Biocartis NV and Biocartis US, Inc.

- The interests and claims of the EUR 16 million unsecured 4.00% convertible bonds due 2027 (ISIN BE0002651322) will be written down to zero pursuant to their terms as part of the enforcement.
- Shareholders of Biocartis Group NV will receive no distribution from the security enforcement and are expected to receive nothing at the time of its wind down.
- With respect to New Biocartis:
  - The Company's EUR 116 million 4.5% Second Ranking Secured Convertible Bonds due 2026 (ISIN BE6338582206) (the "**Bonds**", and the holders of the Bonds, the "**Bondholders**") will be fully equitized in New Biocartis and the Bondholders will become the primary owners of Biocartis's operating business as shareholders of New Biocartis.
  - The Bondholders will recapitalize New Biocartis (and its operating subsidiaries) with EUR 40 million of equity capital, backstopped by a group of supporting Bondholders (the "**Equity Injection**").
  - Following the full equitization of EUR 116 million of Bonds, the write down of EUR 16 million of Unsecured 2027 Bonds, and the closing of the Equity Injection, New Biocartis will have less than EUR 45 million of gross debt and net debt of approximately zero.

## H1 Financial highlights

- **Product related revenue** of EUR 23.5m (H1 2022: EUR 21.3m), including EUR 18.4m from 155k cartridges sold and EUR 5.1m from instrument sales, rentals, and servicing:
  - EUR 17.5m cartridge revenue in oncology, +22% year-on-year, driven by 14% cartridge volume growth and an increase of the average selling price ('ASP') by 7%
  - The contribution of COVID-19 testing to cartridge revenues decreased from EUR 1.7m in H1 2022 to EUR 0.7m in H1 2023, down to 3% of total product related sales
  - ASP per commercial cartridge of EUR 120 in oncology and EUR 115 overall (H1 2022: EUR 113 and EUR 103, resp.)
  - EUR 5.1m revenue from a global Idylla™ installed base of 2,218 instruments, with 133 net new instruments placed in H1 2023 (H1 2022: 102)
  - Continued double-digit growth of oncology cartridge revenue across all regions. Renewed growth in US instrument placements and oncology cartridge sales during Q2 2023 after a slowdown in Q1 that was driven by the impact of a cartridge price increase implemented in Q4 2022.
- **Collaboration revenue** of EUR 6m, an increase of 18% compared to H1 2022 driven by expansion of our network of strategic partners
- **Gross profit on product sales** increased by 36% from EUR 6.6m to EUR 9m, reflecting a gross margin of 40%, compared to 32% in H1 2022 and a further improvement from 37% in Q1 2023. Commercial cartridges are now exclusively produced on the more automated high-throughput manufacturing line ML2 after having decommissioned the older manufacturing line ML1 during Q1 2023
- **EBITDA** of EUR -14.5m (H1 2022: EUR -18.2m) and a **cash position** end H1 2023 of EUR 25.2m

## Organizational update

- *Operational reorganization and cost reduction program*
  - The operational reorganization and cost reduction program announced on 15 June 2023 is in its finalization phase. In total, approximately 125 positions will be reduced. In addition, the role of approximately 20 positions has significantly changed. A proportion of these positions will be phased out during the remainder of 2023, to ensure a smooth handover of activities. The reorganization is realized through a transition to a leaner and more agile management structure and an increased focus on partner funded test menu expansion and a more targeted US commercial strategy to increase oncology test utilization. The reorganization is expected to achieve an annualized cost reduction of approximately EUR 18m. The process has been completed in accordance with the Belgian rules on collective dismissals. Total cost associated with the operational reorganization amount up to EUR 4.3m
  - Going forward, enabling access to molecular diagnostic testing in oncology remains at the core of Biocartis' strategy with a streamlined organization that will focus investments on profitable product revenue generation and strategic partnerships that have the potential to generate significant long-term value
- *Management changes:*
  - Appointment of Roger Moody as new CEO per 24 April 2023, with Herman Verrelst transitioning into the role of Chair of the Board of Directors
  - Appointment of George Cardoza as new CFO and Head of Service Delivery per 7 August 2023 following the resignation of Jean-Marc Roelandt as the Company's CFO per 4 Aug 2023
  - Resignation of Piet Houwen as COO per 1 September 2023 as part of the operational reorganization

- *Cartridge manufacturing* – The transfer of all Idylla™ assays to the second generation cartridge manufacturing line ('ML2') was completed and all commercial cartridge manufacturing production on ML1 was stopped after Q1 2023. 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
- *New Medical Advisory Board* – creation of new Medical Advisory Board announced on 28 August 2023 comprised of renowned practice leaders to assist with expedited growth of diagnostics partnerships and provide valuable expert technology insights, expert knowledge in the field of oncology in general and of pharma needs in particular

## Idylla™ test menu, partnerships & publications

- *Test menu and product registrations*
  - Launch among selected customers on [9 February 2023](#) of the Idylla™ IDH1-2 Mutation Assay Kit (RUO). The test was subsequently launched globally in July 2023
  - Announcement on [2 March 2023](#): 510(k) clearance by the U.S. Food and Drug Administration (FDA) for the Idylla™ MSI Test
  - Japan – End of April 2023, Nichirei Biosciences, Biocartis' distribution partner in Japan, received the approval by the Japanese competent authorities (Ministry of Health, Labor and Welfare) to commercialize the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test in Japan.
- *Partnerships:*
  - Announcement on [4 April 2023](#) of a new partnership agreement with [APIS Assay Technologies Ltd.](#) For development of APIS' [Breast Cancer Subtyping assay](#) on the Idylla™ platform. This assay, already available for in vitro diagnostic use<sup>1</sup> in centralized expert laboratories in the UK, will be commercialized<sup>2</sup> by Biocartis ahead of the Idylla™ version of the assay.
  - Announcement on [10 August 2023](#) of a new post-commercial collaboration program with Lilly to explore via an ongoing Lilly-sponsored study the advantages of adding Idylla™ to molecular diagnostic workflows in global clinical labs and help guide the improvement of US community-based diagnostic workflows.
- *Publications*
  - During H1 2023, 17 new papers were published, providing further evidence of Idylla's™ robust and accurate performance combined with much shorter turn-around times compared to other testing methods. In particular, one retrospective and prospective study on determining EGFR mutations from FFPE tissue samples<sup>3</sup> emphasized that integrating the ultra-rapid Idylla™ as a critical screening step before deploying NGS could provide timely and comprehensive benefits to patients, ultimately leading to better treatment outcomes in non-small cell lung cancer.

## KEY FIGURES H1 2023

The tables below show an overview of the key figures and a breakdown of operating income for H1 2023 and H1 2022. Consolidated financial statements and accompanying notes are included in Biocartis' half-year 2023 report available [here](#) on the Company's website.

Key figures (EUR 1,000)	H1 2023	H1 2022	% Change
<b>Total operating income</b>	<b>29,617</b>	<b>26,771</b>	<b>11%</b>
Cost of goods sold	-13,378	-13,720	-2%
Research and development expenses	-18,091	-19,251	-6%
Sales and marketing expenses	-10,892	-10,050	8%
General and administrative expenses	-8,018	-8,376	-4%
<b>Operating expenses</b>	<b>-50,379</b>	<b>-51,397</b>	<b>-2%</b>
<b>Operating result</b>	<b>-20,762</b>	<b>-24,626</b>	<b>-16%</b>
Net financial result	-10,140	-3,805	166%
Share in the result of associated companies	-375	-432	-13%
Income tax	23	96	-76%
<b>Net result</b>	<b>-31,254</b>	<b>-28,767</b>	<b>9%</b>
Cash flow from operating activities	-29,262	-24,154	21%
Cash flow from investing activities	-1,132	-1,594	-29%
Cash flow from financing activities	29,680	-9,542	-411%
<b>Net cash flow</b> <sup>1</sup>	<b>-714</b>	<b>-35,290</b>	<b>-98%</b>
<b>Cash and cash equivalents</b> <sup>2</sup>	<b>25,178</b>	<b>19,724</b>	<b>28%</b>
Financial debt	152,247	147,166	3%

<sup>1</sup> Excludes the effect of exchange rate differences on the cash balances held in foreign currencies

<sup>2</sup> Including EUR 1,2m of restricted cash in H1 2022 and H1 2021

<sup>1</sup> Registered as IVD in the UK, submission for IVDR CE marking pending

<sup>2</sup> In the European Union and selected export markets

<sup>3</sup> Qui et al. Ultra-rapid Idylla™ EGFR mutation screening followed by next-generation sequencing: An integrated solution to molecular diagnosis of non-small cell lung cancer. *Front Oncol.* 2023

<b>Operating income (EUR 1,000)</b>	<b>H1 2023</b>	<b>H1 2022</b>	<b>% Change</b>
<b>Collaboration revenue</b>	<b>5,987</b>	<b>5,082</b>	<b>18%</b>
Idylla™ system sales	4,000	3,824	5%
Idylla™ system service sales	1,145	977	17%
Idylla™ cartridge sales	18,359	16,477	11%
<b>Product related revenue</b>	<b>23,504</b>	<b>21,278</b>	<b>10%</b>
<b>Total revenue</b>	<b>29,491</b>	<b>26,360</b>	<b>12%</b>
Grants and other income	126	411	-69%
<b>Total operating income</b>	<b>29,617</b>	<b>26,771</b>	<b>11%</b>

- *Total operating income* – Total operating income amounted to EUR 29.6m compared to EUR 26.8m in H1 2022. Product related revenues increased by 10% from EUR 21.3m in H1 2022 to EUR 23.5m in H1 2023. Within product sales, cartridge sales revenues amounted to 18.4m. Revenue from oncology cartridge sales represented EUR 17.5m and grew by 22% year-on-year. Revenue from the sale of Idylla™ SARS-CoV-2 tests<sup>4</sup> continues to decrease and amounted to EUR 0.7m compared to EUR 1.7m in H1 2022. Revenues from the sale, rental and servicing of Idylla™ instruments increased by 7% and amounted to EUR 5.1m (H1 2022: EUR 4.8m). 133 net new instrument placements in H1 2023 increased the global installed base to 2,218, evenly split between reagent rental agreements and straight capital sales. Collaboration revenue amounted to EUR 6m in H1 2023 compared to EUR 5.1m in H1 2022 and largely consisted of development services delivered to our growing network of strategic partners
- *Gross profit* – Gross profit on product sales amounted to EUR 9m, an increase of 32% from EUR 6.6m in H1 2022. The gross margin on products continue to increase, from 32% in H1 2022 to 40% in H1 2023, driven by continued scaling of the high-throughput manufacturing line ML2 and the increasing ASP. 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. The overall cartridge ASP increased from EUR 103 in H1 2022 to EUR 115 in H1 2023, as a result of declining sales of the cheaper Idylla™ SARS-CoV-2 tests and the continued increased contribution of higher-priced novel tests in oncology
- *OPEX* – Total operating expenses (excluding cost of sales) of EUR 37m in H1 2023 slightly decreased by EUR 0.7m from EUR 37.7m in H1 2022. The cost reduction implemented during Q4 2022 was partly offset by the impact of the high inflation which led to a mandatory indexation of wages and salaries in January 2023 of over 11% in Belgium
- *Operating result* – The sustained revenue growth and the increased gross profit contributed to a 20% y-o-y improvement of EBITDA, from EUR -18.2m in H1 2022 to EUR -14.5m in H1 2023
- *Net cash flow and cash position* – Cash burn from operating activities increased from EUR 24.2m to EUR 29.3m, despite the improved operating result, which was offset by EUR 10.3m investments in working capital (H1 2022: EUR 2.6m) and EUR 1m higher interest expenses. Last year, working capital was favorably impacted by the collection of the fire insurance claim. Moreover, a significant amount of transaction fees associated with the recapitalization were paid during the first half of 2023 and trade receivable increased a.o. because of the deferred payment of services to certain collaboration partners that are expected to be collected during the second half of 2023. Investing cash flows amounted to EUR 1.1m and included the drawdown of the convertible note by SkylineDx after having reached an agreed milestone in the development of the Idylla™ version of SkylineDx's Merlin assay. On 16 January 2023, the comprehensive recapitalization was completed, and the financing cash flows included EUR 34.4m of net proceeds from the issuance of EUR 25m of new second lien convertible bonds and the final drawdown of EUR 12m under the convertible term loan

## **IDYLLA™ TEST MENU OUTLOOK**

After having obtained US FDA 510(k) clearance for the Idylla™ MSI Test in Q1 2023 and the global availability of the Idylla™ IDH1-2 Mutation Assay Kit (RUO), 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:

- Idylla™ PIK3CA-AKT1 Mutation Assay – RUO product developed in collaboration with LifeArc
- Idylla™ Merlin CP-GEP Assay – RUO launch in collaboration with SkylineDx
- Idylla™ ThyroidPrint Assay – RUO launch in collaboration with GeneproDx

## **POST-PERIOD EVENTS**

- Announcement of appointment of George Cardoza as new CFO and Head of Service Delivery – see above
- Announcement of new collaboration with Lilly – see above
- Creation of the new Medical Advisory Board – see above
- Comprehensive recapitalization and balance sheet restructuring plan by secured creditors – see above

## **FINANCIAL CALENDAR**

- 9 November 2023 Q3 2023 Business Update

<sup>4</sup> The Idylla™ SARS-CoV-2 Test (CE-IVD) and the Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD)

*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 2023 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 wish to 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.*

## **AUDITOR STATEMENT**

The condensed consolidated interim financial statements for the six-months' period ended 30 June 2023 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 2022. 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 Houthaevae, has performed a limited review, which did not reveal any significant adjustments to the condensed consolidated interim financial statements, and emphasizes the change in the preparation basis towards a basis other than that of going concern. The interim financial report 2022 and the review opinion of the auditor are available on [www.biocartis.com](http://www.biocartis.com).

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### **More information:**

Corporate Communications & Investor Relations Biocartis

e-mail [ir@biocartis.com](mailto:ir@biocartis.com)

tel +32 15 631 729

[@Biocartis](#) [www.linkedin.com/Biocartis](https://www.linkedin.com/Biocartis)

### **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. Idylla™'s continuously expanding menu of molecular diagnostic tests address 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 and sepsis. More information: [www.biocartis.com](http://www.biocartis.com). Follow us on [Twitter](#): @Biocartis\_.

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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*

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