BIOCARTIS

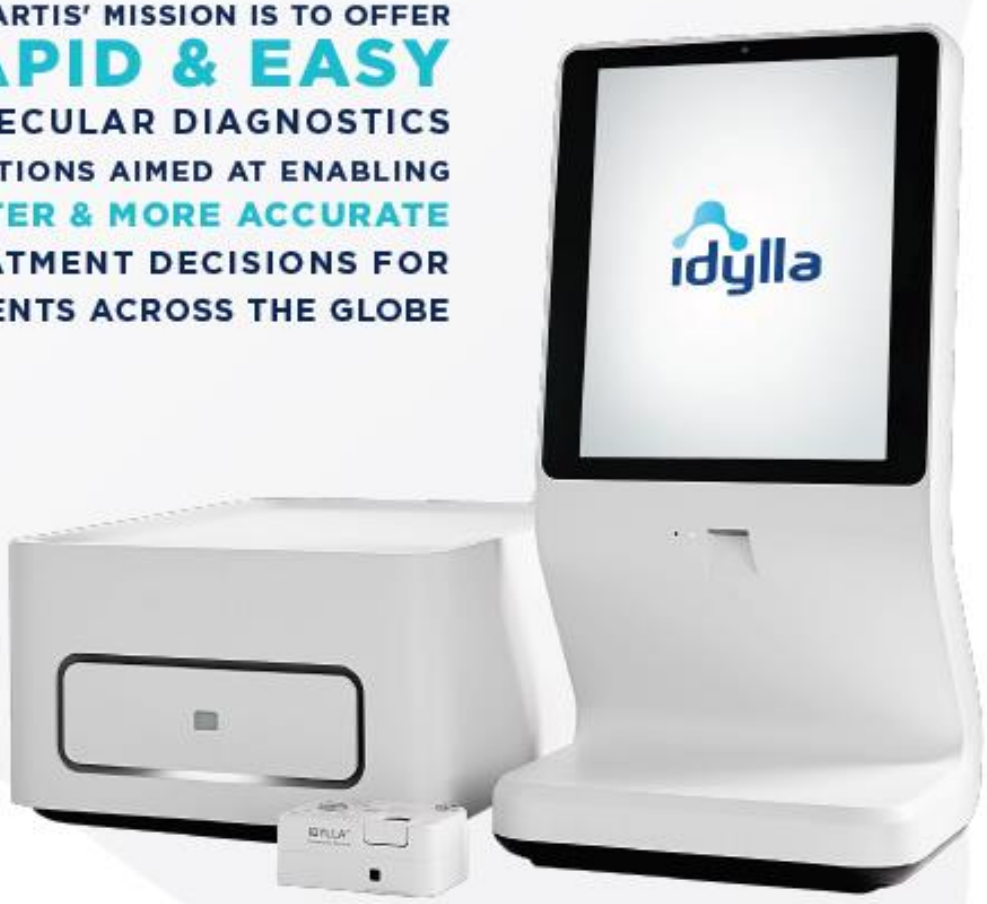
FINANCIAL REPORT H1 2021

BIOCARTIS GROUP NV

BIOCARTIS' MISSION IS TO OFFER

RAPID & EASY

MOLECULAR DIAGNOSTICS SOLUTIONS AIMED AT ENABLING FASTER & MORE ACCURATE TREATMENT DECISIONS FOR PATIENTS ACROSS THE GLOBE



Idylla™
A revolutionary, fully automated system that makes molecular testing convenient and exceptionally fast.
Suitable for any lab.

CONTENT

1. MESSAGE FROM THE CEO

Dear Shareholder,
Dear Stakeholder,

After the very strong performance in H1 2021, both in terms of instrument placements as well as commercial cartridge volumes, the fire was obviously an unfortunate set-back. Although we cannot deny the fire has an impact, this event again showed the incredible resilience of our teams who have been working with relentless focus and dedication to limit the fall-out.

I am proud to announce that we currently expect a smooth restart of the ML2 line by the second half of September 2021. This is also important considering the recent launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel, the upgrade of our existing Idylla™ SARS-CoV-2 Test (CE-IVD) that now also includes Flu A/B and RSV. Ahead of a delayed flu season, this Panel is well positioned to guide healthcare providers in this complex landscape of respiratory infections in 2022.

Furthermore, I am very excited to announce a possible break-through in our cartridge manufacturing with the ongoing evaluation of a new simplified, cost-efficient cartridge design which is expected to significantly lower manufacturing costs for a selection of our Idylla™ assays. Together with the ongoing development of a new technology on Idylla™ which aims to personalize Idylla™ assays while reducing development time and cost, this could prove to be a pivotal development towards sustainable growth in the years to come."

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 2021, 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 FOR THE FIRST HALF OF 2021

KEY HIGHLIGHTS H1 2021

- 156k commercial Idylla™ cartridges sold, almost twice as high as in H1 2020 (+96%);
- Q1 2021 marked by 70% growth, followed by an even stronger +136% in Q2 2021;
- Robust growth in oncology across all regions; solid contribution from infectious diseases, comparable to the H2 2020 volumes against the backdrop of declining global COVID-19 testing volumes.

- 189 new Idylla™ placements in H1 2021 (101 in H1 2020) mainly driven by demand in European and distributor markets as well as by content partners;
- Installed base of 1,770 Idylla™ instruments end of H1 2021;
- Average annualized cartridge consumption per Idylla™ instrument during H1 2021 was 209, in part reflecting high utilization for infectious disease testing.

- Encouraging first market demand for the Idylla™ GeneFusion Assay (RUO);
- First oncology assay US FDA submission for Biocartis with the 510(k) notification for the Idylla™ MSI Test for the detection of MSI and to aid in the differentiation between sporadic colorectal cancer and potential Lynch Syndrome;
- EUR 1.4m grant from VLAIO (Flemish Agency for Innovation & Entrepreneurship), subject to the development of a new Idylla™ technology;
- Post the reporting period, successful CE-IVD launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel ;
- New partnership with SkylineDx for the development of SkylineDx's novel proprietary Merlin Assay on Idylla™ aimed at predicting a patient's risk of nodal metastasis in melanoma;
- Expanded partnership with AstraZeneca announced to improve access to rapid and easy-to-use Idylla™ EGFR testing products at selected hospital sites in European and global distributor markets.

- Total operating income amounted to EUR 23.1m compared to EUR 17.1m last year;
- Product revenues increased by 62% from EUR 11.4m in H1 2020 to EUR 18.5m in H1 2021;
- Total operating expenses (excluding cost of sales) of EUR 39.1m in H1 2021 increased from EUR 34.7m in H1 2020;
- Cash and cash equivalents at 30 June 2021 amounted to EUR 85.0m.

COMMERCIAL HIGHLIGHTS

- Commercial cartridge volume:
  - 156k commercial Idylla™ cartridges sold, almost twice as high as in H1 2020 (+96%);
  - Q1 2021 marked by 70% growth, followed by an even stronger +136% in Q2 2021;
  - Robust growth in oncology across all regions; solid contribution from infectious diseases, comparable to the H2 2020 volumes against the backdrop of declining global COVID-19 testing volumes.
- Installed base:
  - 189 new Idylla™ placements in H1 2021 (101 in H1 2020) mainly driven by demand in European and distributor[1] markets as well as by content partners;
  - Installed base of 1,770 Idylla™ instruments end of H1 2021;
  - Average annualized consumption per Idylla™ instrument during H1 2021 was 209, in part reflecting high utilization for infectious disease testing.
- Regional performance:
  - *Europe* – Strong increase in new Idylla™ placements in European markets, leading to continued growth of cartridge volumes in Europe. Strongest growth in oncology, combined with the acquisition of new EU customers needing rapid SARS-CoV-2 testing for safe access to hospitals, events and travel.
  - *US* – Although Idylla™ placements slowed down in the US because of constrained hospital budgets following the pandemic, US commercial cartridge volumes grew by 150%. Growth driven by increased demand for oncology biomarker testing, although the return to pre-pandemic oncology biomarker testing volumes showed to be more disparate across the US. In infectious diseases, demand for SARS-CoV-2 testing in H1 2021 significantly down from 2020 levels.
  - *Distributor markets* – Strong performance in terms of Idylla™ placements. Cartridge volume regained traction in oncology in all regions[2].
  - *China and Japan* – Continued progress was made in China and Japan[3]. Registration of the Idylla™ instrument in China is expected by the end of this year, while Idylla™ assay registrations are expected to follow earliest end of 2022 in both countries. Furthermore, during H1 2021, the progress in the local manufacturing set-up in China was going well, with local manufacturing of first cartridge volumes needed for local registration of the assays expected in H1 2022.

TEST MENU, PARTNERSHIPS & PUBLICATION HIGHLIGHTS

- Encouraging first market demand for the Idylla™ GeneFusion Assay (RUO[4]), launched on 22 March 2021. The Assay detects, in one single cartridge, a wide range of biomarkers covering all gene fusions[5] considered to be relevant in cancer research[6].
- First oncology assay US FDA submission for Biocartis with the 510(k)[7] notification for the Idylla™ MSI Test for the detection of MSI[8] and to aid in the differentiation between sporadic colorectal cancer and potential Lynch Syndrome on 20 April 2021.
- EUR 1.4m grant from VLAIO[9] announced on 11 May 2021, subject to the development of a new Idylla™ technology.
- Post the reporting period, successful CE-IVD launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel which detects SARS-CoV-2, Flu A/B and RSV nucleic acids in one single cartridge within approx. 90 minutes. Timing of the Emergency Use Authorization ('EUA') submission to the US FDA to be decided.
- New partnership with SkylineDx announced on 22 April 2021 for the development of SkylineDx's novel proprietary Merlin Assay on Idylla™ aimed at predicting a patient's risk of nodal metastasis in melanoma.
- Expanded partnership with AstraZeneca announced on 4 May 2021 to improve access to rapid and easy-to-use Idylla™ EGFR testing products at selected hospital sites in European and global distributor markets.
- 19 new Idylla™ publications, abstracts and posters were published in peer-reviewed journals during H1 2021,

1 Defined as the world excluding European direct markets, US, China and Japan
2 During Q1 2021, the Idylla™ platform, the Idylla™ BRAF Mutation Test (CE-IVD) and the Idylla™ EGFR Mutation Test (CE-IVD) completed registration in Russia, and the Idylla™ MSI Test (CE-IVD) completed registration in Taiwan, as such expanding the commercial footprint for Biocartis' IVD medical devices. Post the reporting period, additional registrations were also completed in Taiwan
3 In China, Biocartis established a joint venture ('China JV') with Guangzhou Wondfo Biotech Co., Ltd (SHE: 300482), a fast-growing diagnostics leader in China. In Japan, Biocartis is collaborating with Nichirei Biosciences
4 RUO = Research Use Only, not for use in diagnostic procedures
5 Biomarkers including gene fusions involving ALK1, ROS1, RET, NTRK1-2-3 as well as MET exon 14 skipping
6 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
7 A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). A 510(k) or Premarket Notification (PMN) with the US FDA is required when introducing a device into commercial distribution for the first time. Source: https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances, last consulted on 17 August 2021
8 MSI or Microsatellite Instability is the result of inactivation of the body's so-called DNA mismatch repair (MMR) system, which normally spontaneously corrects errors that occur during DNA replication
9 Flanders government agency for Innovation & Entrepreneurship

including the publication of two studies[10] by Memorial Sloan Kettering Cancer Center ('MSKCC', New York, US) concluding that Idylla™ EGFR testing (RUO) enables rapid assessment of the most common EGFR mutations with low sample input, even on different sample types, without compromising subsequent more comprehensive NGS[11] testing, which can be useful in cases where EGFR mutation results were negative and further testing is needed. One abstract[12] was presented at the ASCO Annual Meeting taking place virtually between 4-8 June 2021. One abstract on the SeptiCyte© RAPID on Idylla™ was presented at the 31st ECCMID (European Congress of Clinical Microbiology & Infectious Diseases) congress (9-12 July 2021).

OPERATIONAL & ORGANIZATIONAL HIGHLIGHTS

- *Shareholders' Meetings* – All agenda items approved during the ordinary shareholders' meeting held on 14 May 2021, including the re-appointment of Herman Verrelst, CEO of the Company, as director of the Company for a term of four years, and the appointment of Christian Reinaudo as independent director of the Company for a term of three years[13]. All agenda items approved during the extraordinary general shareholders' meeting held on 4 June 2021, including the renewal of the authorization to the Board of Directors to increase the share capital of the Company by up to 75% of the then current amount of the share capital, during a period of five (5) years.
- *Cartridge manufacturing* – Transfer of the Idylla™ EGFR Mutation Test (CE-IVD) to the second cartridge manufacturing line ('ML2') completed during H1 2021. This concluded the transfer of Biocartis' main oncology assays to ML2, which is a key driver of cost optimizations within the Company's cartridge manufacturing activities. The resulting improvement of the gross margin on product sales was however offset by the global shortage of certain reagent supplies caused by the pandemic that forced lower than planned production volumes.

FINANCIAL HIGHLIGHTS

- *Total operating income* – Total operating income amounted to EUR 23.1m compared to EUR 17.6m last year. Product revenues increased by 62% from EUR 11.4m in H1 2020 to EUR 18.5m in H1 2021. Within product sales, cartridge sales revenues increased by 54%. Idylla™ instrument sales revenues of EUR 3.7m doubled on the back of 189 new instrument placements, 88 more than in H1 2020. Collaboration revenues amounted to EUR 2.6m and solely consisted of R&D services provided to partners. The decrease of EUR 2.0m compared to H1 2020 is predominantly driven by the different timing of certain collaboration projects.
- *Idylla™ cartridge average sales price (ASP)* - Idylla™ oncology cartridge ASP was stable at EUR 104. The ASP of the Idylla™ SARS-CoV-2 Test was lower than last year, in line with expectations and resulting in an overall ASP of EUR 95.

10 Arcila ME, Yang S-R, Momeni A, Mata DA, Salazar P, Chan R, Elezovic D, Benayed R, Zehir A, Buonocore DJ, Rekhtman N, Lin O, Ladanyi M, Nafa K, Ultra-Rapid EGFR Mutation Screening Followed by Comprehensive Next-Generation Sequencing: A Feasible, Informative Approach for Lung Carcinoma Cytology Specimens with a High Success Rate., JTO Clinical and Research Reports (2020), doi: https://doi.org/10.1016/j.jtocrr.2020.100077., available online 18 July 2020; Arcila ME et al., Rapid EGFR Mutation Detection Using the Single-Institution Experience of 1200 Cases Analyzed by an In-House Developed Pipeline and Comparison with Concurrent Next-Generation Sequencing Results Idylla Platform, J Mol Diagn 2020, Published on 23 December 2020, 1-12; https://doi.org/10.1016/j.jmoldx.2020.11.009

11 Next Generation Sequencing

12 Behera et al. Circulating tumor DNA mutation as a prognostic marker in melanoma with brain metastasis. J Clin Oncol 39, 2021 (suppl 15; abstr e21560); Only the abstracts at the virtual AMP Europe congress (Association for Molecular Pathology, virtual congress taking place 14-18 June 2021) and ASCO (American Society of Clinical Oncology) in the US were screened

13 To replace CRBA Management BV, permanently represented by Christian Reinaudo, as independent director of the Company

- *Gross margin* – Gross margin on products of 8%, compared to 18% in H1 2020 as a result of the impact of the lower ASP of the Idylla™ SARS-CoV-2 Test. Furthermore, the gross margin was also temporarily impacted by higher COGS because production volumes were lower than expected as the pandemic caused a global shortage of reagent supplies. COGS also included the effect of hiring additional staff in anticipation of increasing volumes in the second half of the year.
- *OPEX* – Total operating expenses (excluding cost of sales) of EUR 39.1m in H1 2021 increased from EUR 34.7m in H1 2020, predominantly as a result of the planned acceleration and diversification of the Idylla™ test menu, both in oncology and in infectious diseases.
- *Net cash flow and cash position* – The net cash outflow from operating and investing activities amounted to EUR 35.8m in H1 2021 compared to EUR 25.6m in H1 2020. The increased outflow is attributable to (a) lower gross margin and (b) higher investment in net working capital and higher capital expenditure resulting from a higher number of Idylla™ instruments placed under reagent rental agreements. The cash and cash equivalents at 30 June 2021 amounted to EUR 85.0m.
- *Revised credit facility* – During H1 2021, Biocartis entered into a new credit facility with KBC Bank, replacing the facilities with KBC Bank and BNP Paribas Fortis that came to maturity in 2020. This facility consists of a EUR 7.5m straight loan and a EUR 7.5m rollover credit line. To date, the new credit facility remains undrawn.

KEY FIGURES H1 2021

The tables below show an overview of the key figures and a breakdown of operating income for H1 2021 and H1 2020. Consolidated financial statements and accompanying notes are included in Biocartis' half-year 2021 report that is available here on the Company's website.

Key figures (EUR 1,000)	H1 2021	H1 2020	% Change
Total operating income	23,057	17,606	31%
Cost of goods sold	-17,059	-9,233	85%
Research and development expenses	-23,389	-20,303	15%
Sales and marketing expenses	-7,740	-7,931	-2%
General and administrative expenses	-7,935	-6,491	22%
Operating expenses	-56,132	-43,958	28%
Operating result	-33,075	-26,352	26%
Net financial result	-4,249	-5,129	-17%
Share in the result of associated companies	-101	-195	-48%
Income tax	149	118	26%
Net result	-37,276	-31,558	18%
Cash flow from operating activities	-33,752	-24,526	38%
Cash flow from investing activities	-2,087	-1,028	103%
Cash flow from financing activities	-3,518	-3,456	2%
Net cash flow [1]	-39,357	-29,010	36%
Cash and cash equivalents[2]	84,905	149,674	-43%
Financial debt	149,412	165,258	-10%

[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 2021 and H1 2020

Operating income (EUR 1,000)	H1 2021	H1 2020	% Change
Collaboration revenue	2,640	4,746	-44%
Idylla™ system sales	3,715	1,837	102%
Idylla™ cartridge sales	14,749	9,584	54%
Product sales revenue	18,463	11,421	62%
Service revenue	748	530	41%
Total revenue	21,851	16,697	31%
Grants and other income	1,206	909	33%
Total operating income	23,057	17,606	31%

Product sales revenue (EUR 1,000)	H1 2021	H1 2020	% Change
Commercial revenue	18,441	10,491	76%
Research & development revenue	22	930	-98%
Total product sales revenue	18,463	11,421	62%

4. PRINCIPAL RISKS RELATED TO THE BUSINESS ACTIVITIES

The principal risks related to Biocartis' business activities are outlined in Biocartis' 2020 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 update on the impact of COVID-19, the impact of the fire incident of 30 July 2021 as described below, and the going concern described in note 6.4, the principal risks have not materially changed from the ones outlined in the 2020 Annual Report.

RISKS RELATED TO COVID-19

During the first half of 2021, the pandemic still impacted the ordinary course of business, but global cancer care started to normalize. Commercial cartridge volumes in oncology grew across all regions and the contribution from the Idylla™ SARS-CoV-2 test remained robust. As a consequence, product income strongly grew by 62% to EUR 18.5m from EUR 11.4m in H1 2020.

The pandemic however started to impact the supply of raw materials. As a result, production volumes in H1 2021 were lower than expected as the pandemic caused a global shortage of reagent supplies, impacting gross margin through higher cost of goods, which also included the effect of hiring additional staff in anticipation of increasing volumes in the second half of the year. Further information on the impact of COVID-19 on the Group's operations and its financial results can be found in sections 3 and 6.3.

RISKS RELATED TO THE FIRE INCIDENT OF 30 JULY 2021

After the fire that broke out at one of the warehouse facilities in Mechelen (Belgium) during the night of 30 July 2021, the Company has taken immediate actions to mitigate the loss of finished products and raw materials as well as the temporary unavailability of the high-throughput ML2 manufacturing line. Aiming to safeguard continued supply to customers as much as possible, actions included (i) the redirection of additional personnel and resources to the unaffected ML1 cartridge manufacturing line to temporarily increase production on this line, (ii) the placement of orders to replenish critical reagents lost in the fire from different suppliers to minimize production delay and (iii) the prioritization of oncology and partner project tests manufacturing. The latter consequently also reduces the Idylla™ SARS-CoV-2 testing volumes.

As a result, Biocartis is able to confirm a 40% cartridge volume growth target for 2021, however subject to the timely availability of reagent raw materials for Idylla™ cartridges in sufficient quantities and the full restart of the ML2 line, which is now expected by the 2nd half of September. Nevertheless, due to the already known delays in the supply of certain assay-specific reagents, certain products may still be temporarily unavailable to meet the entire customer demand and further mitigating action may be required after production resumes on ML2.

A further overview and description of risk factors that may affect the future operating and financial performance of Biocartis and the value of an investment in the Company's securities can be found in Biocartis' annual and half-year reports.

5. CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS FOR THE PERIOD ENDED 30 JUNE 2021

CONDENSED CONSOLIDATED INCOME STATEMENT

In EUR 000	Notes	For the 6 months ended 30 June 2021	30 June 2020
Collaboration revenue	6.5	2,640	4,746
Product sales revenue	6.5	18,463	11,421
Service revenue	6.5	748	530
Total revenue		**21,851**	**16,697**
Other operating income			
Grants and other income	6.6	1,206	909
Total operating income		**23,057**	**17,606**
Cost of sales	6.7	-17,059	-9,233
Research and development expenses	6.8	-23,398	-20,303
Sales and marketing expenses		-7,740	-7,931
General and administrative expenses	6.9	-7,935	-6,491
Total operating expenses		**-56,132**	**-43,958**
Operating loss for the period		**-33,075**	**-26,352**
Financial expense	6.10	-4,703	-5,083
Other financial results	6.10	454	-46
Financial result, net		**-4,249**	**-5,129**
Share in the results of joint ventures		-101	-195
Loss for the period before taxes		**-37,425**	**-31,676**
Income taxes		149	118
Loss for the period after taxes		**-37,276**	**-31,558**
Attributable to owners of the Group		-37,276	-31,558
Earnings per share			
Basic and diluted loss per share	6.11	**-0.65**	**-0.56**

CONDENSED CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE INCOME

In EUR 000	Notes	For the 6 months ended 30 June 2021	30 June 2020
Loss for the period		**-37,276**	**-31,558**
Other comprehensive income (loss), not to be reclassified to profit or loss:			
Re-measurement gains and losses on defined benefit plan		-449	-83
Income taxes on items of other comprehensive income		112	28
Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss:			
Exchange differences on translation of foreign operations		152	86
Total comprehensive loss for the period		**-37,461**	**-31,527**
Attributable to owners of the Group		-37,461	-31,527

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

In EUR 000	Notes	As of 30 June 2021	31 Dec 2020
Assets			
Non-current assets			
Intangible assets		5,377	5,645
Property plant and equipment	6.12	38,381	40,098
Financial assets	6.13	1,140	0
Investment in joint ventures		2,871	2,893
Other non-current assets		13	426
Deferred tax assets		1,437	1,472
		49,219	**50,534**
Current assets			
Inventories		17,544	15,712
Trade receivables		12,015	13,488
Other receivables	6.14	4,865	3,960
Other current assets		2,064	3,155
Cash and cash equivalents*		84,905	123,668
		121,393	123,668
Total assets		**170,612**	**210,517**
Equity and liabilities			
Capital and reserves			
Share capital		-220,657	-220,657
Share premium		711,874	711,874
Share based payment reserve		6,512	6,102
Accumulated deficit		-492,467	-455343
Other comprehensive income		-5,489	-5,152
Total equity attributable to owners of the Group		**-227**	**36,824**
Non-current liabilities			
Provisions		30	0
Borrowings and lease liabilities	6.15	16,221	18,625
Convertible debt	6.15	126,675	125,260
Deferred income	6.16	338	363
		143,264	**140,248**
Current liabilities			
Borrowings and lease liabilities	6.15	6,516	6,673
Trade payables		11,864	13,907
Deferred income	6.16	1,932	1,278
Other current liabilities		7,263	7,587
		27,575	**29,445**
Total equity and liabilities		**170,612**	**210,517**

*Cash and cash equivalents for 30 June 2021 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 2021	30 June 2020
Operating activities			
Loss for the period		-37,276	-31,558
Adjustments for			
Depreciation and amortization		4,799	5,010
Impairment losses		598	721
Income taxes in profit and loss		-149	-118
Financial result, net		4,249	5,129
Net movement in defined benefit obligation		106	-109
Share of net profit of associate and a joint venture		101	195
Share based payment expense		409	381
Other		-78	-64
Changes in working capital			
Net movement in inventories		-3,388	-4,428
Net movement in trade and other receivables and other current assets		1,844	6,975
Net movement in trade payables & other current liabilities		-2,367	-3,159
Net movement in deferred income	6.16	629	87
		-30,523	**-20,938**
Interests paid		-3,227	-3,585
Taxes paid		-2	-3
Cash flow used in operating activities		**-33,752**	**-24,526**
Investing activities			
Interest received		5	7
Acquisition of property, plant & equipment		-952	-1,020
Acquisition of intangible assets		0	-15
Investment financial asset		-1,140	0
Cash flow used in investing activities		**-2,087**	**-1,028**
Financing activities			
Repayment of borrowings	6.15	-3,457	-3,435
Bank charges		-61	-21
Cash flow from financing activities		**-3,518**	**-3,456**
Net increase / (decrease) in cash and cash equivalents		**-39,357**	**-29,010**
Cash and cash equivalents at the beginning of the period		123,668	178,725
Effects of exchange rate changes on the balance of cash held in foreign currencies		594	-41
Cash and cash equivalents at the end of the period*		**84,905**	**149,674**

* 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 2020		**-220,668**	**698,027**	**4,670**	**-5,291**	**-392,259**	**84,480**	**84,480**
Loss for the period						-31,558	-31,558	-31,558
Re-measurement gains and losses on defined benefit plan					-83		-83	-83
Consolidation translation difference						86	86	86
Total comprehensive income					***-83***	***-31,472***	***-31,555***	***-31,555***
Share-based payment expense				381			381	381
Other							0	0
Balance as at 30 June 2020		**-220,668**	**698,027**	**5,051**	**-5,374**	**-423,731**	**53,305**	**53,305**
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**

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 2021 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 2021 have been prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and as adopted by the European Union. The statements should be read in conjunction with the annual financial statements for the year ended 31 December 2020, 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 2020. New standards or interpretations applicable from 1 January 2021 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 CVBA. The following new standards and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2021:

- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform – Phase 2
- 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 but not yet endorsed in the EU)

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

6.3. CURRENT AND EXPECTED IMPACT OF THE COVID-19 SITUATION ON THE FINANCIAL POSITION AND PERFORMANCE OF BIOCARTIS

The first half of 2021 was marked by the gradual normalization of global cancer care after the pandemic outbreak in 2020. The Group delivered strong growth both in terms of instrument placements as well as commercial cartridge volumes. Compared to H1 2020, which was heavily impacted by the pandemic, the number of commercial cartridges sold almost doubled and 189 new Idylla™ instruments were placed. The growth followed the gradual return to pre-pandemic testing levels in oncology in Europe and certain distributor markets. Furthermore, the contribution of the Idylla™ SARS-CoV-2 Test to total commercial cartridge volumes remained robust despite generally declining COVID-19 testing volumes during the first half of the year.

The strong growth of commercial cartridge volumes and Idylla™ instruments resulted in 62% higher product income in H1 2021 compared to H1 2020. The average selling price ('ASP') of the Idylla™ oncology cartridge was stable at EUR 104. The ASP of the Idylla™ SARS-CoV-2 Test was lower than last year, in line with expectations and resulting in an overall ASP of EUR 95**.**. Gross margin on products of 8%, compared to 18% in H1 2020 as a result of the impact of the lower ASP of the Idylla™ SARS-CoV-2 Test. Furthermore, the gross margin was also temporarily impacted by higher COGS because production volumes were lower than expected as the pandemic caused a global shortage of reagent supplies. COGS also included the effect of hiring additional staff in anticipation of increasing volumes in the second half of the year.

- Post the reporting period, the Idylla™ SARS-CoV-2/Flu/RSV Panel was successfully launched as CE-IVD. The Panel detects SARS-CoV-2, Flu A/B and RSV nucleic acids in one single cartridge within approx. 90 minutes. The timing of the Emergency Use Authorization ('EUA') submission to the US FDA of the Idylla™ SARS-CoV-2/Flu/RSV Panel is to be decided. Ahead of a delayed flu season, this Panel is expected to be well positioned to guide healthcare providers in this complex landscape of respiratory infections in 2022.

Operating cash flows did not deviate from the Group's expectations and cash and cash equivalents amounted to EUR 85m at 30 June 2021. Subject to the risks associated with the fire incident and its potential consequences described in section 4, the Group therefore reaffirms a targeted cash position of at least EUR 50m by the end of 2021, including potential investments in upgrading and expanding the infectious disease menu.

At the date of this half-year report, the pandemic had no impact on the basis of preparation of the consolidated financial statements and on the Group's ability to continue to operate as a going concern.

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 interim results for the six months ended 30 June 2021 show a negative result, and the balance sheet includes a loss carried forward. The Board of Directors has examined the statements and accounting standards. Taking into account the cash position and the credit facilities that the Group has at its disposal, the Board of Directors is of the opinion that it can submit the interim financial statements on a going concern basis. Furthermore, and although no assurance can be given, the board is confident that the Group's strategic plans and the corresponding operating plans are viable so that the Group will have access to additional financial resources if and when required.

Revenue recognition relating to collaboration arrangements

Assessing the indicators for revenue recognition under collaboration arrangements requires judgement to determine (i) the nature of the contractual performance obligations and whether they are distinct or should be combined with other performance obligations, and (ii) the pattern of transfer of each promised component identified in the contract, using methods based on key assumptions such as forecasted costs and development timelines of the collaboration arrangements for the assessment of satisfaction of the performance obligation.

For all performance obligations linked to licensing agreements, the Group makes an assessment about whether or not the license is to be considered as a distinct performance obligation or not. The Group determines whether a promise to grant a license of intellectual property is distinct from other promised goods or services in the contract. As such, the Group assesses whether the customer can benefit from a license of intellectual property on its own or together with readily available resources (i.e., whether it is capable of being distinct) and whether the Group's promise to transfer a license of intellectual property is separately identifiable from other promises in the contract (i.e., whether it is distinct in the context of the contract). The assessment of whether a license of intellectual property is distinct is based on the facts and circumstances of each contract, e.g. interdependencies between the license and other services in the contract, the continuing involvement of the Group after the license has been granted.

If the transfer of the license is considered to be a separate performance obligation, revenue relating to the transfer of the license is recognized at a point in time or over time depending on the nature of the license, i.e. granting a right to use the intellectual property or the right to access the IP. Basically, the Group assesses whether the customer has the right to use the intellectual property as it exists at a certain period in time or whether it has access to the intellectual property as it exists at any time during the license period, where the latter requires more on-going activities from the Group.

6.5. REVENUE

The Group's revenue can be aggregated as follows:

In EUR 000	For the 6 months ended,			
	30 June 2021		30 June 2021	30 June 2020
	At a point in time	Over time		
Collaboration revenue				
R&D services	0	2,590	2,590	4,623
License fees	0	50	50	123
Milestones	0	0	0	0
	0	**2,640**	**2,640**	**4,746**
Product related revenue				
Idylla™ system sales revenue	1,878	0	1,878	844
Idylla™ system rental revenue	1,837	0	1,837	993
Cartridge revenue	14,749	0	14,749	9,584
	18,463	**0**	**18,463**	**11,421**

Service revenue				
Idylla™ system service revenue	654	94	748	530
	654	**94**	**748**	**530**
Total	**19,118**	**2,733**	**21,851**	**16,696**

For details related to the movement in deferred income of collaboration agreements, we refer to note 6.19.

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**
2021	709
2022	175
2023	0
2024	0
2025	0
After 2025	0

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

6.5.1. Revenues by region and major customers

	For the 6 months ended	
In EUR 000	**30 June 2021**	**30 June 2020**
Country of domicile	**261**	**256**
Belgium	261	256
Total all foreign countries, of which	**21,590**	**16,441**
United states of America	4,134	6,851
Great Britain	4,341	699
China	765	372
Spain	1,655	1,322
France	2,298	1,396
Germany	1,515	1,322
Rest of the world	6,883	4,479
Total	**21,851**	**16,697**

Revenues in the above table are assigned according to the location of the Group or parent company of the customer. The Group has recognized revenues from one customer representing 13% of the total revenues and three other major customers together represent 11% of the total revenues.

6.6. OTHER OPERATING INCOME

	For the 6 months ended	
In EUR 000	**30 June 2021**	**30 June 2020**
R&D project support (VLAIO & IWT grants)	1,159	312
Other project grants (EU)	0	56
Other income	48	541
Total	**1,206**	**909**

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.

6.7. COST OF SALES

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

	For the 6 months ended	
In EUR 000	**30 June 2021**	**30 June 2020**
Employee benefit expenses	-4,543	-2,332
Material, lab consumables & small equipment	-8,301	-4,233
Depreciation and amortization	-2,339	-1,384
Royalty expense	-774	-687
Facilities, office and other	-1,103	-597
Total	**-17,059**	**-9,233**

The volume of commercial cartridges sold in H1 2021 increased with 96% compared H1 2020, which resulted in higher cost of goods sold, mainly the variable costs increased accordingly such as employee benefit expenses, material, lab consumables & small equipment. Depreciation and amortization increased due to the new Idylla™ instrument placements that were added to the installed based in H1 2021.

6.8. RESEARCH AND DEVELOPMENT EXPENSES

	For the 6 months ended	
In EUR 000	**30 June 2021**	**30 June 2020**
Employee benefit expenses	-12,967	-11,889
Laboratory costs	-7,155	-3,383
Quality, regulatory and intellectual property	-269	-285
Facilities, office & other	-997	-1,588
ICT	-177	-142
Travel, training & conferences	-41	-121
Depreciation and amortization	-1,793	-2,896
Total	**-23,398**	**-20,303**

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 related to the planned acceleration and diversification of the Idylla™ test menu, both in oncology and in infectious diseases.

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

6.9. GENERAL AND ADMINISTRATIVE EXPENSES

In EUR 000	For the 6 months ended 30 June 2021	30 June 2020
Employee benefit expenses	-5,547	-5,017
External advice	-314	-321
Facilities, office & other	-1,087	-230
Human resources	-675	-504
Travel, training & conferences	-25	-138
Depreciation and amortization expenses	-286	-281
Total	**-7,935**	**-6,491**

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. Facilities, office & other increased due to the growing business and the planned acceleration and diversification of the Idylla™ test menu, which resulted in higher ICT, consultancy and insurance costs.

6.10. FINANCIAL INCOME AND EXPENSES

In EUR 000	For the 6 months ended 30 June 2021	30 June 2020
Interest expense	-4,642	-5,050
Other financial expense	-61	-33
Total	**-4,703**	**-5,083**
Other financial result	454	-46
Total	**454**	**-46**
Financial result, net	**-4,249**	**-5,129**

Net financial result amounted to EUR 4.2m per 30 June 2021 compared to EUR 5.1m as per 30 June 2020 and include financial expenses in relation to the Company's convertible bond of EUR 4.1m in H1 2021 compared to EUR 4.5m in H1 2020. The other financial result mainly consists of non-realized foreign 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 2021	**30 June 2020**
Profit/loss for the period attributable to the owners of the Group (in EUR 000)	-37,276	-31,558
Weighted average number of ordinary shares for basic loss per share (in number of shares)	57,545,663	56,695,322
Basic loss per share (EUR)	**-0.65**	**-0.56**

6.12. PROPERTY, PLANT AND EQUIPMENT

	As of	
In EUR 000	**30 June 2021**	**31 Dec 2020**
Property, plant and equipment	38,381	40,098
Total property, plant and equipment	**38,381**	**40,098**

Property, plant and equipment decreased to EUR 38.4m as per end of June 2021 from EUR 40.1m at the end of 2020 (decrease of EUR 1.7m) mainly driven by a depreciation charge of EUR 4.5m and capital expenditures in H1 2021 of EUR 3.4m. The capital expenditures are predominantly related to capitalized Idylla™ systems sold under reagent rental and similar agreements and right-of-use assets.

6.13. FINANCIAL ASSETS

	As of	
In EUR 000	**30 June 2021**	**31 Dec 2020**
Financial asset	1,140	
Total financial asset	**1,140**	**0**

The Group holds a convertible note from GeneproDx, with maturity date of 25 January 2023 (i.e. 2-year duration) and a coupon of 10%. The convertible note from GeneproDx was issued early 2021 and was issued to the Group as payment for the license granted by the Group to GeneproDx at the end of 2020, which was recorded in 2020 as a receivable under 'other current assets'.

6.14. OTHER RECEIVABLES

	As of	
In EUR 000	**30 June 2021**	**31 Dec 2020**
VAT receivables	3,074	2,133
Tax credit research and development	330	310
Other receivables	1,460	1,518
Total	**4,865**	**3,960**

Other receivables include 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.

6.15. FINANCIAL LIABILITIES

The financial debt can be analyzed as follows:

	As of	
In EUR 000	**30 June 2021**	**31 Dec 2020**
Lease liabilities	16,221	18,625
Bank borrowings	0	0
Convertible bond	126,675	125,260
Total non-current	**142,896**	**143,885**
Lease liabilities	6,516	6,615
Bank borrowings	0	58
Total current	**6,516**	**6,673**
Total financial liabilities	**149,412**	**150,557**

In 2013, Biocartis NV refinanced about 50% of its Idylla™ semi-automated cartridge manufacturing line in Mechelen (Belgium) via a sale and lease back operation. This lease has a current lease term till 1 June 2021, carries a 3.35% interest rate and includes a purchase option of EUR 0.1m. As per the end of H1 2021 the lease has been fully paid.

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 2021 EUR 0.5m is outstanding under these two facilities.

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 2021 EUR 7.4m 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 2021, EUR 0.5m 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 126.7m per 30 June 2021.

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 2021.

6.16. DEFERRED INCOME

	As at	
In EUR 000	**30 June 2021**	**31 Dec 2020**
Grants	545	658
Collaboration income	1,725	983
Total	**2,270**	**1,641**
Current	1,932	1,278
Non-current	338	363

	Deferred partner income
As per 31 December 2019	**1,197**
Invoiced	3,369
Recognized in profit or loss	-3,583
As per 31 December 2020	**983**
Invoiced	1,073
Recognized in profit or loss	-330
As per 30 June 2021	**1,726**

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 21 and 31 December 2020.

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 one financial instrument (MyCartis) carried at fair value through OCI in the consolidated balance sheet on 30 June 2021 and 31 December 2020.

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 149.4m (31 December 2020: EUR 150.6m) have a fair value of EUR 149,5m (31 December 2020: EUR 150.6m).

6.17.2. Contingencies

The Group has no new contingencies compared to 31 December 2020.

6.17.3. Commitments

6.17.3.1. Capital commitments

As per 30 June 2021, the Group has EUR 1.7m 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. The Group had no other material capital commitments on 30 June 2021.

6.17.3.2. Operating commitments

As per 30 June 2021, the Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 8.4m. It is expected that the majority of the commitments will be fulfilled in 2021.

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 2021:

- *Fire incident* – See under 'risks related to the fire incident of 30 July 2021;
- *Product registrations Taiwan* – Additional registrations for Idylla™ products have been completed in Taiwan;

- *Launch Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD)* – Successful CE-IVD launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel which detects SARS-CoV-2, Flu A/B and RSV nucleic acids in one single cartridge within approx. 90 minutes. Timing of the Emergency Use Authorization ('EUA') submission to the US FDA for the Idylla™ SARS-CoV-2/Flu/RSV Panel is to be decided.
- *Cartridge manufacturing* – Alongside the ongoing development of a new technology on Idylla™ with the support of VLAIO, aimed at the off-line customization of the Idylla™ cartridge[14] to shorten development lead times for Idylla™ assays, Biocartis is currently also evaluating a new concept for a simplified, cost-efficient Idylla™ cartridge. This should enable an accelerated reduction of the manufacturing cost of Idylla™ cartridges beyond the impact of continued volume growth and the resulting increased utilization of the available manufacturing capacity. The new cartridge concept reduces the complexity of the cartridge, and is ideally suited for infectious disease testing and certain oncology assays. The new concept is expected to run on the existing Idylla™ platform alongside the existing Idylla™ cartridge, which will continue to be used for those assays that are not compatible with the lower complexity cartridge. Post the reporting period, the feasibility of the new Idylla™ cartridge has been externally validated by a reputable global contract manufacturing organization. Subject to the successful design and manufacturing, the new Idylla™ cartridge concept is expected to facilitate the development of a highly competitive franchise of multiplex infectious disease assays with partners and may also be applicable to a number of oncology assays. The decision to invest in the development of new and existing Idylla™ assays using the new Idylla™ cartridge concept and in the accompanying manufacturing equipment, is still subject to completion of the concept design. As a result, the Company decided to review (the timing of) ongoing and future investments in the infectious disease and oncology assay menu.

7. REVIEW REPORT OF THE AUDITOR

Report on the review of the consolidated interim financial information of Biocartis Group NV for the six-month period ended 30 June 2021

The original text of this report is in Dutch

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 2021, the condensed consolidated income statement, the condensed consolidated statement of other comprehensive income, the condensed consolidated statement of changes in equity and the condensed consolidated cash flow statement 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 170 612 (000) EUR and the condensed consolidated income statement shows a consolidated loss (group share) for the period then ended of 37 276 (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

14 Previously referred to as the Idylla™ 'FLEX' technology, aimed to tap into new market opportunities with customized and personalized products

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.

Signed at Zaventem, 1 September 2021

The statutory auditor, Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises CVBA/SCRL,
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 2021 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 2021	Q3 2021 Business Update
24 February 2022	2021 full year results
31 March 2022	Publication 2021 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. o.v.v.e. CVBA, 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	ety 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 or not 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.
COVID-19	COVID-19 or the novel coronavirus is caused by SARS-CoV-2. Coronaviruses are named for the crown-like spikes on their surface (source: www.cdc.org).
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.
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.
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.
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 fusions	Studies over the past decades have uncovered fusion genes, a class of oncogenes that provide immense diagnostic and therapeutic advantages because of their tumor-specific expression. Originally associated with hemotologic cancers, fusion genes have recently been discovered in a wide array of solid tumors, including sarcomas, carcinomas, and tumors of the central nervous system. Fusion genes are attractive as both therapeutic targets and diagnostic tools due to their inherent expression in tumor tissue alone. Therefore, the discovery and elucidation of fusion genes in various cancer types may provide more effective therapies in the future for cancer patients (source: Parker BC, Zhang W. Fusion genes in solid tumors: an emerging target for cancer diagnosis and treatment. Chin J Cancer. 2013;32(11):594-603. doi:10.5732/cjc.013.10178)
(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.
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 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)	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. Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator,

Medical Device	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 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..
Next-Generation Sequencing (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 novel coronavirus that causes coronavirus disease 2019, or COVID-19). Coronaviruses are named for the crown-like spikes on their surface (source: www.cdc.org).
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 caused by the body's response to an infection. The body normally releases chemicals into the bloodstream to fight an infection. Sepsis occurs when the body's response to these chemicals is out of balance, triggering changes that can damage multiple organ systems (source: www.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 mutationns in adults may cause cancer.

Biocartis Group NV
Generaal de Wittelaan 11 B
2800 Mechelen
Belgium

www.biocartis.com

BIOCARTIS
biocartis.com