



HALF-YEAR REPORT

2023

BIOCARTIS GROUP NV

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Biocartis' **vision** is to enable universal access to **personalized medicine** for patients around the world.

Our **mission** is to make **molecular testing** convenient, fast and suitable for any lab



Idylla™

a revolutionary, molecular testing system designed to offer biomarker results within 3 hours for faster treatment decisions.

Suitable for any lab.

1. Message from the CEO



Dear Stakeholder,

I joined the Biocartis team as CEO in April 2023. The Idylla™ Platform drew me to Biocartis, with its unique ability to provide fast targeted oncology testing results and improved patient outcomes around the world. This uniqueness matched with my enthusiasm for taking on new challenges triggered my move to join Biocartis. We have made significant progress on the operational front which I'll discuss later. One of the significant challenges the Company has faced is to obtain new funding to finance its path to profitability. We have been working diligently to resolve that situation and to secure the Company's future.

The Company has established agreement in principle with its Secured Creditors on a recapitalization of its operating subsidiaries and comprehensive balance sheet restructuring transaction that will materially de-lever the operating business by reducing its debt burden by EUR 132 million and recapitalizing it with EUR 40 million of new equity capital under the ownership of the Secured Creditors. This new capital is expected to fund the business through EBITDA break-even by the end of 2024 and ensure business continuity of the operating Biocartis companies, safeguard the interests of customers, suppliers, partners, and employees of Biocartis, and support execution of the growth strategy towards profitability. As a result of this transaction, there will be a change in ownership through enforcement of security by the Secured Creditors of substantially all of the assets of Biocartis to New Biocartis; customers, suppliers, partners, and employees are not expected to see any impact as a result of this ownership change.

This announced recapitalization and balance sheet restructuring plan follows an extensive process by the Board and Management to address Biocartis's leverage and liquidity position. Following that process, it became evident that the difficult market conditions combined with the Company's balance sheet and historic burn rate made outside funding unattainable. Current shareholders of Biocartis Group NV will receive no distribution from the security enforcement and are expected to receive nothing at the time of its winding down. While disappointing to shareholders and unsecured bondholders, this Transaction is necessary, and the EUR 40 million of new equity capital to the operating businesses, combined with the material deleveraging is expected to provide the New Biocartis business entity with funding to operational break even.

The core business performance remains strong, with 22% growth of oncology cartridge revenue, a 40% gross margin on product sales and a 20% improvement in EBITDA to EUR -14.5m in H1 2023. I am convinced that, under the new, recapitalized holding company and in combination with the operational reorganization that is now being completed, the surviving business under new ownership will be able to continue our path to a financially healthy and sustainable business. The restructuring and recapitalization allows the Biocartis business to continue its mission to enable universal access to personalized medicine for patients around the world by making molecular testing convenient, fast, and suitable for any lab."

The Idylla™ Platform provides clinicians actionable results far sooner than Next Generation Sequencing (NGS). This speed enables cancer patients to begin their biomarker-driven therapies sooner, thereby improving their chances of survival. Biocartis' top line performance in H1 2023 underpins the strong fundamentals of the Company and the continued market demand for our platform. A solid 22% growth of core cartridge revenue in oncology with a 40% gross margin on product sales were complemented by a consistent contribution of service revenues from our growing network of strategic partners. Our growth rate shows that speed matters to oncologists and pathologists and our platform is enabling faster results and earlier treatments for patients.

We are focused on satisfying our customers and partners, further expanding our oncology test menu and streamlining our overhead to accelerate the Company's path to profitability. In June we began an operational reorganization to focus on our key product and partner projects and reduce our headcount by

approximately 25%, accelerating our path to becoming financially independent from the need for further capital to fund operations by the end of 2024. A more streamlined organization can focus on profitable revenue generation and strategic partnerships that drive sustainable growth. The operational reorganization has been largely completed and we expect this to be fully behind us by the end of this year.

Also, in the first half of this year, we successfully transitioned all commercial assays from the semi-automated manufacturing line ML1 to the fully automated manufacturing line ML2, leading to a significant reduction in cost of goods sold. This transition is expected to further enhance our future cartridge product gross margin. This transfer will also help us move towards break-even EBITDA due to its automation and our ability to more fully utilize this higher capacity as we grow our cartridge volumes over the coming years.

In summary, during the first half of 2023 we continued to grow, improved gross margins and initiated a reorganization, which together will move us towards break-even EBITDA. The first half was one of significant progress for Biocartis and we will continue to focus on our goals of growing our business and securing our long-term future by becoming EBITDA break-even by the end of 2024.

The support we have and the financing and recapitalization led by our largest investors is paramount for new Biocartis to execute on its vision to enable personalized medicine for patients around the world through universal access to molecular testing.

Roger Moody

CEO

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 2023, 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.

Roger Moody
CEO

Herman Verrelst
Chairman

3. Business review H1 2023

3.1. Key Highlights H1 2023

- Solid performance with 22% growth of oncology cartridge revenue, a 40% gross margin on product sales and a 20% improvement in EBITDA to EUR -14.5m
- Initiated operational reorganization and cost reduction program that is aimed at reaching reach operating break-even operating results by the end of 2024 and is expected to be completed by year-end
- Cash position end H1 2023 of EUR 25.2m

3.1.1. Commercial Highlights

- Product related revenue of EUR 23.5m (H1 2022: EUR 21.3m), including EUR 18.4m from 155k cartridges sold and EUR 5.1m from instrument sales, rentals, and servicing:
 - EUR 17.5m cartridge revenue in oncology, +22% year-on-year, driven by 14% cartridge volume growth and an increase of the average selling price ('ASP') by 7%
 - The contribution of COVID-19 to cartridge revenues decreased as expected from EUR 1.7m in H1 2022 to EUR 0.7m in H1 2023, down to 3% of total product related sales
 - ASP per commercial cartridge of EUR 120 in oncology and EUR 115 overall (H1 2022: EUR 113 and EUR 103, resp.)
 - EUR 5.1m revenue from a global Idylla™ installed base of 2,218 instruments, with 133 net new instruments placed in H1 2023, a 30% increase vs net new placements in H1 2022
 - Continued double-digit growth of oncology cartridge revenue across all regions. Renewed growth in US instrument placements and oncology cartridge sales during Q2 2023 after a slowdown in Q1 that was driven by the impact of a cartridge price increase implemented in Q4 2022.
- Gross profit on product sales increased by 36% from EUR 6.6m to EUR 9m, reflecting a gross margin of 40%, compared to 32% in H1 2022 and a further improvement from 37% in Q1 2023. Commercial cartridges are now exclusively produced on the more automated high-throughput manufacturing line ML2 after having decommissioned the older manufacturing line ML1 during Q1 2023
- Collaboration revenue of EUR 6m, an increase of 18% compared the H1 2022 driven by expansion of our network of strategic partners

3.1.2. Idylla™ Test menu, Partnerships & Publications

- Test menu & product registrations
 - Launch among selected customers on 9 February 2023 of the Idylla™ IDH1-2 Mutation Assay Kit (RUO), the first test developed with the new Idylla™ FLEX technology that separates the generic components of an Idylla™ Test from the test-specific components. The Assay was subsequently launched globally in July 2023.
 - Announcement on 2 March 2023: 510(k) clearance by the U.S. Food and Drug Administration (FDA) for the Idylla™ MSI Test

- End of April 2023, Nichirei Biosciences, Biocartis' distribution partner in Japan, received the approval by the Japanese competent authorities (Ministry of Health, Labor and Welfare) to commercialize the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test in Japan.
- Partnerships:
- Announcement on 4 April 2023 of a new partnership agreement with APIS Assay Technologies Ltd. for development of APIS' Breast Cancer Subtyping Assay on the Idylla™ Platform. This assay, already available for in vitro diagnostic use¹ in centralized expert laboratories in the UK, will be commercialized² by Biocartis ahead of the Idylla™ version of the assay being available
- Publications:
- During H1 2023, 17 new papers were published, providing further evidence of Idylla's™ robust and accurate performance combined with much shorter turnaround times compared to other testing methods. In particular, one retrospective and prospective study on determining EGFR mutations from formalin fixed paraffin embedded (FFPE) tissue samples emphasized that integrating the ultra-rapid Idylla™ as a critical screening step before deploying next generation sequencing (NGS) could provide timely and comprehensive benefits to patients, ultimately leading to better treatment outcomes in non-small cell lung cancer.



¹ Registered as IVD in the UK, submission for IVDR CE-marking pending
² In the European Union and selected export markets

3.1.3. Organizational & Operational highlights

- Operational reorganization and cost reduction program
 - Enabling access to molecular diagnostic testing in oncology remains at the core of Biocartis' strategy with a streamlined organization that will focus investments on profitable product revenue generation and strategic partnerships that have the potential to generate significant long-term value
 - Engaged DC Advisory to assist with a capital restructuring aimed at securing the remaining funding needs and restructure the Company's capital structure.
- Management changes:
 - Appointment of Roger Moody as new CEO per [24 April 2023](#)
 - Announced resignation of Jean-Marc Roelandt as the Company's CFO per [4 August 2023](#)
 - Announced resignation of Piet Houwen as COO as part of the operational reorganization per [1 September 2023](#)
 - Announced appointment of George Cardoza as new CFO and Head of Service Delivery on [8 August 2023](#)
- Cartridge manufacturing – The transfer of all Idylla™ Assays to the second generation cartridge manufacturing line ('ML2') was completed and all commercial cartridge manufacturing production on ML1 was stopped after Q1 2023. Continued scaling of the more automated high-throughput manufacturing line ML2 is expected to further reduce cartridge production cost and contribute to a gross margin on products of 40-45% for the full year 2023

3.1.4. Financial highlights

- *Total operating income* – Total operating income amounted to EUR 29.6m compared to EUR 26.8m last year. Product related revenues increased by 10% from EUR 21.3m in H1 2022 to EUR 23.5m in H1 2023. Within product sales, cartridge sales revenues amounted to 18.4m. Revenue from oncology cartridge sales represented EUR 17.5m and grew by 22% year-on-year. Revenue from the sale of Idylla™ SARS-CoV-2 Tests³ continues to decrease and amounted to EUR 0.7m compared to EUR 1.7m in H1 2022. Revenues from the sale, rental and servicing Idylla™ Instruments increased by 7% and amounted to EUR 5.1m (H1 2022: EUR 4.8m). 133 net new Instrument placements in H1 2023 increased the global installed base to 2,218, evenly split between reagent rental agreements and straight capital sales. Collaboration revenue increased by 18% and amounted to EUR 6m in H1 2023 compared to EUR 5.1m in H1 2022. Collaboration revenue largely consisted of development services delivered to our growing network of strategic partners.
- *Gross profit* – Gross profit on product sales amounted to EUR 9m, an increase of 32% from EUR 6.6m last year. The gross margin on products continue to increase, from 32% in H1 2022 to 40% in H1 2023, driven by continued scaling of the high-throughput manufacturing line ML2 and the increasing ASP. Q1 2023 was the last quarter that included cartridge production on the old manufacturing line ML1, which is now no longer in use for commercial cartridge production. The overall cartridge ASP increased from EUR 103 in H1 2022 to EUR 115 in H1 2023, as a result of

³ The Idylla™ SARS-CoV-2 Test (CE-IVD) and the Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD)

declining sales of the lower priced Idylla™ SARS-CoV-2 Tests and the continued increased contribution of higher-priced novel tests in oncology.

- *OPEX* - Total operating expenses (excluding cost of sales) of EUR 37m in H1 2023 slightly decreased by EUR 0.7m from EUR 37.7m in H1 2022. The cost reduction implemented during Q4 2022 was partly offset by the impact of the high inflation which led to a mandatory indexation of wages and salaries in January 2023 of over 11% in Belgium.
- *Operating result* - The sustained revenue growth and the increased gross profit contributed to a 20% y-o-y improvement of EBITDA, from EUR -18.2m in H1 2022 to EUR -14.6m in H1 2023.
- *Net cash flow and cash position* - Cash burn from operating activities increased from EUR 24.2m to EUR 29.3m, despite the improved operating result, which was offset by EUR 10.3m investments in working capital (H1 2022: EUR 2.6m) and EUR 1m higher interest expenses. Last year, working capital was favorably impacted by the collection of the fire insurance claim. Moreover, a significant amount of transaction fees associated with the recapitalization were paid during the first half of 2023 and trade receivable increased a.o. because of the deferred payment of services to certain collaboration partners that are expected to be collected during the second half of 2023. Investing cash flows amounted to EUR 1.1m and included the drawdown of the convertible note by SkylineDx after having reached an agreed milestone in the development of the Idylla™ version of SkylineDx's Merlin Assay. On [16 January 2023](#), the comprehensive recapitalization was completed, and the financing cash flows included EUR 34.4m of net proceeds from the issuance of EUR 25m of new second lien convertible bonds and the final drawdown of EUR 12m under the convertible term loan.



3.2. Key figures H1 2023

The tables below show an overview of the key figures and a breakdown of operating income for H1 2023 and H1 2022.

Key figures (EUR 1,000)	H1 2023	H1 2022	% Change
Total operating income	29,617	26,771	11%
Cost of sales	-13,378	-13,720	-2%
Research and development expenses	-18,091	-19,251	-6%
Sales and marketing expenses	-10,892	-10,050	8%
General and administrative expenses	-8,018	-8,376	-4%
Operating expenses	-50,379	-51,397	-2%
Operating result	-20,762	-24,626	-16%
Net financial result	-10,140	-3,805	166%
Share in the result of associated companies	-375	-432	-13%
Income tax	23	96	-76%
Net result	-31,254	-28,767	9%
Cash flow from operating activities	-29,262	-24,154	21%
Cash flow from investing activities	-1,132	-1,594	-29%
Cash flow from financing activities	29,680	-9,542	-411%
Net cash flow¹	-714	-35,290	-98%
Cash and cash equivalents ²	25,178	19,724	28%
Financial debt	152,247	147,166	3%

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 2023 and 2022

Operating income (EUR 1,000)	H1 2023	H1 2022	% Change
Collaboration revenue	5,987	5,082	18%
Idylla™ system sales and rentals	4,000	3,824	5%
Idylla™ cartridge sales	18,359	16,477	11%
Product sales revenue	22,359	20,301	10%
Service revenue	1,145	977	17%
Total revenue	29,491	26,360	12%
Grants and other income	126	411	-69%
Total operating income	29,617	26,771	11%

Product sales revenue (EUR 1,000)	H1 2023	H1 2022	% Change
Commercial revenue	22,022	19,899	11%
Research and development revenue	338	401	-16%
Total product sales revenue	22,359	20,301	10%

4. Principal risks related to the business activities

The principal risks related to Biocartis' business activities are outlined in Biocartis' 2022 Annual Report, p.49-58 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 6.3, the principal risks have not materially changed from the ones outlined in the 2022 Annual Report.

5. Condensed consolidated interim financial statements for the period ended 30 June 2023

5.1. Condensed consolidated income statement

In EUR 000	Notes	For the 6 months ended	
		30 June 2023	30 June 2022
Collaboration revenue	6.4	5,987	5,082
Product sales revenue	6.4	22,359	20,301
Service revenue	6.4	1,145	977
Total revenue		29,491	26,360
Other operating income			
Grants and other income	6.5	126	411
Total operating income		29,617	26,771
Cost of sales	6.6	-13,378	-13,720
Research and development expenses	6.7	-18,091	-19,251
Sales and marketing expenses	6.8	-10,892	-10,050
General and administrative expenses	6.9	-8,018	-8,376
Other expenses	6.9		
Total operating expenses		-50,379	-51,397
Operating loss for the year		-20,762	-24,626
Financial expense	6.10	-10,723	-4,749
Other financial results	6.10	583	944
Financial result, net		-10,140	-3,805
Share in the result of joint venture		-375	-432
Loss for the year before taxes		-31,277	-28,863
Income taxes		23	96
Loss for the year after taxes		-31,254	-28,767
Attributable to owners of the Group		-31,254	-28,767
Earnings per share			
Basic and diluted loss per share	6.11	-0.34	-0.50

5.2. Condensed consolidated statement of other comprehensive income

In EUR 000	Notes	For the 6 months ended	
		30 June 2023	30 June 2022
Loss for the year		-31,254	-28,767
Other comprehensive income (loss), not to be reclassified to profit or loss:			
Re-measurement gains and losses on defined benefit plan		-153	-220
Income taxes on items of other comprehensive income		38	65
Other comprehensive income (loss), that may be reclassified to profit and loss:			
Exchange differences on translation of foreign operations		-157	576
Total comprehensive loss for the year		-31,526	-28,346
Attributable to owners of the Group		-31,526	-28,346

5.3. Condensed consolidated statement of financial position

In EUR 000	Notes	As of 30 June 2023	31 Dec 2022
Assets			
Non-current assets			
Intangible assets		4,440	4,770
Property, plant and equipment	6.12	30,004	31,527
Financial assets		4,640	3,640
Investment in joint ventures		2,232	2,538
Other non-current assets		234	204
Deferred tax assets and R&D Investment tax credit		1,802	1,664
		43,352	44,343
Current assets			
Inventories		17,884	18,905
Trade receivables		21,313	16,697
Other receivables	6.13	1,651	2,236
Other current assets		3,603	5,971
Cash and cash equivalents*		25,178	26,125
		69,629	69,934
Total assets		112,981	114,277
Equity and liabilities			
Capital and reserves			
Share capital		-220,293	-220,302
Share premium		639,186	631,722
Share based payment reserve		7,844	7,502
Accumulated deficit		-474,774	-443,363
Other comprehensive income		-5,950	-5,843
Total equity attributable to owners of the Group		-53,987	-30,284
Non-current liabilities			
Provisions		207	204
Borrowings and lease liabilities	6.14	40,498	25,824
Convertible debt	6.14	93,767	75,935
Deferred income	6.15	87	149
		134,559	102,112
Current liabilities			
Borrowings and lease liabilities	6.14	17,982	20,597
Trade payables		6,902	11,747
Deferred income	6.15	870	1,195
Other current liabilities		6,655	8,910
		32,409	42,449
Total equity and liabilities		112,981	114,277

*Cash and cash equivalents for 31 December 2022 and 30 June 2023 include EUR million restricted cash related to KBC Lease financing

5.4. Condensed consolidated cash flow statement

In EUR 000	Notes	For the 6 months ended	
		30 June 2023	30 June 2022
Operating activities			
Loss for the year		-31,254	-28,767
Adjustments for			
Depreciation and amortization		5,190	5,288
Impairment losses	6.12	637	698
Income taxes in profit and loss		-23	-96
Financial result, net		10,141	3,804
Unrealized exchange gains/ losses			
Net movement in defined benefit obligation		-104	-121
Share of net profit of associate and joint venture		374	432
Share based payment expense		342	472
Other		-42	-23
Changes in working capital			
Net movement in inventories**		-1,049	-5,520
Net movement in trade and other receivables and other current assets		-1,808	5,041
Net movement in trade payables & other current liabilities		-7,100	-1,984
Net movement in deferred income	6.15	-387	-157
Cash flow from operating activities before interest and taxes paid		-25,083	-20,933
Interest paid		-4,179	-3,221
Taxes paid			
Cash flow used in operating activities		-29,262	-24,154
Investing activities			
Interest received		3	1
Acquisition of property, plant & equipment**		-135	-467
Acquisition of intangible assets			-128
Investment in joint venture			-1,000
Investment convertible note		-1,000	
Cash flow used in investing activities		-1,132	-1,594
Financing activities			
Proceeds from borrowings		28,125	
Refinancing convertible bond and convertible term loan		34,391	
Net proceeds from the issue of common shares, net of transaction costs			
Repayment of borrowings	6.14	-32,809	-9,498
Bank charges		-27	-44
Cash flow used in financing activities		29,680	-9,542
Net decrease in cash and cash equivalents		-714	-35,290
Cash and cash equivalents at the beginning of the period		26,125	53,522
Effects of exchange rate changes on the balance of cash held in foreign currencies		-233	1,492

Cash and cash equivalents at the end of the period*		25,178	19,724
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* Including EUR 1.2 million restricted cash related to KBC Lease financing

** Including Idylla instruments placed under reagent rental agreements that were held in inventory on 31 December 2022

5.5. Condensed consolidated statement of changes in equity

In EUR 000	Notes	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 2022		-220,657	711,874	6,862	-5,572	-526,405	-33,897	-33,897
Loss for the period						-65,381	-65,381	-65,381
Re-measurement gains and losses on defined benefit plan					-271		-271	-271
Consolidation translation difference						378	378	378
Total comprehensive income					-271	-65,003	-65,274	-65,274
Share-based payment expense				640			640	640
Convertible bond conversion old bond			11				11	11
Convertible bond issue new bond			33,121				33,121	33,121
Capital increase by contribution in kind			-104,071			104,071	0	0
Share issue - contribution in kind 6 September 2022		8	992				1,000	1,000
Capital decrease by incorporation of accumulated losses 14 November 2022			-43,975			43,975	0	0
Share issue - rights offering 2 December 2022		336	24,773				25,108	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 - mandatory conversion convertible bond 16 December 2022		9	10,810				10,819	10,819
Balance as at 31 December 2022		-220,302	631,722	7,502	-5,843	-443,363	-30,284	-30,284
Balance as at 1 January 2023		-220,302	631,722	7,502	-5,843	-443,363	-30,284	-30,284
Loss for the period						-31,254	-31,254	-31,254
Re-measurement gains and losses on defined benefit plan					-108		-108	-108
Consolidation translation difference						-157	-157	-157
Total comprehensive income					-108	-31,411	-31,519	-31,519
Share-based payment expense				342			342	342
Convertible bond - Conversion new bond		6	7,225				7,231	7,231
Convertible term loan - Conversion		3	240				243	243
Balance as at 30 June 2023		-220,293	639,187	7,844	-5,951	-474,774	-53,987	-53,987

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 11B, 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. The Company 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 25 September 2023 by the board of directors of the Company (the 'board of directors').

6.2. Summary of significant accounting policies

6.2.1. Statement of compliance and basis of preparation

These condensed consolidated interim financial statements for the six months ended 30 June 2023 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 2022, which have been prepared in accordance with IFRS as adopted by the EU.

We refer to section 6.3 for further information on the use of a basis of preparation other than going concern for these 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 2023:

- IFRS 17 Insurance Contracts
- Amendments to IFRS 17 Insurance contracts: Initial Application of IFRS 17 and IFRS 9 - Comparative Information
- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting Policies
- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates
- Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction
- Amendments to IAS 12 Income taxes: International Tax Reform - Pillar Two Model Rules (effective immediately but not yet endorsed in the EU - disclosures are required for annual periods beginning on or after 1 January 2023)

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

6.3. 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 consolidated financial statements of Biocartis Group NV ("Parent Company") and its subsidiaries ("Group") are prepared in accordance with International Financial Reporting Standards as adopted by the European Union. These include International Financial Reporting Standards (IFRS) and the related interpretations issued by the International Accounting Standards Board (IASB), and the IFRS Interpretations Committee (IFRIC), effective at the reporting date and adopted by the European Union.

The consolidated financial statements have been prepared on a basis other than that of a going concern.

Despite the business reorganization announced in June 2023 and other cost reduction measures, the recent decrease in EBITDA and net income compared to previous projections and budget made the Board recognize that, contrary to the position through April 2023, additional funding was required to fund the ongoing operations and anticipated projected operating losses in the short run. Under new management, an extensive process was then undertaken by the Board and Management to address Biocartis's leverage and liquidity position. Management and the Board have taken all practicable steps to resolve the situation, including:

- Management have held discussions with numerous existing and potential investors seeking additional funding, and was not successful in attempts to raise additional equity funding given the Company's current unsustainable debt levels;
- An independent international investment bank was retained by the Company, and following an extensive process no buyers were willing and able to buy the Company given existing debt levels;
- Similar engagement with other independent international investment banks led to the same conclusion.

As a result of that process of market soundings in recent months, it became evident that the difficult market conditions for both equity and debt combined with the Company's balance sheet and historic burn rate made outside funding unattainable.

The Board recognized that without such very substantial outside funding, the Company would (a) be in breach of its liquidity covenant imminently and (b) be unable to pay its debts when they fall due in coming months. In other words, the Company would not have enough cash on hand, or access in the market to raise additional funds, to fund its obligations and avoid a liquidity covenant breach.

Discussions were held as from June 2023, including with the assistance of an independent debt advisor, with the Company's current secured lenders regarding potential options around obtaining additional funding to fund the Company's ongoing operating losses and capital spending requirements and to waive the pending liquidity covenant default. The Company had previously reported a material uncertainty about the Company's ability to obtain a waiver of the current debt covenants, however after 30 June 2023, the secured lenders conveyed that they would not waive the Company's covenant obligations. The secured lenders notified the Company of a structure that would recapitalize the operating subsidiaries following an enforcement upon the collateral securing the debt following the imminent covenant breach.

At this point the Board concluded that a default was imminent and that the Company could not continue as a going concern. Such conclusion is bolstered by the fact that the secured lenders are expected to anticipate enforcement against substantially all of the Company's assets, leaving the Parent Company essentially an empty shell without activity or financial means.

The conclusion of the Biocartis Board of Directors that the Biocartis Group's consolidated financial statements for the six months ended 30 June 2023 are prepared on a basis other than that of a going concern has not altered the accounting policies as described in "Significant accounting policies" in the Company's 2022 Annual Report, but has resulted in significant judgements made by management in their application, including:

- The measurement basis of financial liabilities at amortized cost remains unchanged.
- The financial liabilities (as detailed in note 6.14) have been presented based on the contractual due dates at 30 June 2023, even though the expected outcome of the financial restructuring and recapitalization of the operating subsidiaries by the lenders will result in a full or partial extinguishment of certain of these liabilities of the Company over the coming months. Had the presentation and measurement in the condensed consolidated interim financial statements been adjusted towards the due dates of those liabilities that the directors anticipate at the issue of these interim financial statements, the non-current liabilities would amount to EUR 8.8 million, the current liabilities would amount to EUR 176.0 million and the Company's loss for the year after taxes would amount to EUR 63.7 million.

6.4. Revenue

The Group's revenue recognized under IFRS 15 can be aggregated as follows:

In EUR 000	For the 6 months ended			
	30 June 2023		30 June 2023	30 June 2022
	At a point in time	Over time		
Collaboration revenue				
R&D services	0	5,931	5,931	4,932
License revenue	0	50	50	50
Milestones	6	0	6	100
	6	5,981	5,987	5,082
Product related revenue				
Idylla™ System Sales revenue	1,985	0	1,985	1,937
Idylla™ System Rental revenue	2,015	0	2,015	1,887
Cartridge revenue	18,359	0	18,359	16,477
	22,359	0	22,359	20,301
Service revenue				
Idylla™ System Service revenue	814	330	1,145	977
	814	330	1,145	977
Total	23,179	6,311	29,491	26,360

For details related to the movement in deferred income of collaboration agreements, we refer to note 6.15.

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 ratio to 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
2023	6,337
2024	1,339
2025	651
2026	0
2027	0
After 2027	0
Total	8,327

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

6.4.1. Revenues by region and major customers

In EUR 000	For the 6 months ended	
	30 June 2023	30 June 2022
Country of domicile	271	259
Belgium	271	259
Total all foreign countries, of which	29,220	26,101
United States of America	6,016	7,575
China	1,013	624
Spain	2,756	2,109
France	1,978	2,497
Great Britain	3,177	2,634
Germany	2,251	1,994
Rest of the world	12,028	8,667
Total	29,491	26,360

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 2023 there was no customer representing more than 10% of the total revenues, the 5 largest clients together represent 20% of the total revenues.

6.5. Other operating income

In EUR 000	For the 6 months ended	
	30 June 2023	30 June 2022
R&D project support (VLAIO & IWT grants)	128	340
Other project grants (EU)	-	-
Other income	-1	71
Total	126	411

Other income of EUR 0.1m relates to grants received in connection with the development of the new Idylla™ FLEX technology that separates the generic components of an Idylla™ Test from the test-specific components. The Idylla™ FLEX technology aims to shorten the development time of new Idylla™ Assays, allowing to bring them to the market much faster and is expected to facilitate the use of Idylla™ Tests in therapy decisions and molecular surveillance. The Idylla™ IDH1-2 Mutation Assay Kit (RUO) is the first test developed using the Idylla™ FLEX technology. The Assay was launched among selected customers in Q1 2023 and launched more broadly in July 2023.

6.6. 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 2023	30 June 2022
Employee benefit expenses	-3,379	-4,178
Material, lab consumables & small equipment	-6,204	-5,878
Depreciation and amortization	-1,875	-1,869
Royalty expense	-730	-630
Facilities, office and other	-1,190	-1,165
Total	-13,378	-13,720

The volume of commercial cartridges sold in H1 2023 increased with 14% compared to H1 2022. The lower costs of goods sold was mainly driven by the fact that manufacturing of all commercial assays was successfully moved from the semi-automated manufacturing line ML1 to the fully automated manufacturing line ML2.

6.7. Research and development expenses

In EUR 000	For the 6 months ended	
	30 June 2023	30 June 2022
Employee benefit expenses	-11,273	-13,384
R&D consultancy & subcontracting	-2,440	-2,466
Laboratory and cartridge expenses	-537	720
Quality, regulatory and intellectual property	-414	-256
Facilities, office & other	-1,342	-1,481
ICT	-191	-257
Travel, training & conferences	-189	-147
Depreciation and amortization	-1,706	-1,979
Total	-18,091	-19,251

Subcontracting includes 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.

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 increase in laboratory costs is mainly because of the extra efforts that were made in H1 2023 to catch up on several projects that were delayed in 2022 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.

6.8. Sales and marketing expenses

In EUR 000	For the 6 months ended	
	30 June 2023	30 June 2022
Employee benefit expenses	-6,914	-6,533
S&M consultancy & subcontracting	-79	-345
Sales and promotional expenses	-473	-334
Business development	-316	-438
Facilities, office & Other	-837	-513
Travel, training & conferences	-1,031	-867
Depreciation and amortization	-896	-794
Impairment of receivables	-346	-226
Total	-10,892	-10,050

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

The increase in S&M expenses is due to the global inflation and increase in facilities and office costs.

6.9. General and administrative expenses

In EUR 000	For the 6 months ended	
	30 June 2023	30 June 2022
Employee benefit expenses	-4,970	-5,687
External advice	-56	-465
Facilities, office & other	-1,348	-919
Human resources	-791	-721
Travel, training & conferences	-193	103
Depreciation and amortization	-660	-481
Total	-8,018	-8,376

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 decrease in G&A expenses is mainly related to the cost reduction in implemented in Q4 2022.

6.10. Financial income and expenses

In EUR 000	For the 6 months ended	
	30 June 2023	30 June 2022
Interest expense	-9,636	-4,732
Other financial expense	-46	-17
Total	-9,682	-4,749
Other financial result	-458	944
Total	-458	944
Financial result, net	-10,140	-3,805

Net financial expenses increased to EUR 10.1m per 30 June 2023 compared to EUR 3.8m per 30 June 2022 and include the impact of the recapitalization that was initiated in 2022 and completed in 2023.

The total interest and debt appreciation expense associated with the convertible term loan and the two convertible bonds amounted to EUR 8.9m. Interest expenses also include interests, commissions and costs linked to debts and IFRS interest expenses which amount to EUR 0.8m per 30 June 2023.

Other financial expenses are related to bank charges.

Other financial result include the total transaction expenses related to all recapitalization transactions in 2023 so far and amounted to EUR 0.7m per 30 June 2023. Furthermore, the total interest accrual associated with the convertible note from SkylineDx amounts to EUR 0.3m. Other financial result also consists of non-realized exchange gains and losses.

6.11. 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 2023	30 June 2022
Profit/loss for the period attributable to the owners of the Group (in EUR 000)	-31,254	-28,767
Weighted average number of ordinary shares for basic loss per share (in number of shares)	93,231,289	57,545,663
Basic loss per share (EUR)	-0.34	-0.50

6.12. Property, plant and equipment

In EUR 000	As of	
	30 June 2023	31 Dec 2022
Property, plant and equipment	30,004	31,527
Total property, plant and equipment	30,004	31,527

Property, plant and equipment decreased to EUR 30.0m as per end of June 2023 from EUR 31.5m at the end of 2022 (decrease of EUR 1.4m) mainly driven by a depreciation charge of EUR 4.8m, capital expenditures in H1 2023 of EUR 1.9m and disposals of EUR 0.6m. The capital expenditures are predominantly related to capitalized Idylla™ Systems sold under reagent rental and similar agreements and manufacturing equipment.

6.13. Other receivables

	As of	
	30 June 2023	31 Dec 2022
VAT receivables	1,618	1,898
Tax credit research and development	0	318
Other receivables	33	20
Total	1,651	2,236

Other receivables included VAT receivables and amongst others amounts recorded for the government capital grant by STS Strategic Transformation Support) related to the investments in the second cartridge manufacturing facilities in Mechelen.

6.14. Financial liabilities

The financial liabilities are summarized as follows:

In EUR 000	As of	
	30 June 2023	31 Dec 2022
Lease liability	8,756	9,051
Bank borrowings	0	0
Convertible debt	10,148	9,293
Convertible term loan	28,379	15,838
2nd lien secured convertible debt	83,620	66,642
Convertible term loan embedded derivative	3,362	934
Total non-current	134,265	101,759
Lease liability	4,232	5,597
Bank borrowings	13,750	15,000
Total current	17,982	20,597
Total Financial liabilities	152,247	122,355

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 increased 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. Per 30 June 2023 EUR 1.2m is outstanding under this facility. As a security, a debt service reserve account is

to be maintained for the above financing facilities of 2013, 2015 and 2016, 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. Per 30 June 2023 EUR 0.2m is outstanding under this 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 issuer's perspective, both a liability (i.e. host debt instrument) and an equity component (i.e. an embedded share conversion option).

On 1 September 2022, Biocartis launched a comprehensive recapitalization, which included the restructuring of the existing convertible debt and the provision of new convertible debt, summarized as follows:

- 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

Following the amendment, the exchange for new convertible bonds and the partial buy-back, the liability associated with the 4% convertible bonds amounts to EUR 10.1m per 30 June 2023 compared to EUR 9.3m per 31 December 2022.

In 2022, EUR 17.5m was drawn under the new convertible term loan, net of fees. This amount was partly used for the buy-back of EUR 13.7m of the existing 4% convertible bond. In 2023, EUR 12m was drawn under the new convertible term loan, net of fees. Per H1 2023, EUR 0.2m of the convertible term loan has been converted into capital. This convertible term loan only consists of a liability component and an embedded derivative component. The liability component is measured at amortized cost and the derivative component is measured at fair value through profit and loss. Per 30 June 2023, the liability amounts to EUR 28.3m and the embedded derivative amounts to EUR 3.4m.

On 2 September 2022, an offer to exchange the amended existing convertible bonds was made for new 4.5% second lien secured convertible bonds, subject to the subscription of EUR 25.0m of additional newly issued 4.5% convertible bonds and rights offering with extra-legal preferential rights for the existing shareholders of the Company. EUR 92.1m of the existing 4% convertible bonds were exchanged for the new 4.5% convertible bonds. In 2023, EUR 0.7m of the new convertible bonds have been converted into capital. In accordance with IFRS 9, the exchange has been accounted for as an extinguishment of the original liability and the recognition of a new financial liability, amounting to EUR 83.6m per 30 June 2023. The original equity component associated with the existing convertible bonds was not derecognized.

Following the recapitalization transactions, the financial indebtedness at 30 June 2023 amounted to EUR 152.2m compared to EUR 122.4m at 31 December 2022.

The credit facility and guarantees from BNP Paribas Fortis have been cancelled 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, both of which were fully drawn on 30 June 2023. The rollover credit line has been partially paid back and amounts to a liability amount of EUR 6.3m per 30 June 2023.

The KBC Bank credit facilities, the convertible term loans and the new convertible bonds also include a negative pledge that prohibit the Company to create or permit to subsist any security over any of its assets. Except as otherwise permitted, the Company, Biocartis NV and Biocartis US Inc. are also subject to various restrictive covenants and are consequently prohibited from, among others disposing its material assets, incurring financial indebtedness, making investments such as acquisitions, and making loans.

The Convertible Term Loan and the 4.5% Convertible Bonds are subject to a minimum liquidity covenant requiring Biocartis Group NV and the guarantors to maintain liquidity on each month-end of at least EUR 10 million and EUR 8 million, respectively. As per 30 June 2023, all covenants were met, however, the liquidity covenant is expected to be breached in H2 2023 as described in section 6.17 (Events after balance sheet date).

6.15. Deferred income

In EUR 000	As of	
	30 June 2023	31 Dec 2022
Grants	-	-
Partner income	957	1,344
Total	957	1,344
Current	870	1,195
Non-current	87	149

	Deferred partner income
As per 31 December 2021	2,135
Invoiced	258
Recognized in profit or loss	-1,049
As per 31 December 2022	1,344
Invoiced	677
Recognized in profit or loss	-1,064
As per 30 June 2023	957

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

6.16. Other disclosures

6.16.1. Fair value

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

- The carrying amount 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 amount on 30 June 2023 and 31 December 2022.

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

- The carrying amount 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 their 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 instrument carried at fair value through OCI in the consolidated balance sheet on 30 June 2023 and 31 December 2022.

Except for the borrowings (financial liabilities, see note 6.14), the carrying amount of the financial assets and liabilities approximate their fair values. The borrowings with a carrying amount of EUR 152.2m (2022: EUR 117.7m) have a fair value of EUR 152.2m (2022: EUR 120.8m).

6.16.2. Contingencies

The Group has no new contingencies compared to 31 December 2022.

6.16.3. Commitments

6.16.3.1. CAPITAL COMMITMENTS

As per 30 June 2023, the Group has EUR 0.7m 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 and license agreements for which royalties are paid. The Group had no other material capital commitments on 30 June 2023.

6.16.3.2. OPERATING COMMITMENTS

As per 30 June 2023, the Group has operating commitments for a total amount of EUR 9.1m, mostly related to different suppliers for Idylla™ systems and cartridge parts. It is expected that the majority of the commitments will be fulfilled in 2023.

6.16.4. 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.

6.17. Events after balance sheet date

The following events took place after 30 June 2023:

- Announcement of appointment of George Cardoza as new CFO and Head of Service Delivery – see above.
- Announcement on [10 August 2023](#) of a new post-commercial collaboration program with Lilly to explore via an ongoing Lilly-sponsored study the advantages of adding Idylla™ to molecular diagnostic workflows in global clinical labs and help guide the improvement of US community-based diagnostic workflows
- New Medical Advisory Board – creation of new Medical Advisory Board announced on [28 August 2023](#) comprised of renowned practice leaders to assist with expedited growth of diagnostics partnerships and provide valuable expert technology insights, expert knowledge in the field of oncology in general and of pharma needs in particular
- The operational reorganization and cost reduction program announced on [15 June 2023](#) is in its finalization phase. In total, approximately 125 positions will be reduced. In addition, the role of approximately 20 positions has significantly changed. A proportion of these positions will be phased out during the remainder of 2023, to ensure a smooth handover of activities. The reorganization is realized through a transition to a leaner and more agile management structure and an increased focus on partner funded test menu expansion and a more targeted US commercial strategy to increase oncology test utilization. The reorganization is expected to achieve an annualized cost reduction of approximately EUR 18m. The process has been completed in accordance with the Belgian rules on collective dismissals. Total cost associated with the operational reorganization amount up to EUR 4.3m
- The Company announced on 26 September 2023, that it has been informed of an agreement by its secured creditors on a recapitalization of its operating subsidiaries and comprehensive balance sheet restructuring transaction (the “**Transaction**”). The Transaction will safeguard the interests of customers, suppliers, partners, and employees of Biocartis, and help to continue and execute the growth strategy towards profitability of its operations and will provide for the following:
 - The Company’s secured creditors will take ownership of the Biocartis operating subsidiaries through enforcement. Following enforcement, Biocartis Group NV is expected to be wound down in an orderly fashion.
 - A new entity will be incorporated (“New Biocartis”), owned by the secured creditors, to which substantially all the Company’s assets will be transferred upon an anticipated security enforcement by the secured creditors over the Company’s assets that were pledged to such creditors.
 - Lenders under the Company’s first lien convertible term loan facility and KBC have agreed to roll over their first lien debt into New Biocartis (or its wholly owned subsidiaries) and release claims against Biocartis Group NV. KBC have agreed to extend their financing to Biocartis NV and Biocartis US, Inc.
 - The interests and claims of the EUR 16 million unsecured 4.00% convertible bonds due 2027 (ISIN BE0002651322) will be written down to zero pursuant to their terms as part of the enforcement.
 - Shareholders of Biocartis Group NV will receive no distribution from the security enforcement and are expected to receive nothing at the time of its wind down.
 - With respect to New Biocartis:

- The Company's EUR 116 million 4.5% Second Ranking Secured Convertible Bonds due 2026 (ISIN BE6338582206) (the "**Bonds**", and the holders of the Bonds, the "**Bondholders**") will be fully equitized in New Biocartis and the Bondholders will become the primary owners of Biocartis's operating business as shareholders of New Biocartis.
 - The Bondholders will recapitalize New Biocartis (and its operating subsidiaries) with EUR 40 million of equity capital, backstopped by a group of supporting Bondholders (the "**Equity Injection**").
 - Following the full equitization of EUR 116 million of Bonds, the write down of EUR 16 million of Unsecured 2027 Bonds, and the closing of the Equity Injection, New Biocartis will have less than EUR 45 million of gross debt and net debt of approximately zero.
- In terms of financial consequences of the Transaction for Biocartis Group NV: the Company is anticipated to remain with a virtually empty balance sheet, with very limited assets and liabilities. The board of directors will proceed with the wind down of the Company following the completion of the above Transaction.

7. Review report of the auditor

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 2023

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 2023, 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 112 981 (000) EUR and the condensed consolidated income statement shows a consolidated loss (group share) for the period then ended of 31 254 (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 – consolidated interim financial information prepared on a basis other than on a going concern

We draw attention to notes 6.2.1 and 6.3 of the consolidated interim financial information, which indicates that the consolidated interim financial information have been prepared on a basis other than on a going concern. In that context, note 6.3 describes the conclusion of the board of directors that a breach of Biocartis Group NV's liquidity covenant obligations towards the secured lenders is imminent and that the group will not be able to continue to operate as a going concern upon the anticipated enforcement by the secured lenders of their collateral, i.e., substantially all of the group's assets, in a transaction structured as disclosed in note 6.17.

Signed at Zaventem.

The statutory auditor

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

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 11B, 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 2023 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

Generaal De Wittelaan 11B
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

26 September 2023 H1 2023 Results

Biocartis will host a conference call with live webcast presentation today at 14:30 CEST / 13:30 BST (UK) / 08:30 EDT (US) to discuss the H1 2023 results. Participants that want to follow the webcast presentation live, are invited to click on this [link](#). Participants that want to attend the event over the phone are required to register [here](#) in advance of the conference. After registration, each participant will be provided with dial-in numbers and a personal PIN. The conference call and webcast will be conducted in English. A replay of the webcast will be available on the Biocartis investors' website shortly after.

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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)	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
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.
EDTA	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 19 January 2023
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.
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.
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 hydrolyse 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 signalling, 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.”

<p>Medical Device</p>	<p>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.</p>
<p>Metastatic Colorectal Cancer (mCRC)</p>	<p>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.</p>
<p>Molecular Residual Disease (MRD)</p>	<p>Molecular Residual Disease is a small number of cancer cells left in the body after treatment. These cells have the potential to cause relapse in patients</p>
<p>Molecular diagnostics (MDx)</p>	<p>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.</p>
<p>Micro satellite instability (MSI)</p>	<p>MSI is a genetic hyper-mutability condition resulting from MMR that is functioning abnormally.</p>
<p>Multiplexing</p>	<p>The simultaneous detection of more than one analyte or biomarker from a single sample.</p>
<p>Neuroblastoma RAS viral (v-ras) oncogene (NRAS)</p>	<p>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 hydrolyse 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.</p>
<p>Next-Generation Sequencing (NGS)</p>	<p>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.</p>

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.
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 splicing), 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 an infection damages its own tissues. When the infection-fighting processes turn on the body, they cause organs to function poorly and abnormally. Sepsis may progress to septic shock. This is a dramatic drop in blood pressure that can lead to severe organ problems and death. Early treatment with antibiotics and intravenous fluids improves chances for survival (source: mayoclinic.org).

<p>Serine/threonine-protein kinase B-raf (BRAF)</p>	<p>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.</p>
<p>Stakeholder</p>	<p>Interested party.</p>
<p>Surveillance monitoring</p>	<p>Molecular surveillance, where every patient is monitored repeatedly using a molecular test, is a rapidly growing field and represents a significant market opportunity in oncology. The development of an easy-to-use testing solution that can detect patient-specific biomarkers by using a new generation Idylla™ technology aims at decentralizing customized testing and personalized monitoring</p>
<p>White Paper</p>	<p>Customer documentation that explains a specific issue and presents Biocartis standpoint on the matter.</p>

