

# FINANCIAL REPORT

# H1 2020

BIOCARTIS GROUP NV



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WE AIM  
TO PROVIDE  
**DIRECT  
ACCESS**  
TO PERSONALIZED  
MEDICINE FOR  
PATIENTS  
WORLDWIDE



**BIOCARTIS IS AN INNOVATIVE MOLECULAR DIAGNOSTICS COMPANY  
COMMITTED TO REVOLUTIONIZE MOLECULAR ONCOLOGY  
DIAGNOSTICS WITH ITS UNIQUE PROPRIETARY IDYLLA™ PLATFORM**

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## 1. MESSAGE FROM THE CEO



Dear Shareholder,

Dear Stakeholder,

I am pleased to present to you our financial report for the first six months of 2020.

The global pandemic definitely left its marks, but we nevertheless delivered a 12% growth of overall commercial cartridge volumes in H1 2020. Supported by a loyal customer base and a swift recovery towards the end of Q2 2020, the net impact from COVID-19 was limited in Europe: growth of European cartridge volumes remained robust and is now back in line with our pre-pandemic expectations.

After a strong Q1 2020, the recovery was less pronounced in the US. Here, we saw new instrument placements stalling as lockdown measures prevented all new customer prospecting during the entire Q2 2020. As such, we expect a prolonged effect of the pandemic into H2 2020 in the US. RoW<sup>1</sup> volumes were most impacted in H1 2020 and timing of recovery is still uncertain.

However, the need for high quality, rapid and easy diagnostic testing for every patient is more obvious than ever. In oncology, we managed to stabilize our business and return to growth in Europe and the US mainly thanks to Idylla™'s fully automated testing which has shown to be very useful in times where all lab resources are focused on priority pandemic testing.

Next to that, we now see complimentary opportunity in infectious diseases and we have developed an Idylla™ SARS-CoV-2 Test for which we expect strong demand in H2 2020, particularly in the US.

Comforted by the resilience of our oncology business, most notably in Europe, and the expected demand for the Idylla™ SARS-CoV-2 Test, we look ahead with confidence and reinstate our full guidance for 2020.

Herman Verrelst  
CEO Biocartis

## 2. RESPONSIBILITY STATEMENT

The undersigned hereby declare that to the best of their knowledge: a) the condensed consolidated financial statements for the six-months' period ended 30 June 2020, 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 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 financial statements.

Herman Verrelst  
CEO

Christian Reinaudo  
Chairman

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<sup>1</sup> RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan

### 3. BUSINESS REVIEW FOR THE FIRST HALF OF 2020

#### KEY HIGHLIGHTS H1 2020



- Nearly 80k cartridges sold in H1 2020, a year-over-year increase of 12%, despite the COVID-19 pandemic;
- After a strong 68% year-over-year growth in Q1 2020, Q2 2020 volumes came in 20% lower than last year;
- Europe: Strong continued growth in Q1 2020 and recovery by the end of Q2 2020, offsetting the impact of the pandemic in early Q2 2020;
- US: Strong volume growth in Q1 2020, but recovery in Q2 2020 less pronounced, as COVID-19 cases remain high in many States. Prolonged impact of the pandemic expected into H2 2020;
- RoW: After a strong Q1 2020, RoW volumes were most impacted with limited visibility on recovery.



- 101 new Idylla™ instruments placed versus 156 in H1 2019, to a total installed base of 1,411 end H1 2020;
- 50% of the new placements in Europe. Pace of new placements in the US and Rest of World (RoW) markets slowed down due to highly restricted access to customers.



- Submission of the Idylla™ SARS-CoV-2 Test for Emergency Use Authorization ('EUA') with the US FDA;
- Commercialization rights in Europe and RoW for the CE-marked IVD test SeptiCyt® RAPID on Idylla™ from Immunexpress Pvt Ltd ('Immunexpress').



- Partnership with AstraZeneca expanded with a study on liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay (RUO);
- New project with Bristol Myers Squibb Company (BMS) aimed at pursuing the registration of the Idylla™ MSI Test as a companion diagnostic (CDx) test in metastatic colorectal cancer (mCRC) in China.



- Total operating income of EUR 17.6m (H1 2019: EUR 17.3m), including EUR 11.4m product income (H1 2019: EUR 10.0m);
- Cash and cash equivalents of EUR 150m as per end H1 2020.

## COMMERCIAL HIGHLIGHTS

- *Global* – In H1 2020, despite the COVID-19 pandemic, the commercial cartridge volume amounted to nearly 80k cartridges, a year-over-year increase of 12%. After a strong first Q1 2020, commercial cartridge volumes in Q2 2020 were 20% lower than last year as a direct consequence of the pandemic, which also limited the new Idylla™ instrument placements to 101 in H1 2020.
- *Europe* – Cartridge volumes continued to grow in Europe that also accounted for half of the new Idylla™ instrument placements. The negative impact of the pandemic was most notable at the start of Q2 2020, but the strength of the European customer base lead to swift recovery with volumes and growth now tracking to initial pre-pandemic expectations. Slower than expected cartridge growth in the more affected Southern European countries was offset by robust demand in the rest of Europe. The recent resurgence of COVID-19 cases across Europe may slow down the growth in H2 2020.
- *US* – Cartridge volume growth was strong in the US in Q1 2020, but the recovery in Q2 2020 was less pronounced than in Europe as many States are still battling with a high number of COVID-19 cases. Furthermore, COVID-19 measures did not allow new customer prospection to labs, which stalled the growth of both Idylla™ installed base expansion and commercial cartridge volume in these markets. The pandemic is expected to have a prolonged effect into the second half of 2020.
- *RoW* – RoW cartridge growth was most impacted, with a COVID-19 peak that is still not reached in many regions. Latin America was particularly affected. Nevertheless, new market authorizations were obtained for the Idylla™ MSI Test in Colombia, Canada, Malaysia and Singapore, and for the Idylla™ EGFR Mutation Test in Argentina.
- *Japan* – Continued progress in the in vitro diagnostic (‘IVD’) registration preparations for the Idylla™ assays are paving the way to commercialization with Nichirei Biosciences in Japan, with first test registrations to be expected earliest by end 2021.
- *China* – In China, the joint venture (‘China JV’) with Guangzhou Wondfo Biotech Co., Ltd<sup>2</sup> took further steps towards establishing local manufacturing capabilities. Concerning the registration of products, a first CDx partnership was announced on 5 March 2020 with Bristol Myers Squibb Company (BMS), aimed at pursuing the registration in China of the Idylla™ MSI Test as a companion diagnostic (CDx) test in metastatic colorectal cancer<sup>3</sup> (mCRC) (see below). First product registrations in China to be expected earliest by end 2021.

## MENU AND PARTNERSHIP HIGHLIGHTS

- *Partnership AstraZeneca* – On 22 January 2020, Biocartis announced that it entered into a master collaboration agreement with AstraZeneca, a global science-led biopharmaceutical company (LON/STO/NYSE: AZN), to enable collaborative development and commercialization projects between Biocartis and AstraZeneca, such as but not limited to, CDx development projects that may cover any type of indication or biomarker. The first project in that context is a study focused on evaluating if liquid biopsy testing using the Idylla™ cEGFR Mutation Assay (RUO) could provide further benefits to tissue-based EGFR molecular testing.
- *New BMS Immuno-Oncology MSI Project in China* – On 5 March 2020, Biocartis announced a new project under its existing collaboration with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company. While the existing collaboration is aimed at the registration in the US of the Idylla™ MSI Test as a CDx test in metastatic colorectal cancer (mCRC), under the new project, both partners will now also pursue the registration of the Idylla™ MSI test as a CDx test in mCRC<sup>4</sup> in the People’s Republic of China.
- *Expansion Immunexpress partnership* – On 26 March 2020, Biocartis announced the co-commercialization agreement with its partner Immunexpress of the newly CE-marked IVD SeptiCyte® RAPID<sup>5</sup> test on Idylla™, in which Biocartis will lead commercialization in Europe as exclusive distributor of the SeptiCyte® RAPID test, while Immunexpress will lead commercialization in the US. On 16 June 2020, Immunexpress announced to have been awarded a grant from the Biomedical Advanced Research and Development Authority<sup>6</sup> (‘BARDA’) to develop and pursue US FDA Emergency Use Authorization (‘EUA’) for the SeptiCyte® RAPID<sup>7</sup> test on Idylla™.

<sup>2</sup> Wondfo, SHE: 300482, a fast growing diagnostics leader in China

<sup>3</sup> More info [here](#)

<sup>4</sup> mCRC = Metastatic colorectal cancer

<sup>5</sup> The SeptiCyte® RAPID test is a rapid, host-response test that distinguishes sepsis from non-infectious SIRS (systemic inflammatory response syndrome) and is expected to provide actionable results in about one hour. Host-response based tests focus on measuring biomarkers that are indicative of the response of a patient’s immune system to an infection rather than measuring pathogens that are the cause of the infection. Moreover, the SeptiCyte® RAPID test not only discriminates sepsis from SIRS but also correlates with viral sepsis infection, versus procalcitonin (PCT) which increases with severity of bacterial but not viral infection and is also a non-specific marker of inflammation

<sup>6</sup> Part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS). More info [here](#)

<sup>7</sup> More info [here](#)



- *Partnership Exact Sciences* – COVID-19 led to the suspension of the Idylla™ IVD Oncotype DX Breast Recurrence Score® test project. Consequently, the project plan is under evaluation and timing is under review. No launch is to be expected in 2020.
- *Idylla™ publications, abstracts & posters* – During H1 2020, 20 new Idylla™ publications, abstracts and posters<sup>8</sup> were issued, all demonstrating strong data of Idylla™ tests. The studies included, amongst others, a [new US multicenter study](#)<sup>9</sup> published in the ‘American Journal of Clinical Pathology’ which showed that, compared to current standard-of-care testing methods, the Idylla™ platform can substantially improve turnaround time of the results of mutation testing, independent of the size of the laboratory. The study is one of the largest studies performed involving Idylla™, with 20 laboratories of different types and sizes included throughout the US and Puerto Rico, and data from almost 800 colorectal cancer samples. Furthermore, during the virtual annual ASCO meeting<sup>10</sup>), [five Idylla™ abstracts and posters](#)<sup>11</sup> were published by key oncology opinion leaders, including first Idylla™ data from China where amongst others the Idylla™ EGFR Mutation Assay (RUO) showed excellent concordance with other methods.

## ORGANIZATIONAL AND OPERATIONAL HIGHLIGHTS

- *Appointment new CFO* – On 23 April 2020, Biocartis announced the appointment of Jean-Marc Roelandt as the new CFO of the Company with immediate effect. Jean-Marc Roelandt is a senior executive with an established track record of more than 25 years as CFO in globally active publicly listed companies. With a focus on M&A, capital market

<sup>8</sup> Including e-publications ahead of print. Sources: (1) Merlin MS et al. Rapid fully-automated assay for routine molecular diagnosis of BRAF mutations for personalized therapy of low grade gliomas. *Pediatr Hematol Oncol.* 2020 Feb;37(1):29-40. (2) De Luca C et al. Rapid On-site Molecular Evaluation in thyroid cytopathology: A same-day cytological and molecular diagnosis. *Diagn Cytopathol.* 2020 Apr;48(4):300-30. Epub 2020 Jan 6. (3) Lee et al. Reduced sensitivity for EGFR T790M mutations using the Idylla EGFR Mutation Test. *J Clin Path.* May 2020. (4) Lassalle et al. Targeted Assessment of the EGFR Status as Reflex Testing in Treatment-Naive Non-Squamous Cell Lung Carcinoma Patients: A Single Laboratory Experience (LPCE, Nice, France). *Cancers* 2020, 12, 955. April 2020. (5) Delgado-Garcia et al. Clinical performance evaluation of the Idylla™ EGFR Mutation Test on formalin-fixed paraffin-embedded tissue of non-small cell lung cancer. *BMC Cancer* volume 20, Article number: 275, April 2020. Epub ahead of print. (6) Al-Turkmani et al. Rapid EGFR mutation testing in lung cancer tissue samples using a fully automated system and single-use cartridge. *Practical Laboratory Medicine* 20 (2020). (7) Bourrelle A et al. Rapid detection of EGFR mutations in decalcified lung cancer bone metastasis. *Bone Oncol.* 2020. Jan Epub ahead of print. (8) Chevalier L et al. EGFR molecular characterization in non-small cell bronchic cancer: comparative prospective study by NGS and Idylla platform technologies. *Annales de Pathologie.* Feb 2020. (9) Bocciarelli C. et al. Evaluation of the Idylla system to detect the EGFR T790M mutation using extracted DNA. *Pathol Res Pract.* 2020. Jan;216 (1). (10) Sousa et al. Detection of rare and novel EGFR mutations in NSCLC patients: Implications for treatment-decision. *Lung Cancer.* 2020. Jan;139: 35-40. (11) Gralowski J et al. Detection of EGFR Exons 18-21 Hotspot Mutations Using a Fully-Automated, Cartridge-Based Platform with Ultra-Rapid Turnaround Time: A Comparison Study with Conventional Next Generation Sequencing. *USCAP 2020.* (12) Gadde R et al. Validation of the Idylla™ EGFR Assay for Rapid Assessment of EGFR Mutation Status in Non-small Cell Lung Cancer. *USCAP 2020.* (13) Matthews P et al. The impact of in-house biomarker testing on NSCLC patients. *USCAP 2020.* (14) Pécriaux et al. Detection of Microsatellite Instability in a Panel of Solid Tumours With the Idylla MSI Test Using Extracted DNA. *J Clin Pathol* 2020 June. (15) Yaziji H et al. Validation of a Rapid PCR Assay for Microsatellite Instability Testing in Colorectal Cancer. *USCAP 2020.* (16) Dagenborg et al. Neoadjuvant Chemotherapy is Associated With a Transient Increase of Intratumoral T-cell Density in Microsatellite Stable Colorectal Liver Metastases. *Cancer Biol Ther.* 2020 May 3;21(5):432-440. (17) Zwaenepoel K et al. Clinical Performance of the Idylla MSI Test for a Rapid Assessment of the DNA Microsatellite Status in Human Colorectal Cancer. *J Mol Diagn.* March 2020. 22 (3): 386-395. Epub ahead of print Dec 2019. (18) Vessies et al. Performance of Four Platforms for KRAS Mutation Detection in Plasma Cell-Free DNA: ddPCR, Idylla, COBAS z480 and BEAming. *Sci Rep.* 2020. May 15;10(1):8122. (19) Franczak C et al. Evaluation of KRAS, NRAS and BRAF mutations detection in plasma using an automated system for patients with metastatic colorectal cancer. *PLoS One.* 2020 Jan 15; (20) Tsongalis et al., ‘Comparison of Tissue Molecular Biomarker Testing Turnaround Times and Concordance Between Standard of Care and the Biocartis Idylla Platform in Patients With Colorectal Cancer’, *Am J Clin Pathol.* 2020 Jun 11;aqaa044. doi: 10.1093/ajcp/aqaa044. Online ahead of print. See also [www.biocartis.com/publications](http://www.biocartis.com/publications).

<sup>9</sup> Led by researchers from Dartmouth’s and Dartmouth-Hitchcock’s Norris Cotton Cancer Center (Lebanon, New Hampshire, US). Tsongalis et al., ‘Comparison of Tissue Molecular Biomarker Testing Turnaround Times and Concordance Between Standard of Care and the Biocartis Idylla Platform in Patients With Colorectal Cancer’, *Am J Clin Pathol.* 2020 Jun 11;aqaa044. doi:10.1093/ajcp/aqaa044. Online ahead of print

<sup>10</sup> American Society of Clinical Oncology meeting, took place between 8-10 August 2020

<sup>11</sup> R. Gadde et al., ‘Validation of the Idylla™ EGFR Assay for Rapid Assessment of EGFR Mutation Status in Non-small Cell Lung Cancer’, Dartmouth Hitchcock Medical Center, Lebanon, NH; H Yaziji et al., ‘Validation of a Rapid PCR Assay for Microsatellite Instability Testing in Colorectal Cancer’, Vitro Molecular Laboratories, Miami, FL; J Gralowski et al., ‘Detection of EGFR Exons 18-21 Hotspot Mutations Using a Fully-Automated, Cartridge-Based Platform with Ultra-Rapid Turnaround Time: A Comparison Study with Conventional Next Generation Sequencing’, University of New Mexico, Albuquerque, NM; P. Matthews et al., ‘Clinical Impact of Rapid Biomarker Testing in Non-Small Cell Lung Cancer in a Community Setting’, William Osler Health System, Brampton, ON, Canada

transactions and the implementation of adequate financial management infrastructure in dynamic and fast growing companies, he built up a solid expertise in various industries. Prior to joining Biocartis, he was CFO of MDxHealth, a healthcare company that provides actionable genomic information to personalize the diagnosis and treatment of cancer.

- *Progress on ML2* – Further progress was made on the transfer of Idylla™ assays to the second cartridge manufacturing line ('ML2'). After the transfer of the Idylla™ KRAS Mutation Test (CE-IVD), during H1 2020, the Idylla™ NRAS Mutation Test (CE-IVD) and the Idylla™ MSI Test (CE-IVD) were successfully transferred to ML2. The transfer of the EGFR Mutation Test (CE-IVD) is ongoing. The Idylla™ SARS-CoV-2 Test will initially be manufactured on the first manufacturing line ML1, but the transfer to ML2 is planned towards end 2020.



## FINANCIAL HIGHLIGHTS

- *Total operating income* – Total operating income amounted to EUR 17.6m compared to EUR 17.3m last year. Product revenues increased 14% from EUR 10m in H1 2019 to EUR 11.4m in H1 2020. Within product sales, cartridge sales revenues increased 28% on the back of 12% higher volumes and an increasing average selling price. Idylla™ instrument sales revenues decreased by 26% as new Idylla™ placements were hampered by the global COVID-19 measures. Following delays of several partner projects, collaboration revenues of EUR 4.7m decreased by EUR 2.1m year-on-year. H1 2019 also included a licensing fee of EUR 2.5m.
- *Gross profit* – The cost of goods sold increased from EUR 8.7m to EUR 9.2m, but the gross margin on product sales improved from 12% to 19% as increased cartridge volumes lowered the manufacturing cost per cartridge.
- *OPEX* – Total operating expenses (including cost of sales) of EUR 44m remained level with last year.
- *Net cash flow and cash position* – The net cash outflow from operating and investing activities amounted to EUR 25.6m in H1 2020 compared to EUR 33.6m in H1 2019. The reduced outflow is attributable to a lower investment in net working capital and lower capital expenditure resulting from a lower number of Idylla™ instruments placed under reagent rental agreements. The cash and cash equivalents at 30 June 2020 amounted to EUR 150m.



## 4. PRINCIPAL RISKS RELATED TO THE BUSINESS ACTIVITIES

The principal risks related to Biocartis' business activities are outlined in Biocartis' 2019 Annual Report, p.60-79, 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 impact of COVID-19 described below, the principal risks have not materially changed from the ones outlined in the [2019 Annual Report](#).

### COVID-19

Public health epidemics or pandemics, such as the COVID-19 outbreak, could adversely impact our business.

Since the COVID-19 outbreak in December 2019, it has developed into a pandemic, causing significant disruptions to the global economy, including in certain countries in which the Group is operating its business. During the first half of 2020, we have experienced a slow down of our commercial activities and delays of certain partner projects as a result of various measures taken to contain the spreading of the virus.

The extent to which the pandemic will continue to affect our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including but not limited to the duration of the pandemic, the severity and resistance of the virus and the actions taken to contain the virus or treat its impact.

In particular, and although the Group currently expects that significant demand for its pandemic response products could mitigate the impact of COVID-19 on its oncology business, the continued spread of the virus could adversely impact its operations, including among others, the manufacturing and supply chain, sales and marketing and collaboration activities with partners, and could have an adverse impact on the Group's business and financial results.

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.

## 5. CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS FOR THE PERIOD ENDED 30 JUNE 2020

### CONDENSED CONSOLIDATED INCOME STATEMENT

In EUR 000	Notes	For the 6 months ended	
		30 June 2020	30 June 2019
Collaboration revenue	6.5	4,746	6,816
Product sales revenue	6.5	11,421	9,980
Service revenue	6.5	530	351
<b>Total revenue</b>		<b>16,697</b>	<b>17,147</b>
<b>Other operating income</b>			
Grants and other income	6.6	909	151
<b>Total operating income</b>		<b>17,606</b>	<b>17,298</b>
Cost of goods sold	6.7	-9,233	-8,742
Research and development expenses	6.8	-20,303	-20,031
Sales and marketing expenses	6.9	-7,931	-8,811
General and administrative expenses	6.10	-6,491	-6,399
<b>Total operating expenses</b>		<b>-43,958</b>	<b>-43,983</b>
<b>Operating loss for the period</b>		<b>-26,352</b>	<b>-26,685</b>
Financial expense	6.12	-5,083	-2,868
Other financial results	6.12	-46	46
<b>Financial result, net</b>		<b>-5,129</b>	<b>-2,822</b>
Share in the results of associates		-195	-181
<b>Loss for the period before taxes</b>		<b>-31,676</b>	<b>-29,688</b>
Income taxes		118	18
<b>Loss for the period after taxes</b>		<b>-31,558</b>	<b>-29,670</b>
Attributable to owners of the Group		-31,558	-29,670
Attributable to non-controlling interest			
<b>Earnings per share</b>			
Basic and diluted loss per share	6.13	-0.56	-0.53

## CONDENSED CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE INCOME

<u>In EUR 000</u>	<u>Notes</u>	<u>For the 6 months ended</u>	
		<u>30 June 2020</u>	<u>30 June 2019</u>
Loss for the period		-31,558	-29,670
<b>Other comprehensive Income (loss), not to be reclassified to profit or loss:</b>			
Re-measurement gains and losses on defined benefit plan		-83	-27
Income taxes on items of other comprehensive income		28	9
<b>Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss:</b>			
Exchange differences on translation of foreign operations		86	-188
<b>Total comprehensive loss for the period</b>		<b>-31,527</b>	<b>-29,876</b>
Attributable to owners of the Group		-31,527	-29,876
Attributable to non-controlling interest		0	0

## CONDENSED CONSOLIDATED BALANCE SHEET

In EUR 000	Notes	As of	
		30 June 2020	31 Dec 2019
<b>Assets</b>			
<b>Non-current assets</b>			
Intangible assets		5,973	6,294
Property plant and equipment	6.14	41,098	43,421
Investment in joint ventures	6.15	2,185	2,358
Other non-current receivables		13	13
Deferred tax assets		1,456	1,609
		<u>50,725</u>	<u>53,695</u>
<b>Current assets</b>			
Inventories		17,255	14,161
Trade receivables		9,501	10,695
Other receivables	6.16	3,590	8,640
Other current assets		1,986	2,407
Cash and cash equivalents*		149,674	178,725
		<u>182,006</u>	<u>214,628</u>
<b>Total assets</b>		<b><u>232,731</u></b>	<b><u>268,323</u></b>
<b>Equity and liabilities</b>			
<b>Capital and reserves</b>			
Share capital		-220,668	-220,668
Share premium		698,027	698,027
Share based payment reserve		5,051	4,670
Accumulated deficit		-423,731	-392,259
Other comprehensive income		-5,374	-5,291
<b>Total equity attributable to owners of the Group</b>		<u>53,305</u>	<u>84,479</u>
<b>Non-current liabilities</b>			
Provisions		23	49
Borrowings and lease liabilities	6.17	21,058	24,000
Convertible debt	6.17	137,623	136,158
Deferred income		0	461
		<u>158,704</u>	<u>160,668</u>
<b>Current liabilities</b>			
Borrowings and lease liabilities	6.17	6,577	6,420
Trade payables	6.18	6,541	9,070
Deferred income	6.19	2,143	1,595
Other current liabilities		5,461	6,091
		<u>20,722</u>	<u>23,176</u>
<b>Total equity and liabilities</b>		<b><u>232,731</u></b>	<b><u>268,323</u></b>

\*Cash and cash equivalents for 30 June 2020 include EUR 1.2 million restricted cash related to KBC lease financing

## CONDENSED CONSOLIDATED CASH FLOW STATEMENT

In EUR 000	Notes	For the 6 months ended	
		30 June 2020	30 June 2019
<b>Operating activities</b>			
Loss for the period		-31,558	-29,670
<b>Adjustments for</b>			
Depreciation and amortization		5,010	3,713
Impairment losses		721	202
Income taxes in profit and loss		-118	-18
Financial result, net		5,129	2,821
Net movement in defined benefit obligation		-109	-48
Share of net profit of associate and a joint venture		195	181
Share based payment expense		381	825
Other		-64	47
<b>Changes in working capital</b>			
Net movement in inventories		-4,428	-3,496
Net movement in trade and other receivables and other current assets		6,975	1,695
Net movement in trade payables & other current liabilities		-3,159	-2,167
Net movement in deferred income	6.19	87	-600
		<b>-20,938</b>	<b>-26,515</b>
Interests paid		-3,585	-1,664
Taxes paid		-3	-178
<b>Cash flow used in operating activities</b>		<b>-24,526</b>	<b>-28,357</b>
<b>Investing activities</b>			
Interest received		7	1
Acquisition of property, plant & equipment		-1,020	-2,332
Acquisition of intangible assets		-15	-162
Acquisition of investment in a joint venture		0	-2,774
<b>Cash flow used in investing activities</b>		<b>-1,028</b>	<b>-5,267</b>
<b>Financing activities</b>			
Proceeds from the issue of a convertible bond		0	145,542
Net proceeds from the issue of ordinary shares, net of transaction costs		0	53,362
Repayment of borrowings	6.17	-3,435	-19,421
Bank charges		-21	-18
<b>Cash flow from financing activities</b>		<b>-3,456</b>	<b>179,465</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>		<b>-29,010</b>	<b>145,841</b>
Cash and cash equivalents at the beginning of the period		178,725	63,539
Effects of exchange rate changes on the balance of cash held in foreign currencies		-41	-180
<b>Cash and cash equivalents at the end of the period*</b>		<b>149,674</b>	<b>209,200</b>

\* Including EUR 1.2 million restricted cash related to KBC Lease financing

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

In EUR 000	Notes	Attributable to owners of the Group					Total equity attributable to the owners of the Group	Total equity
		Share capital	Share premium	Share based payment reserve	Other comprehensive income	Accumulated deficit		
<b>Balance as at 1 January 2019</b>		<b>-220,718</b>	<b>632,769</b>	<b>3,445</b>	<b>-67</b>	<b>-328,078</b>	<b>87,351</b>	<b>87,351</b>
Loss for the period						-29,670	-29,670	-29,670
Re-measurement gains and losses on defined benefit plan					-27		-27	-27
Consolidation translation difference						-188	-188	-188
<i>Total comprehensive income</i>					-27	-29,858	-29,885	-29,885
Share-based payment expense				825			825	825
Share issue – private placement on 23 January 2019		50	55,450				55,500	55,500
Costs related to private placement on 23 January 2019			-2,309				-2,309	-2,309
Share issue – exercise of stock options on 4 April 2019		0	171				171	171
Issuance of convertible bond on 9 May 2019			11,956				11,956	11,956
Other							0	0
<b>Balance as at 30 June 2019</b>		<b>-220,668</b>	<b>698,037</b>	<b>4,270</b>	<b>-94</b>	<b>-357,936</b>	<b>123,609</b>	<b>123,609</b>
<b>Balance as at 1 January 2020</b>		<b>-220,668</b>	<b>698,027</b>	<b>4,670</b>	<b>-5,291</b>	<b>-392,259</b>	<b>84,480</b>	<b>84,480</b>
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
<i>Total comprehensive income</i>					-83	-31,472	-31,555	-31,555
Share-based payment expense				381			381	381
Other							0	0
<b>Balance as at 30 June 2020</b>		<b>-220,668</b>	<b>698,027</b>	<b>5,051</b>	<b>-5,374</b>	<b>-423,731</b>	<b>53,305</b>	<b>53,305</b>

## 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. The Group has established subsidiaries in Mechelen (Belgium), New Jersey (US), and a joint venture in Hong Kong (China).

The consolidated financial statements have been authorized for issue on 1 September 2020 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 2020 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 2019, 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 2019. New standards or interpretations applicable from 1 January 2020 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 2020:

- Amendments to IAS 1 and IAS 8 Definition of Material
- Amendments to IFRS 3 Business Combinations: Definition of a Business
- Amendments to IFRS 9, IAS 39 and IFRS 7 Interest Rate Benchmark Reform
- Amendments to references to the Conceptual Framework in IFRS standards

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

During the first half of 2020, the COVID-19 outbreak adversely affected the Group's operations, as commercial activities were highly restricted due to lock-down measures taken in certain countries in which the Group is operating its business. The Group therefore withdrew its 2020 guidance for cartridge volume growth (30% annual growth or volumes in the range of 228,000 cartridges) and instrument placements (300-350 new instruments) in its Q1 2020 business update published on 23 April 2020.

The pandemic also makes the critical need for high-quality, rapid and easy diagnostic testing for every patient more obvious than ever. With the support of its partners, the Company therefore brought a unique Idylla™ pandemic response offering to the market. It developed a SARS-CoV-2 Test, targeted to help healthcare providers manage the COVID-19 pandemic through rapid and easy testing of individuals with flu-like symptoms. The Group also acquired commercialization rights for the Immunexpress' SeptiCyte® RAPID test on Idylla™. Recent data indicate that sepsis is the most frequently observed complication in COVID-19. This combined offering will enable Intensive Care Units ('ICU's) to rapidly triage patients with severe disease, during and after this pandemic.

Despite the lingering impact of the pandemic, particularly in the US and the RoW, we expect continued cartridge volume growth with strong demand for the Idylla™ SARS-CoV-2 Test, offsetting a slowdown in the Idylla™ core oncology business. Furthermore, the unique combined offering of the Idylla™ SARS-CoV-2 Test and the SeptiCyte® RAPID (CE-IVD) test on Idylla™ should fuel additional demand for Idylla™ instruments in the hospital intensive care units (ICUs)<sup>12</sup>. Providing that (a) normal business activities will resume in the course of H2 2020 and no new widespread lock-down measures will be imposed and (b) the Idylla™ SARS-CoV-2 Test is granted EUA, Biocartis is therefore reinstating its initial guidance for 2020:

- Targeting a year-over-year commercial cartridge volume growth in the range of 30%, representing a volume of Idylla™ cartridges in the range of 228k;
- Targeting an installed base growth in the range of 300-350 new instrument placements.

COVID-19 also impacted and delayed various partner projects. Furthermore, mobilizing resources for the development of the Idylla™ SARS-CoV-2 Test affected the planning of certain other projects. The revised test menu outlook is now as follows:

- ONCOLOGY MENU:
  - Colorectal cancer menu – Subject to further feedback from US FDA interaction, US FDA 510(k) submission of the Idylla™ MSI Test is expected in Q4 2020 and US FDA submission of PMA (Pre-Market Approval) application for the Idylla™ RAS tests is now expected in H1 2021 (versus end 2020);
  - Lung cancer menu – Minor delay of the RUO launch of the Idylla™ GeneFusion Assay to Q1 2021 (versus end 2020);
  - Breast cancer menu – The plan for the Idylla™ IVD Oncotype DX Breast Recurrence Score® test is under evaluation and the timing is under review. No launch to be expected in 2020.
- INFECTIOUS DISEASE PARTNER MENU:
  - The CE-IVD market release of the SeptiCyte® RAPID test on Idylla™ is expected in Q3 2020 and the US FDA regulatory process is ongoing;
  - 'Emergency Use Authorization' ('EUA') (US) and CE-marking (Europe) of the Idylla™ SARS-CoV-2 Test is pending.

The pandemic had no adverse impact on the cash and cash equivalents during the first half of 2020.

<sup>12</sup> The Idylla™ SARS-CoV-2 Test and the SeptiCyte® RAPID (CE-IVD) test on Idylla™ are intended for use in microbiology labs



On 4 May 2020, Biocartis US, Inc., a subsidiary of the Company, received loan proceeds in the amount of approximately USD 1 million under the Paycheck Protection Program (“PPP”). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”), provides for loans to qualifying businesses for amounts of up to 2.5 times the average monthly payroll expenses of the qualifying business. Loan proceeds may only be used for payroll costs, benefits, rent and utilities. Under the terms of the PPP, certain amounts of the loan may be forgiven if used for qualifying expenses as described in the CARES Act. The Company believes its use of the loan proceeds will meet the conditions for forgiveness of the loan. Any unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with a deferral of payments for the first six months.

Operating cash flows did not deviate from the Company’s expectations and cash and cash equivalents amounted to EUR 150 million at 30 June 2020. The Company therefore reaffirms a targeted cash position of EUR 110 million by the end of 2020.

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 Company’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 2020 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 solid 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.

##### 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 2020		30 June 2020	30 June 2019
	At a point in time	Over time		
<b>Collaboration revenue</b>				
R&D services	0	4,623	4,623	4,350
License fees	73	50	123	2,467
Milestones	0	0	0	0
	<b>73</b>	<b>4,673</b>	<b>4,746</b>	<b>6,816</b>
<b>Product related revenue</b>				
Idylla™ System Sales revenue	844	0	844	1,515
Idylla™ System Rental revenue	993	0	993	984
Cartridge revenue	9,584	0	9,584	7,481
	<b>11,421</b>	<b>0</b>	<b>11,421</b>	<b>9,980</b>
<b>Service revenue</b>				
Idylla™ System Service revenue	358	171	530	351
	<b>358</b>	<b>171</b>	<b>530</b>	<b>351</b>
<b>Total</b>	<b>11,852</b>	<b>4,844</b>	<b>16,696</b>	<b>17,147</b>

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 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).

<u>In EUR 000</u>	<u>Deferred Income</u>
2020	709
2021	24
2022	0
2023	0
2024	0
After 2024	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

<u>In EUR 000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2020</u>	<u>30 June 2019</u>
<b>Country of domicile</b>	<b>256</b>	<b>546</b>
Belgium	256	546
<b>Total all foreign countries, of which</b>	<b>16,441</b>	<b>16,600</b>
United states of America	6,851	5,762
China	372	2,377
Spain	1,322	1,382
France	1,396	870
Germany	1,322	647
Rest of the world	5,178	5,563
<b>Total</b>	<b>16,697</b>	<b>17,147</b>

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 10% of the total revenues and three other major customers together represent 18% of the total revenues.

## 6.6. OTHER OPERATING INCOME

<u>In EUR 000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2020</u>	<u>30 June 2019</u>
R&D project support (VLAIO & IWT grants)	312	151
Other project grants (EU)	56	0
Other grants (USA)	541	0
<b>Total</b>	<b>909</b>	<b>151</b>

The other grants (USA) per June 2020, is related to the PPP, which was granted to Biocartis US, Inc, see also section 6.3. The Group believes its use of the loan proceeds will meet the conditions for forgiveness of the loan, therefore a portion of the loan, a ratio of the payroll costs made per 30 June 2020, has been recognized as other grants.

## 6.7. COST OF SALES

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

<u>In EUR 000</u>	<b>For the 6 months ended</b>	
	<b><u>30 June 2020</u></b>	<b><u>30 June 2019</u></b>
Employee benefit expenses	-2,332	-2,582
Material, lab consumables & small equipment	-4,233	-4,395
Depreciation and amortization	-1,384	-805
Royalty expense	-687	-493
Other	-597	-466
<b>Total</b>	<b><u><u>-9,233</u></u></b>	<b><u><u>-8,742</u></u></b>

## 6.8. RESEARCH AND DEVELOPMENT EXPENSES

<u>In EUR 000</u>	<b>For the 6 months ended</b>	
	<b><u>30 June 2020</u></b>	<b><u>30 June 2019</u></b>
Employee benefit expenses	-11,889	-11,470
Laboratory costs	-3,383	-2,910
Quality, regulatory and intellectual property	-285	-188
Facilities, office & other	-1,588	-875
ICT	-142	-680
Travel, training & conferences	-121	-344
Depreciation and amortization	-2,896	-3,563
<b>Total</b>	<b><u><u>-20,303</u></u></b>	<b><u><u>-20,031</u></u></b>

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 and cartridge costs include consumables and prototype costs related to the development of diagnostic platform prototypes and assays.

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

## 6.9. SALES AND MARKETING EXPENSES

<u>In EUR 000</u>	<b>For the 6 months ended</b>	
	<b><u>30 June 2020</u></b>	<b><u>30 June 2019</u></b>
Employee benefit expenses	-4,877	-5,459
S&M consultancy & subcontracting	-425	-777
Sales and promotional expenses	-179	-246
Business development	-595	-281
Facilities, office & other	-543	-353
Travel, training & conferences	-458	-1,272
Depreciation and amortization	-381	-368
Impairment of receivables	-471	-55
<b>Total</b>	<b><u><u>-7,931</u></u></b>	<b><u><u>-8,811</u></u></b>

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

## 6.10. GENERAL AND ADMINISTRATIVE EXPENSES

<u>In EUR 000</u>	<b>For the 6 months ended</b>	
	<b>30 June 2020</b>	<b>30 June 2019</b>
Employee benefit expenses	-5,017	-4,352
External advice	-321	-498
Facilities, office & other	-230	-696
Human resources	-504	-455
Travel, training & conferences	-138	-242
Depreciation and amortization expenses	-281	-157
<b>Total</b>	<b>-6,491</b>	<b>-6,399</b>

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.

## 6.11. EMPLOYEE BENEFIT EXPENSES

<u>In EUR 000</u>	<b>For the 6 months ended</b>	
	<b>30 June 2020</b>	<b>30 June 2019</b>
Employee benefit expenses	-24,115	-23,864
Average number of full time equivalents	499	448

## 6.12. FINANCIAL INCOME AND EXPENSES

<u>In EUR 000</u>	<b>For the 6 months ended</b>	
	<b>30 June 2020</b>	<b>30 June 2019</b>
Interest expense	-5,050	-2,808
Other financial expense	-33	-60
<b>Total</b>	<b>-5,083</b>	<b>-2,868</b>
Other financial result	-46	46
<b>Total</b>	<b>-46</b>	<b>46</b>
<b>Financial result, net</b>	<b>-5,129</b>	<b>-2,822</b>

Net financial result amounted to EUR 5.1m per 30 June 2020 compared to EUR 2.8m as per 30 June 2019. The increase is related to interest expenses of the Company's convertible bond, which was issued in May 2019. Consequently, as per 30 June 2019 one month of interest expenses was included, compared to six months of interest expenses as per 30 June 2020.

### 6.13. 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 2020	30 June 2019
Profit/loss for the period attributable to the owners of the Group (in EUR 000)	-31,558	-29,670
Weighted average number of ordinary shares for basic loss per share (in number of shares)	56,695,322	55,760,127
<b>Basic loss per share (EUR)</b>	<b>-0.56</b>	<b>-0.53</b>

### 6.14. PROPERTY, PLANT AND EQUIPMENT

In EUR 000	As of	
	30 June 2020	31 Dec 2019
Property, plant and equipment	41,098	43,421
<b>Total property, plant and equipment</b>	<b>41,098</b>	<b>43,421</b>

Property, plant and equipment decreased to EUR 41.1m as per end of June 2020 from EUR 43.4m at the end of 2019 (decrease of EUR 2.3m) driven by a depreciation charge of EUR 4.7m and capital expenditures in H1 2020 of EUR 1.7m. The capital expenditures are predominantly related to capitalized Idylla™ systems, manufacturing equipment sold under reagent rental and similar agreements and right-of-use assets.

### 6.15. INVESTMENTS IN JOINT VENTURES

The Group holds an investment in one joint venture at the end of the reporting period:

Name of joint venture	Principal activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2020	2019
Wondfo-Cartis Ltd.	Commercialization	China	50%	50%

Wondfo-Cartis Ltd. was established in January 2019 for the commercialization of the Idylla™ platform. The Group's net investment amounted to EUR 2.4 million. The joint venture is accounted for using the equity method in the

consolidated financial statements as set out in the Group's accounting policies.

## 6.16. OTHER RECEIVABLES

In EUR 000	As of	
	30 June 2020	31 Dec 2019
VAT receivables	1,731	1,870
Tax credit research and development	310	5,242
Other receivables	1,550	1,528
<b>Total</b>	<b>3,590</b>	<b>8,640</b>

Other receivable mainly decreased due to the collection of a research and development tax credit. In Belgium, research and development tax credits can be effectively repaid if the company has not been able to offset the tax credit against the corporation tax for the last five consecutive tax years.

## 6.17. FINANCIAL LIABILITIES

The financial debt can be analyzed as follows:

In EUR 000	As of	
	30 June 2020	31 Dec 2019
Lease liabilities	20,584	23,942
Bank borrowings	474	58
Convertible bond	137,623	136,158
<b>Total non-current</b>	<b>158,681</b>	<b>160,158</b>
Lease liabilities	6,264	6,295
Bank borrowings	314	125
<b>Total current</b>	<b>6,577</b>	<b>6,420</b>
<b>Total financial liabilities</b>	<b>165,259</b>	<b>166,578</b>

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 2020 EUR 0.1m is outstanding under this facility.

In 2015, Biocartis NV obtained two new financing facilities for the modifications to its first 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 2020 EUR 1.5m 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 increased in 2018 with EUR 2.3m. The interest applicable for this facility equals 1.865% and includes a purchase option of 1% of the financed amount. As per the end of H1 2020 EUR 10.4m 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 2017, Biocartis reached agreement with KBC and BNP Paribas Fortis for a committed multiple purpose credit facility of EUR 27.5m (not covered by a government guarantee). This facility consists of a EUR 18.5m rollover credit

line and a EUR 9m working capital credit line. No amount has been withdrawn on this credit facility per 30 June 2020. The availability of this facility was extended until 30 September 2020.

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%. As per 30 June 2020, EUR 0.8m has been withdrawn on 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 137.6m per 30 June 2020.

In addition, the Group also has access to a bank guarantee line of EUR 0.5m of which EUR 0.5m has been taken up for rental guarantees as per 30 June 2020, and a credit line with a bank of EUR 0.6m for currency hedging, of which EUR 0.0m has been taken up per 30 June 2020.

## 6.18. TRADE PAYABLES

<u>In EUR 000</u>	<u>As of</u>	
	<u>30 June 2020</u>	<u>31 Dec 2019</u>
Trade payables	6,541	9,070
<b>Total trade payables</b>	<b>6,541</b>	<b>9,070</b>

The decrease in trade payables is associated with timing of payments made to suppliers.

## 6.19. DEFERRED INCOME

<u>In EUR 000</u>	<u>As at</u>	
	<u>30 June 2020</u>	<u>31 Dec 2019</u>
Grants	1,014	859
Collaboration income	1,130	1,197
<b>Total</b>	<b>2,143</b>	<b>2,056</b>
Current	2,143	1,595
Non-current	0	461

	<u>Deferred partner income</u>
<b>As per 31 December 2018</b>	<b>2,029</b>
Invoiced	5,605
Recognized in profit or loss	-6,436
<b>As per 31 December 2019</b>	<b>1,197</b>
Invoiced	1,976



Recognized in profit or loss  
**As per 30 June 2020**

-2,043

1,130

Deferred partner income includes  
upfront payments from  
collaboration partners in relation to

the strategic licensing, development and commercialization collaborations.

## 6.20. OTHER DISCLOSURES

### 6.20.1. 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 20 and 31 December 2019.

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 2020 and 31 December 2019.

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 166.2m (31 December 2019: EUR 166.6m) have a fair value of EUR 166.3m (31 December 2019: EUR 165.3m).

## 6.20.2. Contingencies

The Group has no new contingencies compared to 31 December 2019.

## 6.20.3. Commitments

### 6.20.3.1. Capital commitments

As per 30 June 2020, the Group has EUR 1.4m 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 2020.

### 6.20.3.2. Operating commitments

As per 30 June 2020, the Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 10.1m. It is expected that the majority of the commitments will be fulfilled in 2020.

## 6.20.4. 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.

## 6.21. EVENTS AFTER THE BALANCE SHEET DATE

The following events took place after 30 June 2020:

- *US FDA EUA submission Idylla™ SARS-CoV-2 Test* – On 10 August 2020, Biocartis notified US FDA of the intent to commercialize the Idylla™ SARS-CoV-2 Test and applied for Emergency Use Authorization ('EUA'). The test is intended to detect SARS-CoV-2, the virus that causes COVID-19, from nasopharyngeal swabs in viral transport medium. The Idylla™ SARS-CoV-2 Test is targeted to help healthcare providers manage the COVID-19 pandemic through rapid and easy testing of individuals with flu-like symptoms. In addition, the Idylla™ SARS-CoV-2 Test may be used in combination with the recently CE-marked IVD SeptiCyte® RAPID<sup>13</sup> test on Idylla™ to facilitate management of patients within the hospital intensive care unit (ICU). When used together, this combined testing solution on Idylla™ has the unique potential to identify patients with severe disease, as recent data<sup>14</sup> indicate that sepsis is the most frequently observed complication in COVID-19<sup>15</sup>. The US FDA regulatory process of the SeptiCyte® RAPID test on Idylla™ is ongoing. The development and roll-out of the Idylla™ SARS-CoV-2 Test is supported by multiple undisclosed partners as part of a joint commitment to respond to the COVID-19 pandemic. Mobilizing resources for the development of the Idylla™ SARS-CoV-2 Test required certain other projects to be delayed. 'Emergency Use Authorization' (US) and CE-marking (Europe) of the Idylla™ SARS-CoV-2 Test is pending.
- *COVID-19* - As of the date of this report, the COVID-19 pandemic continues to affect the Group's business activities. Please see section 6.3 above for a detailed description of the current and the expected impact of COVID-19 on the financial position and the performance of Biocartis.
- *Expansion collaboration LifeArc* – On 1 September 2020, Biocartis announced the expansion of its collaboration with LifeArc, a UK based independent medical research charity. The new licence and development agreement is an extension of the existing partnership<sup>16</sup> between LifeArc and Biocartis. Under the new agreement, LifeArc

<sup>13</sup> Developed in collaboration with Immunospress. More info [here](#).

<sup>14</sup> Zhou et al., Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, published online 9 March 2020, [https://doi.org/10.1016/S0140-6736\(20\)30566-3](https://doi.org/10.1016/S0140-6736(20)30566-3).

<sup>15</sup> Sepsis developed at a median of 9 days (7–13) after illness onset among all patients, followed by ARDS (12 days [8–15]), acute cardiac injury (15 days [10–17]), acute kidney injury (15 days [13–19.5]), and secondary infection (17 days [13–9]).

<sup>16</sup> In June 2017, Biocartis announced a partnership with LifeArc to develop selected molecular diagnostic tests for use on the Idylla™ platform. For each selected test, LifeArc will act as a development contractor, whereas Biocartis will be responsible for the commercialization of the tests under its own label. More info on [www.biocartis.com/partners](http://www.biocartis.com/partners). On 15 June 2017, MRC Technology changed its name to LifeArc. LifeArc has been involved in helping deliver a number of therapies including Keytruda® (pembrolizumab, marketed by Merck) which is an important immunotherapy treatment for various cancers. The collaboration between Biocartis and LifeArc today is focused on the development and the commercialization of the Idylla™ ABC (Advanced Breast Cancer) assay. This assay is positioned to target a multi-gene panel of predictive and resistance-inducing mutations based on a FFPE sample type.

obtains a non-exclusive licence to use the Idylla™ platform for the development of Idylla™ assays in the area of infectious and immune related diseases, aimed at supporting patient stratification and treatment monitoring of patients with, amongst others, bacterial, fungal and viral infections.



## 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 2020

*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 balance sheet as at 30 June 2020, 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 balance sheet shows total assets of 232 732 (000) EUR and the condensed consolidated income statement shows a consolidated loss (group share) for the period then ended of 31 558 (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.

Zaventem, 2 September 2020

The statutory auditor, Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises CVBA/SCRL,

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 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 Dutch version prevails. An electronic version of the half-year financial report 2020 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 Degraeve  
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2800 Mechelen, Belgium  
+32 15 632 600  
[ir@biocartis.com](mailto: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 2020-2021

- |                                  |                                                                                                |
|----------------------------------|------------------------------------------------------------------------------------------------|
| • Q3 2020 business update        | 12 November 2020                                                                               |
| • Capital Markets Day            | 12 November 2020 (virtual or physical event, depending on the the Belgian COVID-19 guidelines) |
| • 2020 full year results         | 25 February 2021                                                                               |
| • Publication 2020 annual report | 1 April 2021                                                                                   |

## 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 Houthaève  
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: <a href="http://www.cdc.org">www.cdc.org</a> ).
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: <a href="https://wwwn.cdc.gov/clia/">https://wwwn.cdc.gov/clia/</a> ).
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.
(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.
<b>Idylla™ Cartridge</b>	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.
Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of - diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of or compensation for an injury, - investigation, replacement, modification, or support of the anatomy or of a physiological process, - supporting or sustaining life, - control of conception, - disinfection of medical devices, - providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.



Metastatic Colorectal Cancer (mCRC)	Colorectal Cancer (CRC) is the second most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually. According to the International Agency for Research on Cancer, an estimated 694,000 deaths from CRC occur worldwide every year, accounting for 8.5% of all cancer deaths and making it the fourth most common cause of death from cancer.
Molecular diagnostics (MDx)	MDx is a form of diagnostic testing used to detect specific sequences in DNA or RNA that may or may not be associated with disease. Clinical applications of MDx include infectious disease testing, oncology, pharmacogenomics and genetic disease screening.
Micro satellite instability (MSI)	MSI is a genetic hyper-mutability condition resulting from MMR that is functioning abnormally.
Multiplexing	The simultaneous detection of more than one analyte or biomarker from a single sample.
Neuroblastoma RAS viral (v-ras) oncogene (NRAS)	NRAS is a protein that is encoded, in humans, by the NRAS gene. Like other members of the Ras family, the NRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and 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 splicing), have catalytic function (ribozymes), act as

	messengers for protein synthesis (mRNAs), regulate gene expression (miRNAs) or make up the genome of certain viruses.
RoW	RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan.
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: <a href="http://www.cdc.org">www.cdc.org</a> ).
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: <a href="http://www.mayoclinic.org">www.mayoclinic.org</a> ).
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.

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