BIOCARTIS

HALF-YEAR REPORT 2022

BIOCARTIS GROUP NV

BIOCARTIS' VISION IS THAT **UNIVERSAL ACCESS** TO MOLECULAR TESTING WILL ENABLE **PERSONALIZED MEDICINE** FOR PATIENTS AROUND THE WORLD.

OUR MISSION IS TO MAKE **MOLECULAR TESTING ACTIONABLE, CONVENIENT, FAST** AND **SUITABLE FOR ANY LAB.**

CONTENT

1. MESSAGE FROM THE CEO

Dear Shareholder,
Dear Stakeholder,

Our operational performance in H1 2022 marked a pivotal moment on our journey towards profitability as continued strong growth of our core oncology business translated into significantly higher gross margins.

Cartridge revenue in our core oncology business grew by 35% year-on-year, and the gross margin on products increased to 32%. Despite the expected decrease of Idylla™ SARS-CoV-2 product sales, we almost quadrupled gross profit to EUR 6.6m during the first half of the year, fueled by increased average selling prices of cartridges in oncology and economies of scale in our cartridge manufacturing.

We are on track to deliver on our objectives for the entire year, and also made important progress in securing future growth. We are particularly proud of the extended partnership with AstraZeneca for the development of a companion diagnostic for its blockbuster Tagrisso®.

Furthermore, we were very pleased to announce that we entered into several financing arrangements with the support of certain holders of our convertible bonds. These will, upon successful completion, strengthen our cash position with approximately EUR 66m and fundamentally improve our financing structure.

Herman Verrelst

CEO Biocartis

2. RESPONSIBILITY STATEMENT

The undersigned hereby declare that to the best of their knowledge: a) the condensed consolidated interim financial statements for the six-months' period ended 30 June 2022, which have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union, give a true and fair view of the net equity, financial position and results of the Company and the companies included in the consolidation, and b) give a true and fair view of the main events and the impact thereof on the condensed consolidated interim financial statements c) give a true and fair view of the main risks and uncertainties with respect to the remaining months of the fiscal year, and the main transactions with related parties and the impact thereof on the condensed consolidated interim financial statements.

Herman Verrelst
CEO

Christian Reinaudo
Chairman

3. BUSINESS REVIEW H1 2022

KEY HIGHLIGHTS H1 2022

- **Product revenue** of EUR 20.3m (H1 2021: EUR 18.5m), of which EUR 16.5m from 153k cartridges sold and EUR 3.8m from instrument rentals and sales:
    - EUR 14.4m **cartridge revenue in oncology** (+35% year-on-year), double-digit growth across all regions, led by the US, both in cartridge volumes as in Average Selling price (ASP)
    - The contribution of **COVID-19 testing** to cartridge revenues decreased to EUR 1.7m as both volumes and pricing continued to reduce. Revenues are evenly split between Europe and the US
    - **ASP** per commercial cartridge of EUR 113 in oncology and EUR 103 overall
    - EUR 3.8m revenue from a global installed base of 2,014 instruments, with **102** net new instruments placed

- **Gross profit on product** sales increased by **370**% from EUR 1.4m to EUR 6.6m, reflecting a gross margin of 32%, compared to 8% for H1 2021 and 16% for the full year 2021
- **Operating cash burn**[1] of **EUR -19.2m**, EUR 9.4m lower than in H1 2021; Company cash position of EUR 19.7m (unaudited figure) end of H1 2022. The available credit facilities of EUR 15.0m remained fully undrawn as of 30 June 2022

- New partnership with **AstraZeneca** to develop a companion diagnostic for use with Tagrisso® (osimertinib), AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment
- Post the reporting period, start of Biocartis' commercialization in Europe of **SkylineDx's** Merlin Assay as a CE-IVD marked kit, ahead of the launch of an Idylla™ version of the Assay

1 EBITDA plus capital expenditure

REFINANCING

On 1 September 2022, the Company announced a comprehensive recapitalization transaction (the 'Transactions') that will provide adequate capital to support the Company's growth for the foreseeable future. The Transactions, which are supported by key existing investors, is a significant milestone for the Company and will provide for the following:

- Deleveraging via a partial equitization of the 4.00% convertible bonds due 2024 ("Existing Convertible Bonds") equal to 10% of notional amounts outstanding, and maturity extension by 3.5 years to November 2027.
- Allow holders of the Existing Convertible Bonds to exchange into new second lien secured convertible bonds ("New Convertible Notes"), subject to their commitment to participate pro-rata in a fully backstopped EUR 25 million investment into additional New Convertible Notes.
- Allow existing shareholders to participate in the growth of the Company by taking part in a fully covered rights issue of EUR 25 million, which is backstopped in full by certain new investors and KBC Securities (subject to a number of customary & transaction specific conditions).
- Certain existing holders of New Convertible Notes will provide a new senior secured term loan ("New Convertible Term Loans") that will provide the Company with approximately EUR 16 million of additional cash liquidity.

More information can be found in the press release here.

COMMERCIAL HIGHLIGHTS

- **153k commercial cartridges sold** in H1 2022, compared to 156k in H1 2021: oncology cartridge volumes grew by 21% while infectious disease cartridge volumes almost halved as COVID-19 testing continued to reduce
- **Double-digit growth of oncology cartridge volumes in all regions** combined with pricing discipline, delivered 35% growth in oncology cartridge revenue:
    - Sustained growth across Europe with growing contribution of the Idylla™ GeneFusion that is now increasingly used in clinical routine
    - The US remains the fastest growing market in oncology, fueled by an increasing ASP as the proportion of free-of-charge cartridge volumes for market seeding and the initial validation of assays by customers declines
    - Strong performance of the distributor markets[2] and good traction from the commercial partnership with AstraZeneca
- **Total revenue from Idylla™ instruments** increased by 4% to EUR 3.8m in H1 2022, including instruments sold to content partners[3]:
    - Revenue generated from instrument placements at end customers increased by 24% year-on-year, against a 12% increase of the installed base of Idylla™ instruments, and evenly split between revenue from capital sales and reagent rentals
    - The US recorded the strongest growth of instrument revenue, driven by a high proportion of capital sales, representing more than 90% of total US instrument revenue and nearly half of total revenue from sold instruments
    - Continued double-digit growth of instrument revenue in Europe, mostly from rental income that accounts for nearly 90% of total instrument rental income

IDYLLA™ TEST MENU, PARTNERSHIPS & PUBLICATIONS

- *Test menu:*
    - Launch of the fully automated, CE-marked IVD Idylla™ GeneFusion Panel on 20 June 2022
    - Launch of new SeptiCyte RAPID® EDTA[4] (CE-IVD) blood compatible cartridges[5] by Biocartis' partner Immunexpress on 23 August 2022, post the reporting period
- *Product registrations:*
    - Russia – Additional registrations have been completed in June 2022 for the Idylla™ NRAS-BRAF Mutation Test, the Idylla™ KRAS Mutation Test and the Idylla™ MSI Test in Russia. More information on the impact

2 Defined as the world excluding European direct markets, US, China and Japan
3 Partners providing test content so as to develop an Idylla™ version of their assay or test on the Idylla™ platform
4 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 25 July 2022
5 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

of the war in Ukraine and Russia can be found in the disclaimer further in this report under 6.3, Impact of the war in Ukraine.

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

- *Partnerships:*
  - Announcement of a new partnership on 8 February 2022 between Biocartis and Ophiomics, a Lisbon (Portugal) based biotech company with an initial focus on the commercialization of HepatoPredict[6].
  - Announcement of a new agreement with AstraZeneca on 22 June 2022 highlighting the development and planned premarket submission to the US FDA of a novel CDx test on the Idylla™ platform for AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment.
  - Announcement of Biocartis' start of the commercialization in Europe of SkylineDx's innovative Merlin Assay as a CE-IVD marked manual kit, ahead of the launch of an Idylla™ version of the Assay, on 1 September 2022 and post the reporting period.
- *Publications* - During H1 2022, excellent data was published from several new Idylla™ studies, including a study (announced 4 May 2022) by Memorial Sloan Kettering Cancer Center (NY, US), in the *Journal of Molecular Diagnostics* on the Idylla™ GeneFusion Assay (RUO[7]).

ORGANIZATIONAL & OPERATIONAL HIGHLIGHTS

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

6 HepatoPredict will be distributed by Biocartis in Europe as a manual kit mainly addressing centralized expert laboratories, and the test may later be translated into a version on Biocartis' rapid and easy-to-use molecular diagnostics platform Idylla™. HepatoPredict is a prognostic gene expression signature test to help identify which patients will benefit from curative-intent surgery, in particular liver transplantation

7 Research Use Only, not for use in diagnostic procedures

- Global Head of Sales: David Dejans, previously Head of Sales Europe and Distributor markets, will move into the role of Global Head of Sales

FINANCIAL HIGHLIGHTS

- *Total operating income* – Total operating income amounted to EUR 26.8m compared to EUR 23.1m last year. Product revenues increased by 10% from EUR 18.5m in H1 2021 to EUR 20.3m in H1 2022. Within product sales, cartridge sales revenues increased by 11.6%. Excluding the revenue from the sale of Idylla™ SARS-CoV-2 tests[8] that continue to trend downward, cartridge revenues increased 38%. Revenues from Idylla™ Instrument sales amounted to EUR 3.8m (H1 2021: EUR 3.7m). The majority of the 102 net new instruments were placed under reagent rental agreements as opposed to H1 2021 during which immediately recognized capital sales accounted for most of the 189 net placements. Collaboration revenues, almost entirely from R&D services provided to partners, increased by EUR 2.6m to EUR 5.1m.
- *Idylla™ cartridge average sales price (ASP)* – During H1 2022, Idylla™ oncology cartridge ASP increased by 8% to EUR 113, resulting from a growing contribution of the Idylla™ GeneFusion Assay[9] (RUO) and from higher sales from the US where pricing is generally higher than in Europe and other parts of the world. The overall ASP in H1 2022 stood at EUR 103, up from EUR 95 in H1 2021 because of the increased ASP in oncology and a lower contribution of lower priced SARS-CoV-2 tests.
- *Gross margin* – Gross margin on products significantly increased, from 8% in H1 2021 to 32% in H1 2022. Last year, the gross margin was impacted by a higher cartridge COGS (Costs of Goods Sold) because production volumes were lower than expected as the pandemic caused a global shortage of reagent supplies. Moreover, the lower revenues from SARS-CoV-2 tests that have a significantly lower ASP than the other assays, also contributes to an improved gross margin. The total gross profit amounted to EUR 6.6m, or EUR 5.2m more than in H1 2021.
- *OPEX* – Total operating expenses (excluding cost of sales) of EUR 37.7m in H1 2022 decreased by EUR 1.4m from EUR 39.1m in H1 2021. EUR 4.1m lower spending in R&D was partly offset by the post-pandemic normalization of commercial activities, the impact of the 2021 restructuring of the US commercial operations and by global inflation.
- *Net cash flow and cash position* – The operating cash burn of EUR 19.2m (H1 2021: EUR 28.8m) was complemented by working capital investments of EUR 0.6m and a scheduled investment of EUR 1.0m to fund the operations of the Chinese joint venture WondfoCartis. Financial cash flows included EUR 3.1m interest payments and the repayment of EUR 8.6m borrowings, including EUR 6.0m drawn on working capital facilities at the end of 2021. The net cash outflow amounted to EUR 35.5m and resulted in a net cash position of EUR 19.7m. EUR 15m of credit facilities were undrawn and remain fully available awaiting the closing of the refinancing.

8 The Idylla™ SARS-CoV-2 Test (CE-IVD) and the Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD)
9 The contribution in H1 2022 mainly resulted from Idylla™ GeneFusion Assay (RUO) sales, as the Idylla™ GeneFusion Panel (CE-IVD) was only launched late in H1 2022, on 20 June 2022

KEY FIGURES H1 2022

The tables below show an overview of the key figures and a breakdown of operating income for H1 2022 and H1 2021.

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

[1] Excludes the effect of exchange rate differences on the cash balances held in foreign currencies
[2] Including EUR 1,2m of restricted cash in H1 2022 and H1 2021

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

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

4. PRINCIPAL RISKS RELATED TO THE BUSINESS ACTIVITIES

The principal risks related to Biocartis' business activities are outlined in Biocartis' 2021 Annual Report, p.42-55 available on the Biocartis website here. In summary, the principal risks and uncertainties faced by Biocartis relate to strategic and commercial risks, operational risks, regulatory risks and financial risks. Except for the going concern described in note 6.4, the principal risks have not materially changed from the ones outlined in the 2021 Annual Report.

5. CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS FOR THE PERIOD ENDED 30 JUNE 2022

CONDENSED CONSOLIDATED INCOME STATEMENT

In EUR 000	Notes	For the 6 months ended 30 June 2022	30 June 2021
Collaboration revenue	6.5	5,082	2,640
Product sales revenue	6.5	20,301	18,463
Service revenue	6.5	977	748
Total revenue		**26,360**	**21,851**
Other operating income			
Grants and other income	6.6	411	1,206
Total operating income		**26,771**	**23,057**
Cost of sales	6.7	-13,720	-17,059
Research and development expenses	6.8	-19,251	-23,398
Sales and marketing expenses	6.9	-10,050	-7,740
General and administrative expenses	6.10	-8,376	-7,935
Total operating expenses		**-51,397**	**-56,132**
Operating loss for the period		**-24,626**	**-33,075**
Financial expense	6.11	-4,749	-4,703
Other financial results	6.11	944	454
Financial result, net		**-3,805**	**-4,249**
Share in the results of joint ventures		-432	-101
Loss for the period before taxes		**-28,863**	**-37,425**
Income taxes		96	149
Loss for the period after taxes		**-28,767**	**-37,276**
Attributable to owners of the Group		-28,767	-37,276
Earnings per share			
Basic and diluted loss per share	6.12	**-0.50**	**-0.65**

CONDENSED CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE INCOME

In EUR 000	Notes	For the 6 months ended 30 June 2022	30 June 2021
Loss for the period		**-28,767**	**-37,276**
Other comprehensive income (loss), not to be reclassified to profit or loss:			
Re-measurement gains and losses on defined benefit plan		-220	-449
Income taxes on items of other comprehensive income		65	112
Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss:			
Exchange differences on translation of foreign operations		576	152
Total comprehensive loss for the period		**-28,346**	**-37,461**
Attributable to owners of the Group		-28,346	-37,461

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

In EUR 000	Notes	As of 30 June 2022	As of 31 Dec 2021
Assets			
Non-current assets			
Intangible assets		4,858	5,067
Property plant and equipment	6.13	34,751	37,192
Financial assets		1,140	1,140
Investment in joint ventures		2,964	2,344
Other non-current assets		119	16
Deferred tax assets and R&D Investment tax credit		1,470	1,595
		45,302	**47,354**
Current assets			
Inventories		19,902	16,106
Trade receivables		15,310	16,206
Other receivables	6.14	2,474	6,556
Other current assets		2,791	2,736
Cash and cash equivalents*		19,724	53,522
		60,201	95,126
Total assets		**105,503**	**142,480**
Equity and liabilities			
Capital and reserves			
Share capital		-220,657	-220,657
Share premium		711,874	711,874
Share based payment reserve		7,334	6,862
Accumulated deficit		-554,596	-526,405
Other comprehensive income		-5,726	-5,571
Total equity attributable to owners of the Group		**-61,771**	**-33,897**
Non-current liabilities			
Provisions		109	75
Borrowings and lease liabilities	6.15	11,432	14,133
Convertible debt	6.15	129,662	128,151
Deferred income	6.16	227	313
		141,430	**142,672**
Current liabilities			
Borrowings and lease liabilities	6.15	6,072	11,878
Trade payables		9,783	11,560
Deferred income	6.16	1,751	1,822
Other current liabilities		8,238	8,445
		25,844	**33,705**
Total equity and liabilities		**105,503**	**142,480**

*Cash and cash equivalents for 30 June 2022 include EUR 1.2m restricted cash related to KBC lease financing

CONDENSED CONSOLIDATED CASH FLOW STATEMENT

In EUR 000	Notes	For the 6 months ended 30 June 2022	30 June 2021
Operating activities			
Loss for the period		-28,767	-37,276
Adjustments for			
Depreciation and amortization		5,288	4,799
Impairment losses	6.13	698	598
Income taxes in profit and loss		-96	-149
Financial result, net		3,804	4,249
Net movement in defined benefit obligation		-121	106
Share of net profit of associate and a joint venture		432	101
Share based payment expense		472	409
Other		-23	-78
Changes in working capital			
Net movement in inventories		-5,520	-3,388
Net movement in trade and other receivables and other current assets		5,041	1,844
Net movement in trade payables & other current liabilities		-1,984	-2,367
Net movement in deferred income	6.16	-157	629
		-20,933	**-30,523**
Interests paid		-3,221	-3,227
Taxes paid		0	-2
Cash flow used in operating activities		**-24,154**	**-33,752**
Investing activities			
Interest received		1	5
Acquisition of property, plant & equipment		-467	-952
Acquisition of intangible assets		-128	0
Investment financial asset		0	-1,140
Investment in joint venture		-1,000	0
Cash flow used in investing activities		**-1,594**	**-2,087**
Financing activities			
Repayment of borrowings	6.15	-9,498	-3,457
Bank charges		-44	-61
Cash flow from financing activities		**-9,542**	**-3,518**
Net increase / (decrease) in cash and cash equivalents		**-35,290**	**-39,357**
Cash and cash equivalents at the beginning of the period		53,522	123,668
Effects of exchange rate changes on the balance of cash held in foreign currencies		1,492	594
Cash and cash equivalents at the end of the period*		**19,724**	**84,905**

* Including EUR 1.2m restricted cash related to KBC Lease financing

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

In EUR 000	Notes	Attributable to owners of the Group						
		Share capital	Share premium	Share based payment reserve	Other comprehensive income	Accumulated deficit	Total equity attributable to the owners of the Group	Total equity
Balance as at 1 January 2021		**-220,657**	**711,874**	**6,102**	**-5,152**	**-455,343**	**36,824**	**36,824**
Loss for the period						-37,276	-37,276	-37,276
Re-measurement gains and losses on defined benefit plan					-337		-337	-337
Consolidation translation difference						152	152	152
Total comprehensive income					***-337***	***-37,124***	***-37,461***	***-37,461***
Share-based payment expense				410			410	410
Other							0	0
Balance as at 30 June 2021		**-220,657**	**711,874**	**6,512**	**-5,489**	**-492,467**	**-227**	**-227**
Balance as at 1 January 2022		**-220,657**	**711,874**	**6,862**	**-5,572**	**-526,405**	**-33,897**	**-33,897**
Loss for the period						-28,767	-28,767	-28,767
Re-measurement gains and losses on defined benefit plan					-155		-155	-155
Consolidation translation difference						576	576	576
Total comprehensive income					***-155***	***-28,191***	***-28,346***	***-28,346***
Share-based payment expense				472			472	472
Other							0	0
Balance as at 30 June 2022		**-220,657**	**711,874**	**7,334**	**-5,726**	**-554,596**	**-61,771**	**-61,771**

6. NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

6.1. GENERAL INFORMATION

Biocartis Group NV, a company incorporated in Belgium with registered address at Generaal de Wittelaan 11 B, 2800 Mechelen, Belgium (the 'Company') and its subsidiaries (together, the 'Group') commercialize an innovative and proprietary molecular diagnostics ('MDx') platform that offers accurate, highly reliable molecular information from virtually any biological sample, enabling fast and effective diagnostics treatment selection and treatment progress monitoring

The Group's mission is to become a global, fully integrated provider of novel molecular diagnostics solutions with industry-leading, high clinical value tests within the field of oncology and infectious disease. The Group has established subsidiaries in Mechelen (Belgium), New Jersey (US), Milan (Italy) and a joint venture in Hong Kong (China).

The consolidated financial statements have been authorized for issue on 31 August 2022 by the board of directors of the Group (the 'board of directors').

6.2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies for preparing these consolidated financial statements are explained below.

6.2.1. Statement of compliance and basis of preparation

These condensed consolidated interim financial statements for the six months ended 30 June 2022 have been prepared in accordance with IAS 34 Interim Financial Statements as adopted by the European Union. The statements should be read in conjunction with the annual financial statements for the year ended 31 December 2021, which have been prepared in accordance with IFRS as adopted by the EU.

The accounting policies adapted in the preparation of the condensed interim financial statements are consistent with those applied in the preparation of the financial statements for the year ended 31 December 2021. New standards or interpretations applicable from 1 January 2022 do not have an impact on the condensed consolidated interim financial statements.

The consolidated financial statements are presented in Euro (EUR) and all values are rounded to the nearest thousand (EUR000), except when otherwise indicated.

These condensed interim financial statements have been subject to a review by the Group's external auditor Deloitte Bedrijfsrevisoren BV. The following new standards and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2022:

- Amendments to IFRS 16 Leases: COVID-19-Related Rent Concessions beyond 30 June 2021 (applicable for annual periods beginning on or after 1 April 2021)
- Amendments to IAS 16 Property, Plant and Equipment: Proceeds before Intended Use (applicable for annual periods beginning on or after 1 January 2022)
- Amendments to IAS 37 Provisions, Contingent Liabilities and Contingent Assets: Onerous Contracts – Cost of Fulfilling a Contract (applicable for annual periods beginning on or after 1 January 2022)

- Amendments to IFRS 3 Business Combinations: Reference to the Conceptual Framework (applicable for annual periods beginning on or after 1 January 2022)
- Annual Improvements to IFRS Standards 2018-2020 (applicable for annual periods beginning on or after 1 January 2022)

The above application of new standards did not have a significant impact on the financial position and the result of the Group.

6.3. 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. We do not expect any credit losses related to sales realized with the Russian distributor. Supplier exposure is limited to 1 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.

6.4. CRITICAL ACCOUNTING JUDGEMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

In the application of the Group's accounting policies, which are described above, the Group is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods. The following areas are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year:

Going concern

The going concern valuation rules were used for the consolidated interim accounts of the Company and this notwithstanding the loss of the period and the negative cash used in operations. The board of directors motivates the use of going concern valuation rules as follows: The past years, the Company continued to execute on its growth strategy, building strong fundamentals that are expected to lead to sustainable profitability as it continues to scale. Between 2016 and 2021, commercial cartridge volumes have grown at a compound annual growth rate of 67%. Biocartis' technology is widely validated, and the global installed base now exceeds 2,000 Idylla™ instruments. Revenue and gross profit from product sales and instrument servicing have grown at a compound annual growth rate of 44% and 49%, respectively between 2016 and 2021. The Company offers a broad menu of more than 10 tests in over 70 countries across the world and has a healthy pipeline of novel high value-added tests. Biocartis has invested in fully automated and scalable manufacturing and the growing cartridge volumes are expected to significantly reduce the manufacturing cost per cartridge. The financial results for the first half of 2022 demonstrate that the Company is well on track to deliver on its objectives for 2022 aimed at further growing product revenues, improving gross margins, and reducing its cash burn.

On 30 June 2022, cash and cash equivalents amounted to EUR 19.7 million and EUR 15 million from available credit facilities remained undrawn, providing the Company with sufficient cash to fund its business activities until the end of 2022.

On 1 September 2022, the Company announced a comprehensive recapitalization transaction (the 'Transactions') that will provide adequate capital to support the Company's growth for the foreseeable future. The Transactions, which are supported by key existing investors, is a significant milestone for the Company and will provide for the following:

- Deleveraging via a partial equitization of the 4.00% convertible bonds due 2024 ("Existing Convertible Bonds") equal to 10% of notional amounts outstanding, and maturity extension by 3.5 years to November 2027.
- Allow holders of the Existing Convertible Bonds to exchange into new second lien secured convertible bonds ("New Convertible Notes"), subject to their commitment to participate pro-rata in a fully backstopped EUR 25 million investment into additional New Convertible Notes.
- Allow existing shareholders to participate in the growth of the Company by taking part in a fully covered rights issue of EUR 25 million, which is backstopped in full by certain new investors and KBC Securities (subject to a number of customary & transaction specific conditions).
- Certain existing holders of New Convertible Notes will provide a new senior secured term loan ("New Convertible Term Loans") that will provide the Company with approximately EUR 16 million of additional cash liquidity.

The various financial arrangements involving the new convertible term Loan and the exchange offer of the new convertible bonds will require the approval of the shareholders while the amendments of the existing convertible bond will require consent from the required majority of holders of the existing convertible bond. To date, holders of 65% of the existing convertible bonds have committed to vote in favor of such amendments. Furthermore, the Company will pursue an equity raise of EUR 25 million which is backstopped in full by certain new investors and KBC Securities (subject to a number of customary and transaction specific conditions). Subject to obtaining all required approvals and raising equity of at least EUR 25 million, which is fully backstopped, the various arrangements will provide the Company with approximately EUR 66 million of cash proceeds (after the repurchase of a portion of the existing convertible bonds as agreed with the new convertible term lenders but excluding advisory and commitment fees). Based on the projected operating cash burn for the remainder of 2022 and 2023, the successful closing of the recapitalization transaction the Company projects to have sufficient cash to fund its operating, investing and financing activities for at least the next twelve months, which is the applicable horizon for the going concern assessment.

The board of directors acknowledges that there are inherent material uncertainties associated with the execution of the recapitalization transaction but believes that the Company has structured a substantial refinancing, securing the necessary funding to support continued growth towards profitability, while restructuring its convertible debt. Although no assurance can be given, the Board of Directors therefore believes that the required approvals will be obtained and that the Company will be able to raise at least EUR 25 million of new equity. As a result, the board of directors is of the opinion that the application of valuation rules assuming the Group's ability to operate as a going concern are justified. If the proposed recapitalization cannot or not timely be executed, the Company will extend the cash runway to continue to operate by reducing its operating expenses and suspending planned investments in various areas of the business while seeking alternative financing arrangements. There can however be no assurance that such arrangements will become available in a timely manner, or at all.

More information can be found in the press release here.

6.5. REVENUE

The Group's revenue can be aggregated as follows:

In EUR 000	For the 6 months ended,			
	30 June 2022		30 June 2022	30 June 2021
	At a point in time	Over time		
Collaboration revenue				
R&D services	0	4,932	4,932	2,590
License fees	0	50	50	50
Milestones	100	0	100	0
	100	**4,982**	**5,082**	**2,640**
Product related revenue				
Idylla™ system sales revenue	1,937	0	1,937	1,878
Idylla™ system rental revenue	1,887	0	1,887	1,837
Cartridge revenue	16,477	0	16,477	14,749
	20,301	**0**	**20,301**	**18,463**
Service revenue				
Idylla™ system service revenue	768	209	977	748
	768	**209**	**977**	**748**
Total	**21,169**	**5,191**	**26,360**	**21,851**

For details related to the movement in deferred income of collaboration agreements, we refer to note 6.16.

R&D service revenue is recognized over time as the services are rendered to the customer based on the progress over the activities i.e. a rato the services performed. Over the reporting period, the majority of the collaborations for which revenues were recognized, included a quarterly or monthly payment structure. Consequently, the Group recognized either an accrued income or deferred income on the balance sheet over the course of the reporting period.

In general, customers do not have a right-of return and/or are not entitled to refunds in the context of product related sales.

The below table corresponds to the revenue expected to be recognized in the future relating to (partially) unsatisfied performance obligations. This table excludes potential future R&D service revenue of pending collaborations for which the associated services are performed on an hourly invoicing basis (IFRS 15.121).

In EUR 000	Deferred income
2022	280
2023	651
2024	0
2025	0
2026	0
After 2026	0

For more information regarding the revenue statement above, we refer to chapter 3, under 'Commercial highlights'.

6.5.1. Revenues by region and major customers

In EUR 000	For the 6 months ended 30 June 2022	30 June 2021
Country of domicile	**259**	**261**
Belgium	259	261
Total all foreign countries, of which	**26,101**	**21,590**
United states of America	7,575	4,134
Great Britain	2,634	4,341
China	624	765
Spain	2,109	1,655
France	2,497	2,298
Germany	1,994	1,515
Rest of the world	8,667	6,883
Total	**26,360**	**21,851**

Revenues in the above table are assigned according to the location of the Group or parent company of the customer. In the first half of 2022 there was no customer representing more than 10% of the total revenues, the 5 largest clients together represent 22% of the total revenues.

6.6. OTHER OPERATING INCOME

In EUR 000	For the 6 months ended 30 June 2022	30 June 2021
R&D project support (VLAIO & IWT grants)	340	1,159
Other project grants (EU)	0	0
Other income	71	48
Total	**411**	**1,206**

The other operating income mainly consists out of grants that were awarded to support R&D activities. In 2021, the Group was awarded a new grant from VLAIO, for the ongoing development of a new generation Idylla™ technology. Other grants ended during H2 2021, explaining the decrease in R&D project support.

6.7. COST OF SALES

The cost of goods sold in relation to the product sales is as follows:

In EUR 000	For the 6 months ended 30 June 2022	30 June 2021
Employee benefit expenses	-4,178	-4,543
Material, lab consumables & small equipment	-5,878	-8,301
Depreciation and amortization	-1,869	-2,339
Royalty expense	-630	-774
Facilities, office and other	-1,165	-1,103
Total	**-13,720**	**-17,059**

The volume of commercial cartridges sold in H1 2022 remained approximately on the same level as H1 2021 (decrease of 2%). The lower costs of goods sold was mainly driven by the fact that more cartridges were produced on the semi-automated and cost efficient ML2 line.

6.8. RESEARCH AND DEVELOPMENT EXPENSES

	For the 6 months ended	
In EUR 000	**30 June 2022**	**30 June 2021**
Employee benefit expenses	-13,384	-12,967
Laboratory costs	-1,746	-7,155
Quality, regulatory and intellectual property	-256	-269
Facilities, office & other	-1,481	-997
ICT	-257	-177
Travel, training & conferences	-147	-41
Depreciation and amortization	-1,979	-1,793
Total	**-19,251**	**-23,398**

Laboratory costs include consumables and prototype costs related to the development of diagnostic platform prototypes and assays, expenses in relation to services provided by research and development providers such as services related to the development of assay cartridges, instrument and console of the various diagnostic platforms, manufacturing equipment design and engineering services. The decrease in laboratory costs is mainly because of the extra efforts that were made in H1 2021 to catch up on several projects that were delayed in 2020 and which needed more consumables and other investments in materials.

The remaining expenses relate to quality, regulatory, patenting, building facilities, ICT, office, maintenance of equipment, logistics, travel, training and conferences.

6.9. SALES AND MARKETING EXPENSES

	For the 6 months ended	
In EUR 000	**30 June 2022**	**30 June 2021**
Employee benefit expenses	-6,533	-5,775
S&M consultancy & subcontracting	-345	-210
Sales and promotional expenses	-334	-367
Business development	-438	-251
Facilities, office & other	-513	-446
Travel, training & conferences	-867	-250
Depreciation and amortization	-794	-344
Impairment of receivables	-226	-95
Total	**-10,050**	**-7,740**

Sales and promotional expenses relate to costs of external market research, advertisement, and promotional activities related to the Group's products

S&M expenses increased due to the post-pandemic normalization of commercial activities, global inflation and the impact of the 2021 restructuring of the US commercial operations.

6.10. GENERAL AND ADMINISTRATIVE EXPENSES

In EUR 000	For the 6 months ended 30 June 2022	30 June 2021
Employee benefit expenses	-5,687	-5,547
External advice	-465	-314
Facilities, office & other	-919	-1,087
Human resources	-721	-675
Travel, training & conferences	-103	-25
Depreciation and amortization expenses	-481	-286
Total	**-8,376**	**-7,935**

External advice expenses include fees, service and consulting expenses related to legal, human resources, investor relations, accounting, audit and tax services. Facilities, office & other include office, insurance and other miscellaneous expenses used in general and administrative activities.

The increase in G&A expenses is due to the global inflation and post-pandemic normalization.

6.11. FINANCIAL INCOME AND EXPENSES

In EUR 000	For the 6 months ended 30 June 2022	30 June 2021
Interest expense	-4,732	-4,642
Other financial expense	-17	-61
Total	**-4,749**	**-4,703**
Other financial result	944	454
Total	**944**	**454**
Financial result, net	**-3,805**	**-4,249**

Net financial result amounted to EUR 3.8m per 30 June 2022 compared to EUR 4.2m as per 30 June 2021 and include financial expenses in relation to the Company's convertible bond of EUR 4.2m in H1 2022 compared to EUR 4.1m in H1 2021. The other financial result mainly consists of non-realized foreign exchange gains and losses.

6.12. LOSS PER SHARE

The Group has stock option plans that may be settled in common shares of the Group, and which are considered anti-dilutive given that the Group's operations were loss making over the reporting period. As such, the basic and diluted earnings per share are equal. The basis for the basic and diluted earnings per share is the net loss for the year attributable to the owners of the Group.

	For the 6 months ended 30 June 2022	30 June 2021
Profit/loss for the period attributable to the owners of the Group (in EUR 000)	-28,767	-37,276
Weighted average number of ordinary shares for basic loss per share (in number of shares)	57,545,663	57,545,663
Basic loss per share (EUR)	**-0.50**	**-0.65**

6.13. PROPERTY, PLANT AND EQUIPMENT

In EUR 000	As of 30 June 2022	31 Dec 2021
Property, plant and equipment	34,751	37,192
Total property, plant and equipment	**34,751**	**37,192**

Property, plant and equipment decreased to EUR 34.8m as per end of June 2022 from EUR 37.2m at the end of 2021 (decrease of EUR 2.4m) mainly driven by a depreciation charge of EUR 5.0m, capital expenditures in H1 2022 of EUR 1.5m and disposals of EUR 0.7m. The capital expenditures are predominantly related to capitalized Idylla™ systems sold under reagent rental and similar agreements and manufacturing equipment.

6.14. OTHER RECEIVABLES

In EUR 000	As of 30 June 2022	31 Dec 2021
VAT receivables	1,987	2,448
Tax credit research and development	318	330
Other receivables	170	3,777
Total	**2,474**	**6,555**

Other receivables include VAT receivables, and the other receivables included at the end of 2021 amounts related to the insurance claim in relation to the fire incident of 2021.

6.15. FINANCIAL LIABILITIES

The financial debt can be analyzed as follows:

In EUR 000	As of 30 June 2022	31 Dec 2021
Lease liabilities	11,432	14,133
Bank borrowings	0	0
Convertible bond	129,662	128,151
Total non-current	**141,094**	**142,284**
Lease liabilities	6,072	5,878
Bank borrowings	0	6,000
Total current	**6,072**	**11,878**
Total financial liabilities	**147,166**	**154,163**

In 2015, Biocartis NV obtained two new financing facilities for the modifications to the current cartridge production line. The first new facility entails an investment credit for an amount of EUR 0.6m, with a payment term of 5 years and an interest rate of 1.93%. The second one entails a leasing facility for EUR 4.4m that carries a 1.77% interest, includes a purchase option of 1% of the financed amount and has a duration of 54 months. As per the end of H1 2022 the two facilities has been fully paid.

In 2016, Biocartis NV obtained a lease financing facility for the development of a second cartridge production line in Mechelen, for EUR 15m. This facility was increase in 2018 with EUR 2.3m. The interest applicable for this facility equals 1.87% and includes a purchase option of 1% of the financed amount. As per the end of H1 2022 EUR 4.3m is outstanding under this facility. As a security, a debt service reserve account is to be maintained for all of the above financing facilities, the current debt service account amounts to EUR 1.2m.

In 2018, Biocartis NV obtained an investment credit of EUR 1m from a bank to finance mold investments related to its first cartridge manufacturing facility. The investment credit has a payment term of 5 years and an interest rate of 2.53%. In total EUR 0.8m has been withdrawn on this credit facility. As per 30 June 2022, EUR 0.4m is outstanding under this credit facility.

On 9 May 2019, the Group issued a convertible bond of EUR 150m, with a maturity date of 9 May 2024 (i.e. 5-year duration) and a coupon of 4%. The bond can be converted into new/existing ordinary shares of the Group upon the discretion of the bondholder. Under IAS 32- Financial instruments: Presentation the convertible bond is a compound financial instrument and contains, from the issue's perspective, both a liability (i.e. host debt instrument) and an equity component (i.e. an embedded share conversion option). The liability amounts to EUR 130m per 30 June 2022.

The credit facility and guarantees from BNP Paribas Fortis have been canceled in 2021 and replaced by a revised credit facility of KBC. This facility consists of a EUR 7.5m straight loan and a EUR 7.5m rollover credit line. No amounts have been withdrawn on this credit facility as per 30 June 2022.

6.16. DEFERRED INCOME

	As at	
In EUR 000	**30 June 2022**	**31 Dec 2021**
Grants	0	0
Collaboration income	1,978	2,135
Total	**1,978**	**2,135**
Current	1,751	1,822
Non-current	227	313

	Deferred partner income
As per 31 December 2020	**983**
Invoiced	1,894
Recognized in profit or loss	-742
As per 31 December 2021	**2,135**
Invoiced	982
Recognized in profit or loss	-1,140
As per 30 June 2022	**1,978**

Deferred partner income includes upfront payments from collaboration partners in relation to the strategic licensing, development and commercialization collaborations.

6.17. OTHER DISCLOSURES

6.17.1. Fair value

The fair value of the financial assets has been determined on the basis of the following methods and assumptions:

- The carrying value of the cash and cash equivalents and the current receivables approximate their value due to their short term character;
- Other current financial assets such as current other receivables are being evaluated on the basis of their credit risk and interest rate. Their fair value is not significantly different than its carrying value on 30 June 2022 and 31 December 2021.

The fair value of the financial liabilities has been determined on the basis of the following methods and assumptions:

- The carrying value of current liabilities approximates their fair value due to the short-term character of these instruments;
- Loans and borrowings are measured based on their interest rates and maturity date. Most interest-bearing debts have fixed interest rates and its fair value is subject to changes in interest rates and individual creditworthiness. The fair value measurement is classified as level 2.

Fair value hierarchy

The Group uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

- Level 1 — quoted (unadjusted) prices in active markets for identical assets and liabilities
- Level 2 — other techniques for which all inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly
- Level 3 — techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data

The Group has no financial instrumentcarried at fair value through OCI in the consolidated balance sheet on 30 June 2022 and 31 December 2021.

Except for the borrowings (financial liabilities, see note 6.18), the carrying amount of the financial assets and liabilities approximate their fair values. The borrowings with a carrying amount of EUR 147.2m (31 December 2021: EUR 154.2m) have a fair value of EUR 147,2m (31 December 2021: EUR 154.2m).

6.17.2. Contingencies

The Group has no new contingencies compared to 31 December 2021.

6.17.3. Commitments

6.17.3.1. Capital commitments

As per 30 June 2022, the Group has EUR 1.2m capital commitments mainly related to the upgrade of its cartridge production lines located in Mechelen (Belgium) for which the Group is engaged in several contractual arrangements with specified suppliers. The Group had no other material capital commitments on 30 June 2022.

6.17.3.2. Operating commitments

As per 30 June 2022, the Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 8.1m. It is expected that the majority of the commitments will be fulfilled in 2022.

6.17.4. Related-party transactions

Transactions between the Group and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes. Apart from the remuneration of key management and the transactions with the joint venture, there were no other transactions with related parties.

6.18. EVENTS AFTER THE BALANCE SHEET DATE

The following events took place after 30 June 2022:

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

7. REVIEW REPORT OF THE AUDITOR

Biocartis Group NV

Report on the review of the consolidated interim financial information for the six-month period ended 30 June 2022

The original text of this report is in Dutch

Report on the review of the consolidated interim financial information of Biocartis Group NV for the six-month period ended 30 June 2022

In the context of our appointment as the company's statutory auditor, we report to you on the consolidated interim financial information. This consolidated interim financial information comprises the condensed consolidated statement of financial position as at 30 June 2022, the condensed consolidated income statement, the condensed consolidated statement of comprehensive income, the condensed consolidated statement of changes in equity and the condensed consolidated statement of cash flows for the period of six months then ended, as well as selective notes.

Report on the consolidated interim financial information

We have reviewed the consolidated interim financial information of Biocartis Group NV ("the company") and its subsidiaries (jointly "the group"), prepared in accordance with International Accounting Standard (IAS) 34, "Interim Financial Reporting" as adopted by the European Union.

The condensed consolidated statement of financial position shows total assets of 105 503 (000) EUR and the condensed consolidated income statement shows a consolidated loss (group share) for the period then ended of 28 767 (000) EUR.

The board of directors of the company is responsible for the preparation and fair presentation of the consolidated interim financial information in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union. Our responsibility is to express a conclusion on this consolidated interim financial information based on our review.

Scope of review

We conducted our review of the consolidated interim financial information in accordance with International Standard on Review Engagements (ISRE) 2410, "Review of interim financial information performed by the independent auditor of the entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit performed in accordance with the International Standards on Auditing (ISA) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion on the consolidated interim financial information.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the consolidated interim financial information of Biocartis Group NV has not been prepared, in all material respects, in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union.

Emphasis of matter

We draw attention to note 6.4 of the condensed consolidated interim financial information, indicating that the company is currently in the process of executing certain recapitalization transactions that include various conditions and components which have not been realised yet. The company's ability to continue its operations for the next twelve months depends on its ability to timely and sufficiently complete these recapitalization transactions, or get access to alternative ways of financing. Management has assessed that there are material uncertainties associated with the execution of the recapitalization transactions, as included in note 6.4 of the condensed consolidated interim financial information. Our conclusion is not modified in respect of this matter.

Signed at Zaventem,

The statutory auditor

Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises BV/SRL
Represented by Nico Houthaeve

8. DISCLAIMER AND ADDITIONAL INFORMATION

8.1. GENERAL INFORMATION

About Biocartis

Biocartis Group NV is a limited liability company organized under the laws of Belgium and has its registered office at Generaal de Wittelaan 11 B, 2800 Mechelen, Belgium. Throughout this report, the term 'Biocartis NV' refers to the non-consolidated Belgian subsidiary company and references to 'the Group' or 'Biocartis' include Biocartis Group NV together with its subsidiaries.

Use of the Idylla™ trademark, logo and CE-marking

Biocartis and Idylla™ are registered trademarks in Europe, the United States and other countries. The Biocartis and Idylla™ trademark and logo are used trademarks owned by Biocartis. This report is not for distribution, directly or indirectly, in any jurisdiction where to do so would be unlawful. Any persons reading this press release should inform themselves of and observe any such restrictions. Biocartis takes no responsibility for any violation of any such restrictions by any person. Please refer to the product labeling for applicable intended uses for each individual Biocartis product. This report does not constitute an offer or invitation for the sale or purchase of securities in any jurisdiction. No securities of Biocartis may be offered or sold in the United States of America absent registration with the United States Securities and Exchange Commission or an exemption from registration under the U.S. Securities Act of 1933, as amended.

As defined by Belgian law, Biocartis has to publish its financial report in the English and Dutch language. In case of difference in interpretation, the English version prevails. An electronic version of the half-year financial report 2022 is available on the Biocartis website. Other information on the Biocartis website or on other websites is not a part of this half-year report.

8.2. CONTACT INVESTOR RELATIONS

Biocartis Investor Relations
Renate Degrave, Head of Corporate Communications and Investor Relations
Generaal de Wittelaan 11 B
2800 Mechelen, Belgium
+32 15 632 600
ir@biocartis.com

8.3. LISTING

Biocartis is listed on Euronext Brussels since 27 April 2015 under the symbol BCART. Biocartis' ISIN code is BE0974281132.

8.4. FINANCIAL CALENDAR

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

8.5. FINANCIAL YEAR

The financial year starts on 1 January and ends on 31 December.

8.6. AUDITOR INFORMATION

Deloitte Bedrijfsrevisoren B.V, represented by:
Nico Houthaeve
Gateway Building
Luchthaven Nationaal 1J
1930 Zaventem
Belgium

8.7. FORWARD-LOOKING STATEMENT

Certain statements, beliefs and opinions in this report 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 report 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 report, 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 report 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 report 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 report.

9. GLOSSARY

Assay	In the field of diagnostics, an assay is a process or method aimed at determining the presence or amount (quantitative assay) of a certain substance in a sample.
Application	In the context of the Idylla™ platform, an application is a specific Nucleic Acid detection assay (test) that is to run on the system. Applications have their own specific requirements.
Batch Record	The set of records of all relevant process information in any physical or electronic format.
Biopsy (solid/liquid)	The Idylla™ platform is capable of processing both solid biopsies (FFPE tissue which is the standard tissue type for solid tumor diagnostics, and fresh (frozen) tissue samples) and liquid biopsies. These are easier to obtain sample types such as blood plasma or urine. Liquid biopsy-based assays will facilitate monitoring of treatments and disease progression, and possible earlier disease detection.
Serine/threonine-protein kinase B-raf (BRAF)	BRAF is a protein that, in humans, is encoded by the BRAF gene. The BRAF protein is involved in sending signals within cells and in cell growth. Certain inherited BRAF mutations cause birth defects. Alternatively, other acquired mutations in adults may cause cancer.
CE-mark	The CE-mark is a mandatory conformance mark on many products placed on the market in the European Union. With the CE-marking on a product, the manufacturer ensures that the product is in conformity with the essential requirements of the applicable European Union directives. The letters "CE" stand for 'Conformité Européenne' ('European Conformity').
Clinical data	Safety and/or performance information that are generated from the clinical use of a medical device.
Companion Diagnostics (CDx)	CDx is a bio-analytical method designed to assess: (i) whether a patient will respond favorably to a specific medical treatment; (ii) what the optimal dose is for a patient; and (iii) whether the patient can expect certain side effects from a medical treatment. Any prescription of a drug with a CDx is based on the outcome of the CDx. CDx tests are also used in the drug development process.
CLIA	The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease (source: https://wwwn.cdc.gov/clia/).
Consumables	Materials that are in direct or indirect contact with final product.
COVID-19	In 2019, a new coronavirus was identified as the cause of a disease outbreak that originated in China. The virus is now known as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease it causes is called coronavirus disease 2019 (COVID-19) (source: mayoclinic.org).
ctDNA	This is circulating tumor DNA.
Deoxyribonucleic acid (DNA)	DNA is a nucleic acid molecule that contains the genetic instructions used in the development and functioning of living organisms.
Distributor	Person or legal entity that furthers the marketing and/or selling of a device from the original place of manufacture to the ultimate user without modifying the device, its packaging or its labelling.
Epidermal growth factor receptor (EGFR)	EGFR is a protein found on the surface of certain cells which can cause them to divide. It is found in abnormally high levels on the surface of many types of cancer cells.
Export or distributor markets	Defined as the world excluding European direct markets, US, China and Japan.
Emergency Use Authorization (EUA)	This is an authorization given by the FDA Commissioner pursuant to section 564 of the US Federal Food, Drug, and Cosmetic Act, as amended (the 'FD&C Act'), which allows unapproved medical products or unapproved uses of approved medical products to be used in the United States in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear threat agents when there are no adequate, approved, and available alternatives.
US Food and Drug Administration (FDA)	The FDA is a federal agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the regulation and supervision of, among other things, medical devices.
Formalin fixed, paraffin embedded (FFPE)	FFPE tissues are samples, typically from suspected tumors, that are fixed or mixed with formalin to preserve the structural integrity of the sample. The sample is then embedded into a type of paraffin wax so that it can be sliced into very fine slices, 5-10 microns thick. Treating samples in this manner enables the samples to be stained with dyes to analyze abnormalities in tissue that is suspected of cancer.

Gene signature	RNA expression or gene signature tests are particularly interesting since these often have a high market value. These are based on the differential mRNA expression levels that are calculated into a clinically meaningful score, namely the 'signature' that guides patient management decisions.
Gene fusions	Gene fusions represent an important class of somatic alterations in cancer and have become important biomarkers for cancer diagnosis, prognosis and the selection of targeted therapies. The discovery and research for further understanding of fusion genes across multiple cancer types may provide more effective therapies in the future (source: Stransky et al., The landscape of kinase fusions in cancer. Nat Commun. 5, 4846, 2014; Mertens et al. The emerging complexity of gene fusions in cancer. Nat Rev Cancer 15, 371-381, 2015).
ICU	Intensive Care Unit.
Idylla™ Platform	Combination of the Idylla™ Instrument (hardware and software) and the Idylla™ Console (hardware and software) using the Idylla™ cartridge technology.
Idylla™ Cartridge	Refers to the disposable container containing the necessary reagents to perform a test with the Idylla™ system.
Immunoassay	Immunoassays are assays that measure biomarkers through antigen-antibody interaction technologies. In most cases such assays are used to measure biomarkers of the immune system itself, e.g. HCV or HIV antibodies produced by the bodies, which are detected by means of HCV or HIV antigens.
Influenza	Also known as 'the flu' is a highly contagious respiratory tract infection caused by the family of influenza viruses.
In vitro diagnostics or In vitro diagnosis (IVD)	IVD is a diagnostic test outside of a living body in contrast to "in vivo", in which tests are conducted in a living body (for example an X-ray or CT-scan).
Investigational Use Only (IUO)	An Investigational Use Only (IUO) product is an IVD product, in the testing phase of product development that is being shipped or delivered for product testing prior to full commercial marketing.
Kirsten rat sarcoma-2 virus oncogene (KRAS)	KRAS is a protein that, in humans, is encoded by the KRAS gene. Like other members of the Ras family, the KRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyze guanosine triphosphate), and is an early player in many signal transduction pathways. The protein product of the normal KRAS gene performs an essential function in normal tissue signaling, and the mutation of a KRAS gene is associated with the development of many cancers.
KOL	Key Opinion Leader.
Manufacturer	Natural or legal person responsible for the design, manufacture, fabrication, assembly, packaging or labelling of a medical device, for assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on their behalf by a third party.
MDSAP (Medical Device Single Audit Program)	The MDSAP allows medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program's main mission is to "...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."
Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of - diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of or compensation for an injury, - investigation, replacement, modification, or support of the anatomy or of a physiological process, - supporting or sustaining life, - control of conception, - disinfection of medical devices, - providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
Metastatic Colorectal Cancer (mCRC)	Colorectal Cancer (CRC) is the second most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually. According to the International Agency for Research on Cancer, an estimated 694,000 deaths from CRC occur worldwide every year, accounting for 8.5% of all cancer deaths and making it the fourth most common cause of death from cancer.

Molecular diagnostics (MDx)	MDx is a form of diagnostic testing used to detect specific sequences in DNA or RNA that may or may not be associated with disease. Clinical applications of MDx include infectious disease testing, oncology, pharmacogenomics and genetic disease screening.
Micro satellite instability (MSI)	MSI is a genetic hyper-mutability condition resulting from MMR that is functioning abnormally.
Multiplexing	The simultaneous detection of more than one analyte or biomarker from a single sample.
Neuroblastoma RAS viral (v-ras) oncogene (NRAS)	NRAS is a protein that is encoded, in humans, by the NRAS gene. Like other members of the Ras family, the NRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyze guanosine triphosphate) and is an early player in many signal transduction pathways. The protein product of the normal NRAS gene performs an essential function in normal tissue signaling, and the mutation of a NRAS gene is associated with the development of many cancers.
Next-Generation Sequencin (NGS)	Sequencing is the process of determining the precise order of nucleotides within a DNA molecule. It includes any method or technology that is used to determine the order of the four bases—adenine, guanine, cytosine, and thymine—in a strand of DNA. The high demand for low-cost sequencing has driven the development of high-throughput sequencing technologies that parallelize the sequencing process, producing thousands or millions of sequences concurrently. High-throughput sequencing technologies are intended to lower the cost of DNA sequencing beyond what is possible with standard dye-terminator methods.
Performance study	Performance study means a study undertaken to establish or confirm the analytical or clinical performance of a device.
Polymerase chain reaction (PCR)	The specific and exponential amplification of DNA sequences by consecutive thermal cycling steps. Real-time PCR is a form of PCR whereby the amplified sequences are made visible by means of fluorescent labelling in real time, i.e., as they become synthesized. Real-time PCR can be used to estimate the quantity of target DNA sequences in a multiplexed way. PCR and real-time PCR can also be used to detect and quantify RNA sequences after a DNA copy has been made from the RNA sequence by means of a reverse transcriptase enzyme.
Protein	Polypeptide chain built from the 20 natural amino acids. Proteins are synthesized from a messenger RNA copy of a gene and can have many functions in the cytoskeleton of the cell, enzymatic, messenger functions in cells and blood such as immune cytokines, DNA binding proteins that regulate expression, etc.
Prototype	(First) materialization of the intended product.
Regulatory authority	A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction and can take legal action to ensure that medical devices marketed within its jurisdiction comply with legal requirements.
Respiratory Syncytial Virus (RSV)	RSV is a major cause of lower respiratory tract infection that is a frequent infection in children.
Research Use Only (RUO)	This is a category of non-approved (i.e. no CE-marking and FDA approval) medical device products that can solely be used for research purposes. Many producers introduce their products first as RUO and/or IUO products, prior to obtaining 510(k) clearance or PMA approval.
Ribonucleic acid (RNA)	RNA, like DNA, is a nucleic acid molecule. RNAs have a variety of different functions in living cells. They can have a scaffolding role in the build-up of complexes (ribosomes, SNRPs), provide sequence recognition (translation, RNA spicing), have catalytic function (ribozymes), act as messengers for protein synthesis (mRNAs), regulate gene expression (miRNAs) or make up the genome of certain viruses.
SARS-CoV-2	The virus that causes COVID-19.
Screening Test	An initial or preliminary test. Screening tests do not tell you if you definitely have a disease or condition. Rather, positive results indicate that you may need additional tests or a doctor's evaluation to see if you have a particular disease or condition.
Sepsis	Sepsis is a potentially life-threatening condition that occurs when the body's response to a infection damages its own tissues. When the infection-fighting processes turn on the bod they cause organs to function poorly and abnormally. Sepsis may progress to septic shoc This is a dramatic drop in blood pressure that can lead to severe organ problems and deat Early treatment with antibiotics and intravenous fluids improves chances for survival (sourc mayoclinic.org).
Serine/threonine-protein kinase B-raf (BRAF)	BRAF is a protein that, in humans, is encoded by the BRAF gene. The BRAF protein is involved in sending signals within cells and in cell growth. Certain inherited BRAF

	mutations cause birth defects. Alternatively, other acquired mutations in adults may cause cancer.
Stakeholder	Interested party.
White Paper	Customer documentation that explains a specific issue and presents Biocartis standpoint on the matter.

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