## **BIOCARTIS ANNOUNCES 2022 RESULTS AND 2023 OUTLOOK**

The Company will host a conference call with live webcast presentation today at 14:30 CET / 13:30 GMT (UK) / 08:30 EST (US) to discuss the full year 2022 results

**Mechelen, Belgium, 23 February 2023** – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its operational highlights and financial results for 2022, prepared in accordance with IFRS as adopted by the European Union, as well as selected post period events and its outlook for 2023.

**Commenting on the 2022 results and post-reporting period events, Herman Verrelst, Chief Executive Officer of Biocartis, said:** "2022 was a successful year, both operationally and financially. In a troubled macroeconomic environment, we continued to scale our core oncology business and delivered on our financial objectives with strong 30% growth of oncology revenues, a doubling of the gross margin on product sales to 34%, and a sizeable EUR 18.1m or 32% reduction of our operating cash burn. Furthermore, we laid solid foundation for continued future growth. The regulatory approval of the ldylla™ instrument in China and of the ldylla™ MSI Test as a companion diagnostic test (CDx<sup>1</sup>) in Japan will broaden our global commercial footprint. The extension of the collaboration with AstraZeneca aimed at developing a CDx for Tagrisso<sup>®</sup> and the commercialization of SkylineDx's Merlin™ Assay and Ophiomics' HepatoPredict show that partnerships are a powerful means to rapidly expand the menu of oncology tests and to make it available to any lab. Now that we also successfully recapitalized the company with EUR 66m of gross cash proceeds and a strengthened capital structure, we are in a strong position to take another significant step towards profitability. Several new regulatory approvals and new product launches are planned for 2023, including the launch of the ldylla™ IDH1-2 Mutation Assay Kit (RUO), the first assay developed with our new Idylla™ FLEX technology that significantly shortens development times and that will allow us to bring more tests to the impact of significant cost inflation, and we are confident that in 2023 we will continue to grow product related revenues, again improve the gross margin on product sales and further reduce the operating cash burn."

# **KEY MESSAGES 2022 RESULTS**

- Total operating income of EUR 58m (2021: EUR 54.9), of which EUR 57.5m revenue, an increase of 19% from EUR 48.3m in 2021
- Product revenue of EUR 45m (2021: EUR 40.5m), of which EUR 35.9m from 334k cartridges sold and EUR 9.2m from instrument rentals and sales:
  - EUR 31.3m cartridge revenue in oncology, a 30% year-on-year increase, double-digit growth across all regions, led by the US, both in cartridge volumes and in average selling price (ASP)
  - COVID-19 testing needs were fading, decreasing the revenue contribution from SARS-CoV-2 tests to EUR 3.5m
  - Continued increase of ASP per commercial cartridge to EUR 106 (2021: EUR 96). Oncology ASP at EUR 116 (+11%)
  - Global Idylla<sup>™</sup> installed base of 2,085 instruments, 173 net new instruments placed

- Gross profit on product sales increased from EUR 6.6m in 2021 to EUR 15.2m in 2022, an increase of 132% reflecting a gross margin of 34%, compared to 16% in 2021
- **Operating cash burn**<sup>2</sup> of EUR -38.5m, a reduction of more than a third or EUR 18.1m lower than in 2021
- Comprehensive recapitalization:
  - EUR 66m gross cash proceeds across convertible debt (EUR 41m) and equity (EUR 25m)
  - Convertible debt restructured and extended by 2.5 years
  - Fully completed post the reporting period on 16 January 2023, adding EUR 36.1m to the year-end cash position of EUR 26.1m
- Partnerships:
  - Extension of the collaboration with AstraZeneca aimed at developing a companion diagnostic (CDx) for use with Tagrisso<sup>®</sup> (osimertinib), AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment
  - Start of Biocartis' commercialization in Europe of SkylineDx's Merlin Assay as a CE-IVD, ahead of the launch of an Idylla<sup>™</sup> version of
     the

## 2023 OUTLOOK

Building on the strong performance of 2022, Biocartis expects to take a next significant step towards operating profitability, with:

- Product related revenues<sup>3</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>4</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 current foreign currency exchange rates.

Biocartis will host a conference call with live webcast presentation today at 14:30 CET / 13:30 GMT (UK) / 08:30 EST (US) to discuss the full year 2022 results. The live webcast presentation will be available through <u>this link</u> on the day of the event. Only participants who want to ask a question and/or follow the event over the phone, are requested to register for the webcast presentation <u>here</u>. Upon registration, each participant will be provided with dial-in numbers and a unique personal PIN. The conference call and webcast will be conducted in English. A replay of the webcast will be available on the <u>Biocartis investors' website</u> shortly after.

## Commercial highlights

• 334k cartridges sold in 2022, compared to 326k in 2021: 14% year-on-year growth in oncology, offset by the continued decrease of COVID-19 testing, causing volumes in infectious disease to decrease by 36% year-on-year

- Oncology cartridge revenues grew 30% in 2022: double-digit growth of cartridge volumes across all regions coupled with a consistently increasing ASP of EUR 116 (+11%):
  - Sustained growth across Europe with growing adoption of the higher-priced Idylla<sup>™</sup> GeneFusion Panel in routine clinical use since its launch in June 2022
  - The US continues to combine the highest growth of oncology cartridge volumes with sustained pricing discipline. Several new customers among the top 10 cancer centers adopted Idylla<sup>™</sup> in 2022. The ASP in oncology, traditionally higher in the US than in our other markets, benefitted from a favorable product mix and a smaller proportion of free-of-charge cartridge volumes for market seeding and the initial validation of assays
  - Strong performance of the distributor markets<sup>5</sup> supported by the commercial agreement with AstraZeneca aimed at increasing access to Idylla™ EGFR testing products for patients with non-small cell lung cancer
- Total revenue from Idylla<sup>™</sup> instruments increased by 3% to EUR 9.2m in 2022, including instruments sold to content partners<sup>6</sup>:
  - Revenue generated from instrument placements at end customers increased by 36% year-on-year, against a 9% increase of the installed base of Idylla<sup>™</sup> instruments, which is evenly split between sold and rented instruments
  - Certain clinical trials that were planned to start in 2022 and requiring the sale of a significant number of Idylla<sup>™</sup> instruments were delayed by our content partners in light of the uncertain economic environment
  - Instrument revenue in the US more than doubled, even though several new customers deferred the investment decision and adopted Idylla<sup>™</sup> through Biocartis' free-of-charge evaluation program under which they can temporarily use the instrument while only paying for the cartridge consumption. Subject to the favorable outcome of the evaluation, revenues from the ultimate sale or rental of such instruments are therefore delayed by 6 months on average
  - 173 net new instruments placed. Several instruments were reclaimed following a focused review of non-performing reagent rental agreements to eliminate non-profitable investments in capital expenditure

#### Idylla<sup>™</sup> test menu, partnerships & publications

- Test menu:
  - Launch of the fully automated, CE-marked IVD Idylla<sup>™</sup> GeneFusion Panel on 20 June 2022
  - Launch of new SeptiCyte RAPID<sup>®</sup> (CE-IVD) EDTA<sup>7</sup> blood compatible cartridges<sup>8</sup> by Biocartis' partner Immunexpress on <u>23 August 2022</u>
  - Start of the commercialization on <u>1 September 2022</u> in Europe of SkylineDx's innovative Merlin Assay as a CE-IVD marked manual kit, ahead of the launch of an Idylla<sup>™</sup> version of the Assay
- *Product registrations:* 
  - 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<sup>™</sup> MSI Test in Japan. Nichirei Biosciences plans the commercial launch of the Idylla<sup>™</sup> MSI Test as a CDx in Japan in Q1 2023

- China Regulatory approval of the Idylla<sup>™</sup> instrument on 16 September 2022 by the Chinese regulatory authorities NMPA, an important step towards the further regulatory and commercialization of Idylla<sup>™</sup> assays in China
- Partnerships:
  - Announcement of a new partnership on <u>8 February 2022</u> between Biocartis and <u>Ophiomics</u>, a Lisbon (Portugal) based biotech company with an initial focus on the commercialization of <u>HepatoPredict</u><sup>9</sup>. The commercialization in Europe of the test as a CE-marked IVD kit started on <u>10 October 2022</u>
    - Announcement of an extension of the collaboration with AstraZeneca on <u>22 June 2022</u> highlighting the development and planned premarket submission to the US FDA of a novel CDx test on the Idylla<sup>™</sup> platform for AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment
- *Publications* During 2022, 42 new papers with excellent data were published on <u>several new Idylla<sup>™</sup> studies</u>, including:
  - A study (announced <u>4 May 2022</u>) by Memorial Sloan Kettering Cancer Center (NY, US), in the *Journal of Molecular Diagnostics* on the <u>Idylla™ GeneFusion Assay</u> (RUO<sup>10</sup>), highlighting the quicker turnaround and the lower tissue requirements compared to immunohistochemistry and molecular methods, while also circumventing the infrastructure dependencies associated with NGS and fluorescence in situ hybridization.
  - A large prospective study (announced <u>8 November 2022</u>) demonstrating that the Idylla<sup>™</sup> EGFR Mutation Test (CE-IVD) leads to the significant reduction of the time-to-treatment by on average 16.8 days or 48% compared to NGS testing for EGFR positive patients

## Organizational and operational highlights

- Commercial milestones Double milestone announced on <u>15 June 2022</u> with the selling of the 1,000,000th commercial Idylla<sup>™</sup> cartridge and the placement of the 2,000th Idylla<sup>™</sup> instrument since commercial launch
- Shareholders' Meetings All agenda items were approved during the <u>ordinary shareholders' meeting</u> held 13 May 2022 and the <u>extraordinary</u> <u>shareholders' meeting</u> held 14 November 2022 which approved the various components of the Company's comprehensive recapitalization
- Cartridge manufacturing Except for the Septicyte RAPID<sup>®</sup> test, the transfer of all assays to the second cartridge manufacturing line ('ML2') was completed during 2022, further unlocking economies of scale and reducing manufacturing costs
- ISO 27001 certification ISO 27001 certification of Biocartis announced on <u>24 August 2022</u> for the design, development, maintenance, service provision and support of the Idylla<sup>™</sup> 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, joined 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 more than 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, moved into the role of Global Head of Sales
- In Q4 2022, the organization was streamlined across all areas of the business to withstand the impact of the significant cost inflation. Compared to 31 December 2021, the workforce decreased by 16%

## Financial highlights

- Total operating income Total operating income amounted to EUR 58m, compared to EUR 54.9m in 2021, and included EUR 45m from product sales (2021: EUR 40.5m; +11%), EUR 11.1m from various collaborations with partners (2021: EUR 6.1m; +83%), EUR 1.4m from instrument servicing (2021: EUR 1.7m; -20%) and EUR 0.5m other income (2021: EUR 6.6m; -93%)
  - Revenues from cartridge sales grew 13% year-on-year to EUR 35.9m. Cartridge sales in the core oncology business increased by 30%, while sales of the SARS-CoV-2 cartridges decreased by 49% and only represented 7.7% of total product revenues. 334k cartridges were sold in 2022 (2021: 326k) at an ASP of EUR 106 (2021: EUR 96).
  - The strong 30% growth of oncology cartridge revenue resulted from growing cartridge volumes (+14% year-on-year) and an increased ASP of EUR 116, compared to EUR 105 in 2021. The ASP in oncology continues to develop favorably as the contribution from high value-adding assays such as the Idylla<sup>™</sup> Genefusion Assay (RUO) continues to increase. A continued focus on pricing discipline and a gradually increasing contribution from sales in the US where prices are generally higher than in Europe and other parts of the world, also support the steady increase of the cartridge ASP. Conversely, the fading COVID-19 testing need resulted in 36% lower cartridge volumes in infectious diseases, while the ASP of EUR 63 also decreased 18% year-on-year
  - Revenues from the sale and rental of the Idylla<sup>TM</sup> instrument amounted to EUR 9.2m, a 3% increase year-on-year. The installed base grew with 173 instruments to 2,085 instruments, net of conversions from instruments previously placed free-of-charge under short-term evaluation programs and returns of non-performing instruments under reagent rental agreements aimed at reducing non-profitable capital investments. As a direct result of the uncertain economic climate, the planned sale of a significant number of instruments was delayed following the decision by certain content partners to delay clinical trials that were planned to start in 2022
  - Income from collaborations amounted to EUR 11.1m compared to EUR 6.1m in 2021, and mainly included R&D services provided to our pharma and content partners, aimed at expanding the Idylla<sup>™</sup> test menu and at developing companion diagnostic tests that will unlock additional market potential in the US and in other markets
  - Other income of EUR 0.5m related to grants received in connection with the development of the new Idylla<sup>™</sup> FLEX technology that is expected to facilitate the use of Idylla<sup>™</sup> tests in therapy decisions and molecular surveillance. The first product that is based on this Idylla<sup>™</sup> FLEX technology, the Idylla<sup>™</sup> IDH1-2 Mutation Assay Kit (RUO), was launched in 2023. In 2021, other income included an insurance claim of EUR 4.6m for damages caused by the fire in a warehouse in July 2021
- Cost of goods sold Cost of goods sold decreased by 12% to EUR 29.8m, while cartridge volumes and the number of newly placed instruments remained comparable to 2021. Contrary to 2021, a year of disrupted reagent supply and the temporary unavailability of manufacturing capacity caused by the fire in one of Biocartis' warehouses, most cartridges were produced on the high-throughput automated manufacturing line ML2 in 2022, unlocking significant economies of scale. The gross margin on product sales more than doubled from 16% in 2021 to 34% in 2022, as a

direct result of lower manufacturing costs per cartridge and the lower contribution of low-priced SARS-CoV-2 tests. In the first quarter of 2023, more than 90% of the commercial cartridge production will have been transferred to ML2 and a plan to fully decommission ML1 will be implemented over the year

- OPEX Total operating expenses, excluding the cost of goods sold, decreased 10% year-on-year from EUR 83.6m to EUR 75.2m. Apart from the fire damages of EUR 3.2m incurred in 2021, operating expenses decreased by EUR 5.2m, despite the impact of global inflation. Investments in various R&D programs were cut back by EUR 9.7m. The increase of EUR 3.8m in sales & marketing reflected normalized commercial activities post the pandemic and the full year impact of the restructuring of the US commercial operations implemented at the end of 2021. General & administrative spending levels remained stable at EUR 16.2m, an increase of 4% year-on-year that merely reflected cost inflation. In Q4 of 2022, the organization was streamlined to offset the expected continued inflation of costs in 2023, including the mandatory indexation of salaries in Belgium of 11%, effective January 2023. Among others, the workforce was reduced by 16% across the entire organization since 31 December 2021
- Recapitalization On 1 September 2022, Biocartis launched a comprehensive recapitalization, providing EUR 66m of gross proceeds and comprising:
  - the amendment of the existing 4% convertible bonds of EUR 135m, including a.o. the mandatory conversion of 10% of these convertible bonds into common shares at the conversion rate of EUR 12.89 and the extension of the maturity date until 9 November 2027
  - a new first lien secured convertible term loan of EUR 30.1m, partly used for the buy-back of EUR 16.3m of existing 4% convertible bonds for EUR 13.7m in cash
  - an exchange of the amended existing convertible bonds for new 4.5% second lien secured convertible bonds, subject to the subscription of EUR 25m of additional newly issued 4.5% convertible bonds, and
  - a rights offering with extra-legal preferential rights for the existing shareholders of the Company of EUR 25.1m

On 31 December 2022, the recapitalization transactions were partly completed. Following the amendment, the buy-back and the exchange offer, EUR 14.8m of existing 4% convertible bonds remained outstanding and EUR 92.1m of the 4% convertible bonds had been exchanged for the new 4.5% convertible bonds. EUR 18.1m was drawn under the new convertible term loan and 33,476,932 new shares were issued on 2 December 2022 through a rights offering of EUR 25.1m. Post year-end, the recapitalization completed on 16 January 2023 with the second drawdown of EUR 12m under the new convertible term loan and the funding of the additional new 4.5% convertible bonds for EUR 25m

- Financial results The net financial expense of EUR 0.01m included the impact of the recapitalization. In accordance with IFRS, the amendment and the exchange were considered as an extinguishment of the existing 4% convertible bond and the issuance of the new 4.5% convertible bond. The difference between the derecognition of the existing convertible bond and the new convertible bond was recorded as a gain of EUR 10.5m in the income statement. The interest and debt appreciation expense associated with the convertible term loan and the two convertible bonds amounted to EUR 10.2m
- Cash flows and cash balance The cash flow from operating and investing activities amounted to EUR -50.3m, a significant reduction of EUR 19.2m compared to EUR 69.5m in 2021. The reduction resulted from a.o. (a) EUR 15.6m improvement of the operating result, (b) EUR 5.8m lower investments in working capital, (c) EUR 1.8m lower capital expenditure, offset by (d) investments in the Chinese joint venture Wondfo-Cartis (EUR 1m) and in a convertible note issued by SkylineDx (of which EUR 2.5m was already made available by Biocartis). The net proceeds

from financing activities of EUR 22.5m reflected (a) a net new drawdown of EUR 9m on working capital facilities from KBC Bank, (b) EUR 18.1m proceeds from the first drawdown under the new convertible term loans, (c) the cash buy-back of existing convertible bonds for EUR 13.7m, (d) the scheduled reimbursement of EUR 6.6m of lease obligations, (e) EUR 25.1m proceeds of the rights issue, net of (f) EUR 9.6m fees associated with the recapitalization transactions. The cash and cash equivalents at 31 December 2022 amounted to EUR 26.1m.

Post year-end, the recapitalization transaction was completed on 16 January 2023, adding EUR 36.1m of net cash, from the second drawdown on the convertible term loan and the issuance of EUR 25m of additional 4.5% convertible bonds

Balance sheet – In accordance with IFRS 9, the new 4.5% convertible bonds were partly recorded as a liability and partly as equity. Following the recapitalization transactions, the financial indebtedness at 31 December 2022 amounted to EUR 117.8m compared to EUR 154.2m at 31 December 2021. The shareholders' equity increased by EUR 8.2m as a result of a.o. (a) the recognition of EUR 22.8m equity value attributed to the new convertible bond, (b) the issuance of new shares for EUR 23m, net of fees, following the rights offering and (c) the loss for the year of EUR
 47.7m

#### **KEY FIGURES 2022**

The tables below show an overview of the key figures and a breakdown of operating income for 2022 and 2021. A consolidated income statement, balance sheet, cash flow statement and statement of changes in shareholder equity of Biocartis Group NV is presented in the paragraph 'Financial information' below.

| Key figures (EUR 1,000)                     | 2022     | 2021     | % Change |
|---|----------|----------|----------|
| Total operating income                      | 57,976   | 54,898   | 6%       |
| Cost of sales                               | -29,799  | -33,922  | -12%     |
| Research and development expenses           | -38,393  | -48,054  | -20%     |
| Sales and marketing expenses                | -20,595  | -16,763  | 23%      |
| General and administrative expenses         | -16,236  | -15,560  | 4%       |
| Other expenses                              | -        | -3,244   |          |
| Operating expenses                          | -105,023 | -117,543 | -11%     |
| Operating result                            | -47,047  | -62,645  | -25%     |
| Net financial result                        | 10       | -8,411   | -100%    |
| Share in the result of associated companies | -884     | -659     | 34%      |
| Income tax                                  | 240      | 243      | -1%      |
| Net result                                  | -47,681  | -71,472  | -33%     |

| Cash flow from operating activities    | -44,855 | -65,716 | -32%    |
|--|---------|---------|---------|
| Cash flow from investing activities    | -5,431  | -3,748  | 45%     |
| Cash flow from financing activities    | 22,463  | -1,204  | -1,965% |
| Net cash flow <sup>1</sup>             | -27,823 | -70,668 | -61%    |
| Cash and cash equivalents <sup>2</sup> | 26,125  | 53,522  | -51%    |
| Financial debt                         | 117,803 | 154,162 | -24%    |

<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 2022 & 2021

| Operating income (EUR 1,000)     | 2022   | 2021   | % Change |
|----------------------------------|--------|--------|----------|
| Collaboration revenue            | 11,068 | 6,053  | 83%      |
| Idylla™ system sales and rentals | 9,172  | 8,869  | 3%       |
| ldylla™ cartridge sales          | 35,864 | 31,618 | 13%      |
| Product sales revenue            | 45,036 | 40,486 | 11%      |
| Service revenue                  | 1,377  | 1,730  | -20%     |
| Total revenue                    | 57,481 | 48,269 | 19%      |
| Grants and other income          | 495    | 6,629  | -93%     |
| Total operating income           | 57,976 | 54,898 | 6%       |

## IDYLLA™ TEST MENU OUTLOOK

In 2023, Biocartis expects to achieve certain 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™ MSI Test 510(k) pending review by the US FDA
- SeptiCyte<sup>®</sup> RAPID on Idylla<sup>™</sup> EDTA submission of 510(k) to the US FDA (in collaboration with Immunexpress)
- Idylla™ IDH1-2 Mutation Assay Kit Test (RUO) Global availability to all customers
- Idylla™ PIK3CA-AKT1 Mutation Assay RUO in collaboration with LifeArc
- Idylla™ Merlin CP-GEP Assay RUO in collaboration with SkylineDx
- Idylla™ ThyroidPrint Assay RUO in collaboration with GeneproDx

# POST-PERIOD EVENTS

- Announcement on <u>16 January 2023</u> of the completion of the final steps of the comprehensive recapitalization transactions
- Announcement on <u>9 February 2023</u> of the launch among selected customers of the Idylla<sup>™</sup> IDH1-2 Mutation Assay Kit Test (RUO), the first test developed with the new Idylla<sup>™</sup> FLEX technology that separates the generic components of an Idylla<sup>™</sup> test from the test-specific components
- Announcement on 22 February 2023 of the resignation of Mr. Roald Borré as Director of the Company and the appointment of Mr. Bryan Dechairo independent Company а new Board member and member of the Audit Committee of the as

## FINANCIAL CALENDAR

| • | 30 March 2023  | Publication Annual Report 2022                          |    |      |          |        |
|---|----------------|---|----|------|----------|--------|
| • | 20 April 2023  | Q1 2023 Business Update                                 |    |      |          |        |
| • | 12 May 2023    | Annual General Shareholders' Meeting Biocartis Group NV |    |      |          |        |
| • | 31 August 2023 | H1 2023 results   |    |      |          |        |
| • | 9 Novemb       | er 2023   | Q3 | 2023 | Business | Update |
| • | 31 August 2023 | H1 2023 results   | Q3 | 2023 | Business | Update |

#### **Financial information**

The consolidated financial statements have been prepared in accordance with IFRS, as adopted by the EU. The financial information included in this press release is an extract from the full IFRS consolidated financial statements, which will be published on 30 March 2023. The financial information in this press release was not audited by the statutory auditor.

## **Consolidated income statement**

|                         | Years ended 3 | 31 December |
|-------------------------|---------------|-------------|
| In EUR 000              | 2022          | 2021        |
| Revenue                 |               |             |
| Collaboration revenue   | 11,068        | 6,053       |
| Product sales revenue   | 45,036        | 40,486      |
| Service revenue         | 1,377         | 1,730       |
|                         | 57,481        | 48,269      |
| Other operating income  |               |             |
| Grants and other income | 495           | 6,629       |
|                         |               |             |

| Total operating income  | 57,976   | 54,898   |
|---|----------|----------|
| Operating expenses  |          |          |
| Cost of sales   | -29,799  | -33,922  |
| Research and development expenses   | -38,393  | -48,054  |
| Sales and marketing expenses  | -20,595  | -16,763  |
| General and administrative expenses   | -16,236  | -15,560  |
| Other expenses  | 0        | -3,244   |
|   | -105,023 | -117,543 |
| Operating loss for the year   | -47,047  | -62,645  |
| Financial expense   | -11,289  | -9,488   |
| Other financial results   | 11,299   | 1,077    |
| Financial result, net   | 10       | -8,411   |
| Share in the results of associates  | -884     | -659     |
| Loss for the year before taxes  | -47,921  | -71,715  |
| Income taxes  | 240      | 243      |
| Loss for the year after taxes   | -47,681  | -71,472  |
| Attributable to owners of the Company<br>Attributable to non-controlling interest | -47,681  | -71,472  |
| Earnings per share  |          |          |
| Basic and diluted loss per share  | -0.79    | -1.26    |

# **Consolidated balance sheet**

|            | As of 31 D | ecember |
|------------|------------|---------|
| In EUR 000 | 2022       | 2021    |

| ssets                                  |          |          |
|--|----------|----------|
| Non-current assets                     |          |          |
| Intangible assets                      | 4,770    | 5,067    |
| Property plant and equipment           | 31,527   | 37,192   |
| Financial assets                       | 3,640    | 1,140    |
| Investment joint ventures              | 2,538    | 2,344    |
| Other non-current receivables          | 204      | 16       |
| Deferred tax assets                    | 1,664    | 1,595    |
|  | 44,343   | 47,354   |
| Current assets                         |          |          |
| Inventories                            | 18,905   | 16,106   |
| Trade receivables                      | 16,697   | 16,206   |
| Other receivables                      | 2,236    | 6,556    |
| Other current assets                   | 5,971    | 2,736    |
| Cash and cash equivalents*             | 26,125   | 53,522   |
|  | 69,934   | 95,126   |
| Total assets                           | 114,277  | 142,480  |
| quity and liabilities                  |          |          |
| Capital and reserves                   |          |          |
| Share capital                          | -220,302 | -220,657 |
| Share premium                          | 618,575  | 711,874  |
| Share based payment reserve            | 7,502    | 6,862    |
| Accumulated deficit                    | -425,663 | -526,405 |
| Other comprehensive income             | -5,843   | -5,571   |
| Total equity attributable to owners of |          |          |
| the Company                            | -25,731  | -33,897  |

| <b>Non-current liabilities</b><br>Provisions<br>Borrowings and lease liabilities<br>Convertible debt<br>Deferred income | 204<br>25,824<br>71,382<br>149<br><b>97,559</b> | 75<br>14,133<br>128,151<br><u>313</u><br><b>142,672</b> |
|---|---|---|
| Current liabilities   |   |   |
| Borrowings and lease liabilities  | 20,597  | 11,878  |
| Trade payables  | 11,747  | 11,560  |
| Deferred income   | 1,195   | 1,822   |
| Other current liabilities   | 8,910   | 8,445   |
|   | 42,449  | 33,705  |
| Total equity and liabilities  | 114,277   | 142,480   |

\* Cash and cash equivalents for 31 December 2021 and 2022 include EUR 1.2 million restricted cash related to KBC Lease financing

# Consolidated cash flow statement

|                                   | Years ended | 31 December |
|-----------------------------------|-------------|-------------|
| In EUR 000                        | 2022        | 2021        |
| Operating activities              |             |             |
| Loss for the year                 | -47,681     | -71,472     |
| Adjustments for                   |             |             |
| Depreciation and amortization     | 10,481      | 9,845       |
| Impairment losses                 | 1,178       | 1,362       |
| Income taxes in profit and loss   | -240        | -243        |
| Financial result, net             | -10         | 8,411       |
| Unrealized exchange gains/ losses |             | 1,134       |

| Net movement in defined benefit obligation  | -143   | 69                                 |
|---|--|------------------------------------|
| Share of net profit of associate and a joint venture  | 884  | 659                                |
| Share based payment expense<br>Other  | 640<br>-78   | 760<br>-162                        |
| Changes in working capital<br>Net movement in inventories   | -5,297   | -2,737                             |
| Net movement in trade and other receivables and other current assets  | · · · · ·  | -5,916                             |
| Net movement in trade payables & other current liabilities  | 652  | -1,489                             |
| Net movement in deferred income   | -791<br><b>-38,826</b>                             | 494<br><b>-59,285</b>              |
| Interests paid  | -6,027   | -6,429                             |
| Taxes paid  | -2   | -2                                 |
| Taxes paid<br>Cash flow used in operating<br>activities   |  | -2<br>-65,716                      |
| Cash flow used in operating   |  |                                    |
| Cash flow used in operating<br>activities<br>Investing activities<br>Interests received<br>Acquisition of property, plant &   |  |                                    |
| Cash flow used in operating<br>activities<br>Investing activities<br>Interests received   | <b>-44,855</b><br>6                                | -65,716                            |
| Cash flow used in operating<br>activities<br>Investing activities<br>Interests received<br>Acquisition of property, plant &<br>equipment<br>Acquisition of intangible assets<br>Acquisition of investment in a joint  | <b>-44,855</b><br>6<br>-1,569<br>-368              | - <b>65,716</b><br>7<br>-3,686     |
| Cash flow used in operating<br>activities<br>Investing activities<br>Interests received<br>Acquisition of property, plant &<br>equipment<br>Acquisition of intangible assets<br>Acquisition of investment in a joint<br>venture<br>Investment convertible note                                | <b>-44,855</b><br>6<br>-1,569<br>-368              | -65,716<br>7<br>-3,686<br>-69      |
| Cash flow used in operating<br>activities<br>Investing activities<br>Interests received<br>Acquisition of property, plant &<br>equipment<br>Acquisition of intangible assets<br>Acquisition of investment in a joint<br>venture   | - <b>44,855</b><br>6<br>-1,569<br>-368<br>-1,000   | -65,716<br>7<br>-3,686<br>-69      |
| Cash flow used in operating<br>activities<br>Investing activities<br>Interests received<br>Acquisition of property, plant &<br>equipment<br>Acquisition of intangible assets<br>Acquisition of investment in a joint<br>venture<br>Investment convertible note<br>Cash flow used in investing | -44,855<br>6<br>-1,569<br>-368<br>-1,000<br>-2,500 | -65,716<br>7<br>-3,686<br>-69<br>0 |

| Refinancing transactions Convertible bond, convertible term loan                         | 10,782  | 0       |
|--|---------|---------|
| Net proceeds from the issue of common<br>shares, net of transaction costs                | 23,055  | 0       |
| Repayment of borrowings  | -26,301 | -7,089  |
| Bank charges   | -73     | -115    |
| Cash flow from financing activities  | 22,463  | -1,204  |
|  |         |         |
| Net increase / (decrease) in cash and<br>cash equivalents                                | -27,823 | -70,668 |
| Cash and cash equivalents at the beginning of the year                                   | 53,522  | 123,668 |
| Effects of exchange rate changes on<br>the balance of cash held in foreign<br>currencies | 426     | 522     |
| Cash and cash equivalents at the<br>end of the year*                                     | 26,125  | 53,522  |

\* Including EUR 1,2m restricted cash related to KBC Lease financing

# Consolidated statement of changes in shareholder equity

| ?  | A 44             | 1. 4                                       | the Crear                            |                                  |                            |   |                           |
|--|------------------|--|--------------------------------------|----------------------------------|----------------------------|---|---------------------------|
| <u>In EUR 000</u>                                      | Share<br>capital | <u>le to owners of</u><br>Share<br>premium | Share<br>based<br>payment<br>reserve | Other<br>comprehensive<br>income | Accumulated<br>deficit     | Total equity<br>attributable to<br>the owners of<br>the Group | Total equity              |
| Balance as at 1 January<br>2021<br>Loss for the period | -220,657         | 711,875                                    | 6,102                                | -5,152                           | <b>-455,343</b><br>-71,472 | <b>36,824</b><br>-71,472                                      | <b>36,82</b> 4<br>-71,472 |

| Re-measurement gains and<br>losses on defined benefit<br>plan |          |                  |       | -419   |          | -419             | -419             |
|---|----------|------------------|-------|--------|----------|------------------|------------------|
| Consolidation translation difference                          |          |                  |       |        | 410      | 410              | 410              |
| Total comprehensive   |          |                  |       | -419   | -71,062  | -71,481          | -71,481          |
| <i>income</i><br>Share-based payment                          |          |                  |       | -419   | -/1,002  | -/1,401          | -/1,401          |
| expense   |          |                  | 760   |        |          | 760              | 760              |
| Other   | <u> </u> |                  |       |        |          |                  |                  |
| Balance as at 31 December<br>2021                             | -220,657 | 711,875          | 6,862 | -5,571 | -526,405 | -33,897          | -33,897          |
| Balance as at 1 January<br>2022                               | -220,657 | 711,875          | 6,862 | -5,571 | -526,405 | -33,897          | -33,897          |
| Loss for the period   |          |                  |       |        | -47,681  | -47,681          | -47,681          |
| Re-measurement gains and losses on defined benefit            |          |                  |       |        |          |                  |                  |
| plan  |          |                  |       | -272   |          | -272             | -272             |
| Consolidation translation<br>difference                       |          |                  |       |        | 378      | 378              | 378              |
| Total comprehensive   |          |                  |       | 252    | 17 202   |                  |                  |
| <i>income</i><br>Share-based payment                          |          |                  |       | -272   | -47,303  | -47,574          | -47,574          |
| expense payment   |          |                  | 640   |        |          | 640              | 640              |
| Convertible bond – conversion old bond                        |          | -6,323           |       |        |          | -6,323           | -6,323           |
| Convertible bond – issue                                      |          | 25 162           |       |        |          | 25 162           | 25 162           |
| new bond<br>Share issue - rights offering                     | 336      | 25,162<br>24,773 |       |        |          | 25,162<br>25,108 | 25,162<br>25,108 |

| Costs related to rights offering               |          | -2,053   |       |        |          | -2,053  | -2,053  |
|--|----------|----------|-------|--------|----------|---------|---------|
| Share issue - conversion                       |          | _,       |       |        |          | _,      | _,      |
| convertible term loan                          | 2        | 240      |       |        |          | 242     | 242     |
| Share issue - contribution in                  |          |          |       |        |          |         |         |
| kind   | 8        | 992      |       |        |          | 1,000   | 1,000   |
| Share issue - mandatory conversion convertible |          |          |       |        |          |         |         |
| bond   | 9        | 11,956   |       |        |          | 11,965  | 11,965  |
| Capital increase by contribution in kind       |          | -104,071 |       |        | 104,071  | 0       | 0       |
| Capital decrease by incorporation of           |          |          |       |        |          |         |         |
| accumulated losses                             |          | -43,975  |       |        | 43,975   | 0       | 0       |
| Other  |          |          |       |        |          |         |         |
| Balance as at 31 December                      |          |          |       |        |          |         |         |
| 2022   | -220,302 | 618,574  | 7,502 | -5,843 | -425,663 | -25,730 | -25,730 |

#### --- END ----

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#### **About Biocartis**

With its revolutionary and proprietary Idylla<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup>'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, Flu, RSV and sepsis. For more information, visit www.biocartis.com or follow Biocartis on Twitter @Biocartis\_, Facebook or LinkedIn.

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#### 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 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.

1 A companion diagnostic (CDx) is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product.

2 EBITDA + CAPEX (operating loss (EUR 47,047k) plus acquisition of property, plant and equipment (EUR 1,569k) and intangible assets (EUR 368k) minus depreciation and amortization (EUR 10,481k)
3 Including revenue from instrument servicing
4 Excluding revenue from instrument servicing

5 Defined as the world excluding European direct markets, US, China and Japan
6 Partners providing test content so as to develop an Idylla<sup>™</sup> version of their assay or test on the Idylla<sup>™</sup> platform
7 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
8 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

9 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<sup>™</sup>. HepatoPredict is a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation 10 Research Use Only, not for use in diagnostic procedures