

PART 2

# PERFORMANCE 2020

# 1 KEY ACHIEVEMENTS IN 2020

## HIGHLIGHTS 2020

- ❖ Installed base of 1,581 Idylla™ instruments and 230k cartridges sold in 2020, +31% versus 2019
- ❖ EUR 31.9m product revenues (+32% compared to 2019)
- ❖ Operating income increased by 47% to EUR 55.6m
- ❖ Strengthening the oncology business through the expansion of the partnerships with AstraZeneca and Bristol-Myers Squibb and a new partnership with GeneproDx<sup>17</sup>
- ❖ Partner funded expansion of the Idylla™ infectious diseases test menu, together with Immunexpress, LifeArc and Endpoint Health<sup>18</sup>
- ❖ Infectious diseases strategy sparked by the launch of the first pandemic Idylla™ test menu, consisting of the market release of the SeptiCyte® RAPID test on Idylla™ (CE-IVD)<sup>19</sup> and the Idylla™ SARS-CoV-2 Test<sup>20</sup> (CE-IVD)
- ❖ US FDA 510(k) submission, led by Immunexpress, of the SeptiCyte® RAPID test on Idylla™ completed in December 2020
- ❖ 366 employees<sup>6</sup>, 33 nationalities & balanced gender diversity 51% men and 49% women

## 2 BUSINESS REVIEW 2020

### COMMERCIAL HIGHLIGHTS

❖ **Global** – Despite the global pandemic, the number of commercial cartridges sold in 2020 grew by 31% to 230k, from 175k in 2019. After a strong first quarter of 2020, commercial cartridge volumes in oncology were significantly impacted by the disruption and de-prioritization of global cancer care. Restricted access to hospitals also hampered new customer prospection and slowed down new Idylla™ instrument placements in the first half of the year. Testing volumes in oncology started to recover towards the end of Q2, but the global

surge of COVID-19 cases in Q4 ultimately tempered the year-over-year growth in oncology. To bridge the shortfall in oncology and to respond to its customers' need for COVID-19 testing, Biocartis developed the Idylla™ SARS-CoV-2 Test. Strong demand for this test in Q4, especially in the US, enabled the Company to meet its pre-pandemic guidance with 31% growth in commercial cartridge volumes and the placement of 335 new Idylla™ instruments. As per year-end, the total Idylla™ installed base amounted to 1,581 Idylla™ instruments<sup>21</sup>.

*Thanks to additional strong demand for the Idylla™ SARS-CoV-2 Test, US commercial cartridge volumes tripled compared to 2019. New Idylla™ instrument placements in the US also increased year-over-year and accounted for one third of total placements.*

✎ **Europe** – Sales in Europe proved to be very resilient throughout 2020. After the slow-down in Q2 2020, both cartridge volumes and instrument sales were rapidly tracking pre-pandemic expectations. When growth slowed down again in Q4 as a direct result of renewed lock-down measures across large parts of Europe, lagging sales in oncology were supplemented

✎ **US** – After strong growth in Q1 2020, demonstrating the continued success of the direct US sales strategy, sales in the US slowed down due to the global pandemic. Cartridge volumes in oncology nevertheless grew by 20% year-over-year. Thanks to additional strong

✎ **Distributor markets**<sup>22</sup> – In 2020, several countries that are served through distributors were hit specifically hard by the pandemic, often compounded by a significant weakening of local currency versus the Euro. As a result, declining volumes in amongst others Latin-America, India, Pakistan and Turkey outweighed continued growth in other parts of the world. New market authorizations were obtained for the Idylla™ MSI Test in Colombia, Canada, Malaysia and Singapore,

✎ **China commercialization** – In 2020, Wondfo-Cartis, the joint venture with Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, took further steps towards establishing local manufacturing capabilities. Concerning the registration of products, a **CDx<sup>23</sup> partnership** was announced on 5 March 2020

✎ **Japan commercialization** – Continued progress in the in vitro diagnostic ('IVD') registration preparations for the Idylla™ assays, paving the way to commercialization

by demand for the Idylla™ SARS-CoV-2 Test, CE-IVD marked since 10 November 2020. Together with **SeptiCyte® RAPID**<sup>19</sup> on Idylla™, released as CE-IVD in European markets on 6 October 2020, the Idylla™ SARS-CoV-2 Test is ideally positioned to alleviate the pressure on intensive care units (ICUs) and is expected to drive further growth in 2021.

demand for the Idylla™ SARS-CoV-2 Test, US commercial cartridge volumes tripled compared to 2019. New Idylla™ instrument placements in the US also increased year-over-year and accounted for one third of total placements.

and for the Idylla™ EGFR Mutation Test in Argentina during H1 2020. End of October 2020, medical device registration certificates were issued for the Idylla™ platform and the Idylla™ EGFR Mutation Test by the Taiwan FDA. Post the reporting period, in February 2021, the Idylla™ platform, the Idylla™ BRAF Mutation Test (CE-IVD) and the Idylla™ EGFR Mutation Test (CE-IVD) completed registration in Russia, as such expanding the distribution network for Biocartis' IVD medical devices.

with Bristol Myers Squibb Company (BMS), aimed at pursuing the registration in China of the Idylla™ MSI Test as a CDx test in metastatic colorectal cancer (mCRC). First product registrations in China are to be expected earliest by 2022. Compliance testing of the Idylla™ Instrument and Console with the China NMPA was successfully completed in January 2021.

with Nichirei Biosciences in Japan. First Idylla™ assays registrations in Japan are expected in the course of 2022.

## TEST MENU AND PARTNERSHIP HIGHLIGHTS



**Oncology:** In 2020, Biocartis further strengthened its footprint in oncology activities through progress in its test menu and the launch of several new and expanded partnerships:

- ❖ **Partnership AstraZeneca** – On [22 January 2020](#), Biocartis announced a master collaboration agreement with lung cancer targeted therapy leader AstraZeneca aimed at rapid and easy testing and expanded its partnership to, amongst others, the area of liquid biopsy testing using the [Idylla™ ctEGFR Mutation Assay](#).
- ❖ **Partnership Bristol-Myers Squibb in China** – On [5 March 2020](#), Biocartis announced the expansion of its partnership with Bristol-Myers Squibb Company, to now also pursue, after the US, the registration of the Idylla™ MSI test as a CDx test in mCRC<sup>24</sup> in China.
- ❖ **Idylla™ GeneFusion Assay** – Biocartis made progress in its oncology test menu, more specifically in the lung cancer domain with the development of the [Idylla™ GeneFusion Assay](#), for which a EUR 1.2m grant from VLAIO was announced on [30 September 2020](#).
- ❖ **Partnership Exact Sciences** – On [29 October 2020](#), Biocartis and Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation) announced to have agreed to terminate their collaboration<sup>25</sup>. As part of a termination settlement, Genomic Health, Inc. agreed to pay USD 12m to Biocartis and licensed certain rights and transferred certain assets to Biocartis.
- ❖ **Partnership GeneproDx** – On [3 November 2020](#), Biocartis announced to have signed a license, development and commercialization agreement with [GeneproDx](#), a molecular diagnostics company based in Santiago, Chile, for the development of GeneproDx's novel genomic test [ThyroidPrint®](#) on the Idylla™ platform. Under the terms of the agreement, GeneproDx will take the lead in the development of the Idylla™ ThyroidPrint® test, whereas Biocartis will be responsible for the distribution of the ThyroidPrint® on Idylla™ through its growing commercial infrastructure of Idylla™ instruments across the globe<sup>26</sup>.
- ❖ **Partnership Amgen** – Motivated by a strong demand from partners and customers, Biocartis gave priority to the development of the Idylla™ SARS-CoV-2 Test and re-allocated resources accordingly. Consequently, Biocartis delayed the US FDA submission of the PMA (Pre-Market Approval) application for the Idylla™ RAS tests.

**Infectious diseases:** Against the backdrop of the pandemic, in 2020, Biocartis paved the way to the gradual build-out of its infectious disease test menu on Idylla™:

- ✕ In **Partnership Immunexpress** – In **March 2020**, the agreement with Immunexpress<sup>7</sup> was expanded with a co-commercialization agreement for the **SeptiCyte® RAPID** test for use on the Idylla™ platform. End of December 2020, the 510(k) submission with the US FDA of the SeptiCyte® RAPID on Idylla™, led by Immunexpress, was completed.
- ✕ In **Idylla™ SARS-CoV-2 Test** – In **August 2020**, Biocartis submitted a notification of intent to distribute and request for ‘Emergency Use Authorization’ (EUA) from the US FDA for the Idylla™ SARS-CoV-2 Test.
- ✕ In **Partnership LifeArc** – In **September 2020**, Biocartis announced that the agreement with LifeArc<sup>27</sup> was expanded to now also include the development of highly innovative prototype assays in the field of infectious and immune related diseases on the Idylla™ platform.
- ✕ In **COVID-19 Testing Industry Consortium** – In **October 2020**, Biocartis announced to have joined the COVID-19 Testing Industry Consortium, led by Bristol-Myers Squibb Company which is aimed at improving, innovating and accelerating all aspects of COVID-19 testing<sup>28</sup>. A first Whitepaper on ‘**COVID-19 Back-to-Work**’ was published by the COVID-19 Testing Industry Consortium in January 2021.
- ✕ In **SeptiCyte® RAPID on Idylla™** – Also in **October 2020**, Biocartis announced the market release of the SeptiCyte® RAPID test on Idylla™ (CE-IVD).
- ✕ In **Idylla™ SARS-CoV-2 Test** – In **November 2020**, Biocartis announced the CE-IVD launch of its Idylla™ SARS-CoV-2 Test.
- ✕ In **Partnership Endpoint Health** – Also in **November 2020**, Biocartis announced the signing of a new partnership with Endpoint Health aimed at the development and commercialization of a novel CDx test on Idylla™ for critical illnesses.

**Idylla™ performance data:** During 2020, 29 new Idylla™ papers were published, bringing the total number of Idylla™ papers end of 2020 to 84. Next to the Idylla™ papers, also several dozens of abstracts and posters were published in 2020 at large scientific conferences, including ASCO, AMP, ESMO and ECP<sup>29</sup>. Some highlights:

- ✕ In **June 2020**, Biocartis announced the publication of a new **US multicenter study**<sup>30</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 was 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.
- ✕ In **August 2020**, during the virtual annual ASCO, five Idylla™ abstracts and posters 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.
- ✕ In **September 2020**, the **FACILITATE study**, launched as part of the agreement between Biocartis and AstraZeneca, was selected for presentation at the renowned European Society for Medical Oncology (‘ESMO’) Virtual Congress. The study concluded that Idylla™ reduced turnaround time by more than a week versus reference methods, allowing earlier patient management decisions.
- ✕ In **November 2020**, at the annual meeting of the ‘Association for Molecular Pathology’ (AMP), ten Idylla™ studies were published which highlighted the strengths of the Idylla™ platform and assays<sup>31</sup> in terms of performance, ease of use and turnaround time, as well as Idylla™’s capacity to overcome the obstacles of working with small amounts of sample<sup>32</sup>.
- ✕ Also in **November 2020**, a global multi-center real world study<sup>33</sup> with the Idylla™ MSI Assay was published and demonstrated excellent performance of the Idylla™ MSI Assay (RUO) with a very low failure rate. The study was the largest so far published for Biocartis.



## ORGANIZATIONAL AND OPERATIONAL HIGHLIGHTS

- ❖ **Management team** – Following the departure of former CFO Ewoud Welten as announced on [27 January 2020](#), Biocartis announced on [23 April 2020](#) the appointment of [Jean-Marc Roelandt](#), a senior executive with an established track record of more than 25 years as CFO in globally active publicly listed companies, as the new CFO of the Company.
- ❖ **Cartridge manufacturing** – In 2020, further progress was made in 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-BRAF Mutation Test (CE-IVD) and the Idylla™ MSI Test (CE-IVD) were successfully transferred to ML2. The transfer of the Idylla™ EGFR Mutation Test (CE-IVD) is near completion. Transferring the production of key Idylla™ assays to this line is driving cost optimizations within the Company's cartridge manufacturing activities.
- ❖ **Ordinary and Extraordinary General Shareholders' Meeting** – During the ordinary [shareholders' meeting](#) held on 8 May 2020, the shareholders of the Company approved all agenda items, including the re-appointment of Ann-Christine Sundell, Luc Gijssens BV, represented by Luc Gijssens, and Roald Borré, as independent directors of the Company. [Christine Kuslich](#), PhD was appointed as new independent director of the Company. During the [extraordinary general shareholders' meeting](#) held on 25 September 2020, the shareholders of the Company approved all agenda items, including the renewal of the authorization to the Board of Directors to increase the share capital of the Company by up to 20% of the then current amount of the share capital, during a period of one year.
- ❖ **Convertible bonds** – On 7 December 2020, Biocartis announced its agreement with a holder of part of its outstanding EUR 150m 4% Senior Unsecured Convertible Bonds due 2024 (the 'Bonds') regarding the exercise of [conversion rights](#) in relation to EUR 15m aggregate principal amount of Bonds<sup>34</sup>. Biocartis agreed to this incentivized conversion of the Bonds, as it allowed to reduce its debt at attractive market conditions while strengthening the Company's shareholders' equity at a premium to the then current share price.

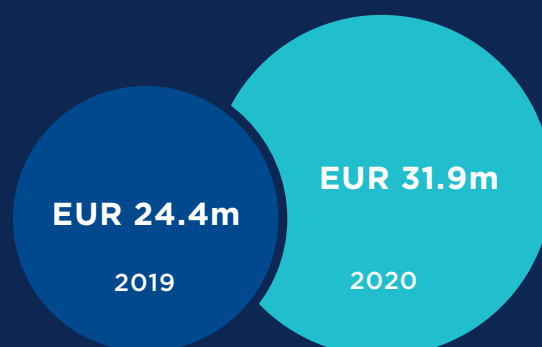
## 2.2.4 FINANCIAL HIGHLIGHTS

### PRODUCT SALES REVENUES

Total product sales increased year-over-year by 32% to EUR 31.9m in 2020 from EUR 24.2m in 2019.

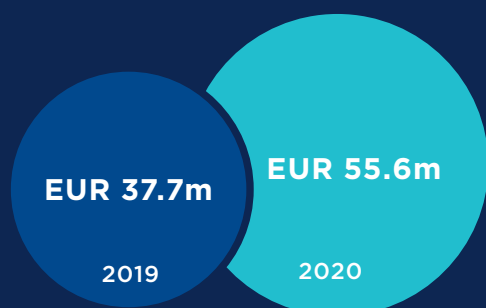
Income from cartridge sales of EUR 24.8m grew 38% year-over-year for total cartridge volume of 243k cartridges, of which 230k were commercial cartridges and 13k R&D cartridges. In addition to 31% growth of commercial cartridge volumes, good progress was made on the average selling price ('ASP') of commercial cartridges, which increased by 7% in 2020.

Idylla™ platform sales increased by 14% for a similar level of new Idylla™ instrument placements as in 2019 (335 in 2020, compared to 337 in 2019).



### TOTAL OPERATING INCOME

Total operating income amounted to EUR 55.6m in 2020, representing a year-over-year growth of 47% and included a settlement payment of EUR 10.3m (USD 12m) received in connection with the termination of the collaboration with Genomic Health, Inc. for the development of the Oncotype DX Breast Recurrence Score® test on Idylla™.



### OPEX

Total operating expenses (excluding cost of sales) amounted to EUR 76.1m, an increase of 6% compared to EUR 72m in 2019. Cautious cost management triggered by the pandemic and prioritizing the development of the Idylla™ SARS-CoV-2 Test, led to the delay and carry-over of certain projects to 2021.

### OPERATIONAL CASH FLOW

Revenue growth, gross margin improvement and lower than planned operating expenses reduced the total cash flow used in operating and investing activities from EUR 59.7m in 2019 to EUR 43.3m in 2020.

### CONVERTIBLE BOND

Biocartis' debt was reduced by EUR 13.6m following the incentivized conversion of 10% of total outstanding Bonds. Biocartis paid a cash incentive of EUR 4.3m to the relevant bondholder as part of the transaction.

### CASH POSITION

# 123.7m

Biocartis' cash position as per 31 December 2020 amounted to EUR 123.7m compared to EUR 178.7m as per 31 December 2019.

### COST OF GOODS SOLD

Cost of goods sold increased to EUR 26.3m, 23% higher than in 2019 on the back of 31% higher commercial cartridge volumes and leading to an improved gross margin on products of 18% (2019: 12%).

**Additional details** – See key figures 2020 below for more details on the 2020 financials.

## KEY FIGURES 2020

The tables below show an overview of the key figures and a breakdown of operating income for 2020. A consolidated income statement, balance sheet, cash flow statement and statement of changes in shareholder equity of Biocartis Group NV is presented in part 4, Financial report 2020.

KEY FIGURES (EUR 1,000)	2020	2019	% CHANGE
<b>Total operating income</b>	<b>55,559</b>	<b>37,732</b>	<b>47%</b>
Cost of sales	-26,284	-21,328	23%
Research and development expenses	-45,783	-39,844	15%
Sales and marketing expenses	-15,736	-18,011	-13%
General and administrative expenses	-14,618	-14,151	3%
<b>Operating expenses</b>	<b>-102,421</b>	<b>-93,334</b>	<b>10%</b>
<b>Operational result</b>	<b>-46,862</b>	<b>-55,602</b>	<b>-16%</b>
Net financial result	-15,768	-7,934	99%
Share in the result of associated companies	-532	-631	-16%
Income tax	228	99	130%
<b>Net result</b>	<b>-62,934</b>	<b>-64,068</b>	<b>-2%</b>
Cash flow from operating activities	-39,267	-54,254	-28%
Cash flow from investing activities	-4,007	-5,496	-27%
Cash flow from financing activities	-11,523	175,023	-107%
<b>Net cash flow</b>	<b>-54,797</b>	<b>115,273</b>	<b>-148%</b>
<b>Cash and cash equivalents<sup>1</sup></b>	<b>123,668</b>	<b>178,725</b>	<b>-31%</b>
Financial debt	150,558	166,578	-10%

<sup>1</sup> Including EUR 1.2m of restricted cash (as a guarantee for KBC Lease financing)

OPERATING INCOME (EUR 1,000)	2020	2019	% CHANGE
<b>Collaboration revenue</b>	<b>9,989</b>	<b>12,451</b>	<b>-20%</b>
Idylla™ system sales	7,085	6,220	14%
Idylla™ cartridge sales	24,808	18,004	38%
<b>Product sales revenue</b>	<b>31,893</b>	<b>24,224</b>	<b>32%</b>
Service revenue	1,246	769	62%
<b>Total revenue</b>	<b>43,128</b>	<b>37,444</b>	<b>15%</b>
Grants and other income	12,431	288	4216%
<b>Total operating income</b>	<b>55,559</b>	<b>37,732</b>	<b>47%</b>

PRODUCT SALES REVENUE BY TYPE (EUR 1,000)	2020	2019	% CHANGE
Commercial revenue	30,709	22,862	34%
Research & Development revenue	1,184	1,362	-13%
<b>Total product sales revenue</b>	<b>31,893</b>	<b>24,224</b>	<b>32%</b>



## Income statement

Total operating income increased by EUR 17.8m or 47% to EUR 55.6m in 2020. Collaboration revenue amounted to EUR 10m, a decrease of 20% from 2019. R&D service revenue decreased by EUR 0.9m, license fees by EUR 0.7m and milestone revenue by EUR 0.9m. The collaboration with Genomic Health, Inc., a subsidiary of Exact Sciences Corporation, for the development of the Oncotype DX Breast Recurrence Score® test on Idylla™ was initially delayed and ultimately terminated because of the pandemic and a decision by Exact Sciences Corporation to shift priorities to other initiatives. Genomic Health, Inc. paid a settlement fee of EUR 10.3m, which is recorded as other income.

Revenue from product sales increased by 32% from EUR 24.2m in 2019 to EUR 31.9m in 2020, and included Idylla™ cartridge sales of EUR 24.8m (EUR 18.0m in 2019) and Idylla™ system revenues of EUR 7.1m (EUR 6.2m in 2019). Idylla™ cartridge sales included revenue from the sale of 230k commercial cartridges and of 13k R&D cartridges.

Services revenue amounted to EUR 1.2m in 2020 versus EUR 0.8m in 2019. Grant income increased to EUR 1.2m and related to the recognition of subsidies awarded in relation to the establishment of a second cartridge manufacturing line, and to the development of the Idylla™ SARS-CoV-2 Test and the Idylla™ GeneFusion Assay (RUO). In addition to the aforementioned settlement fee paid by Genomic Health, Inc. other income included the proceeds of a USD 1.0m loan received under the US Paycheck Protection Program ('PPP'), established as part of the Coronavirus Aid, Relief and Economic Security Act ('CARES Act'). On October 29, 2020 Biocartis submitted a loan forgiveness application for the full amount of the loan plus applicable interest to its lender. The lender approved the forgiveness application and recommended full forgiveness to the Small Business Administration ('SBA'). While no response has yet been received from the SBA, the Company believes its use of the loan proceeds met the conditions for forgiveness of the loan.

Total operating expenses amounted to EUR 102.4m in 2020, compared to EUR 93.3m in 2019. The increase was primarily driven by the cost of goods sold that increased by EUR 5m or 23% to EUR 26.3m. The increased cost of goods sold reflected the increase in commercial cartridge volume of 31%, partly offset by a reduction in the cartridge manufacturing cost, leading to an improvement of the gross margin on products to 18% (2019: 12%).

Total operating expenses, excluding the cost of goods sold, amounted to EUR 76.1m in 2020, compared to EUR 72.0m in 2019. The increase of EUR 4.1m resulted from increased R&D expenses, offset by lower spending in sales and marketing. The increase in R&D expenses was largely driven by the development of the Idylla™ SARS-CoV-2 Test. Sales and marketing expenses decreased by EUR 2.3m, in part because the pandemic significantly hampered normal commercial activities for a good part of the year. Travel was restricted and numerous conferences and events were cancelled due to global lockdown measures.

The operating loss for 2020 amounted to EUR 46.9m, an improvement of EUR 8.7m or 16% compared to 2019.

Net financial expenses amounted to EUR 15.8m in 2020 compared to EUR 7.9m, and included expenses associated with the Company's convertible bond, and commitment fees for the multiple purpose credit. In 2020, the interest expense on the convertible bond increased to EUR 6.0m compared to EUR 3.0m in 2019. The bond was issued in May 2019 and last year therefore only included one coupon. Similarly, the debt appreciation expense amounted to EUR 2.7m, compared to EUR 2.2m in 2019. The financial expenses also included a cash payment of EUR 4.3m in connection with the incentivized exercise of conversion rights in relation to EUR 15 million aggregate principal amount of Bonds (see details in the section balance sheet).

## Balance sheet

In 2020, total assets reduced from EUR 268.3m in 2019 to EUR 210.5m. Non-current assets amounted to EUR 50.5m compared to EUR 53.7m, mostly because of the depreciation of intangible assets and property, plant and equipment (EUR 9.7m) and an impairment charge of EUR 1.6m, offset by investments of EUR 3.0m in new equipment. Financial assets amounted to EUR 2.9m (2019: EUR 2.4m) and included the investment in the China joint venture Wondfo-Cartis. In 2020, the Company invested an additional EUR 1.0m in the joint venture and recorded its share of EUR 0.5m in Wondfo-Cartis' net loss for the year.

End 2020, current assets amounted to EUR 160.0m, or EUR 54.4m less than in 2019. Cash and cash equivalents of EUR 123.7m reduced by EUR 55.1m. Accounts receivable increased by EUR 2.8m as a direct result of higher levels of cartridge sales towards the end of the year. Inventory increased by EUR 1.6m, mostly finished cartridges in order to meet increased demand. Other receivables decreased by EUR 4.7m from EUR 8.6m in 2019, to EUR 4.0m in 2020, following the collection of a tax credit on research and development. Other current assets increased by EUR 0.7m.

End 2020, total financial debt amounted to EUR 150.6m compared to EUR 166.6m end of 2019. The reduction resulted

from the incentivized conversion (EUR 13.6m) of part of the convertible bond and the net reduction of EUR 5.1m of lease obligations, offset by the appreciation of EUR 2.7m of the convertible bond. The incentivized conversion resulted from an agreement with a holder of part of the Company's EUR 150m 4% senior unsecured convertible Bonds regarding the exercise of conversion rights in relation to EUR 15 million aggregate principal amount of Bonds. The Company agreed to the incentivized conversion of the Bonds, as it allowed the Company to reduce the reported debt at attractive market conditions and to strengthen the shareholders' equity at a premium to the share price. The amount of the debt reduction in exchange for the new ordinary shares amounts to EUR 9.3m or EUR 8 per share, 70% higher than the closing price on 4 December 2020. The total debt reduction amounts to EUR 13.6m and was recorded as a credit to the share premium in the equity attributable to the owners of the Company.

Current liabilities end of 2020 amounted to EUR 29.4m, compared to EUR 23.2m end of 2019. Trade accounts payable increased by EUR 4.8m to EUR 13.9m. Other current liabilities included payroll related provisions and amounted to EUR 7.6m, representing an increase of EUR 1.5m compared to end 2019.

## Cash flow statement

The cash flow from operating activities in 2020 amounted to EUR -39.3m, a decrease of EUR 15m from EUR -54.3m in 2019. The improvement resulted from reduced operating losses and a net reduction in working capital, partly offset by increased financial expenses.

The cash flow from investing activities in 2020 amounted to EUR -4.0m, EUR 1.5m less than in 2019, and included the capital contribution made to the China joint venture, capitalized Idylla™ systems as well as investments in laboratory and manufacturing equipment.

Financing activities used EUR 11.5m cash for the incentivized conversion of part of the convertible bond (EUR 4.3m), interest on the convertible bond (EUR 6.0m) and the scheduled repayment of lease and other obligations.

The total cash flow for 2020 amounted to EUR -54.8m compared to EUR 115.3m in 2019, which included EUR 198.8m net proceeds from the issuance of new ordinary shares (EUR 53.4m) and the convertible bond (EUR 145.5m).

## 3 IMPACT OF COVID-19

### BUSINESS IMPACT

The pandemic deprioritized and disrupted cancer care globally. Patient access to hospitals was significantly restricted throughout almost the entire year and customer prospection was severely hampered. Despite the global pandemic, the number of commercial cartridges sold in 2020 grew by 31% to 230k, from 175k in 2019. After a strong first quarter of 2020, commercial cartridge volumes in oncology were significantly impacted by the disruption and de-prioritization of global cancer care. Restricted access to hospitals also hampered new customer prospection and slowed down new Idylla™ instrument placements in the first half of the year. Testing volumes in oncology started to recover towards the end of Q2, but the global surge of COVID-19 cases in Q4 ultimately tempered the year-on-year growth in oncology. To bridge the shortfall in oncology and to respond to its customers' need for COVID-19 testing, Biocartis developed the Idylla™ SARS-CoV-2 Test. Strong demand for this test in Q4, especially in the US, enabled

Biocartis to meet its pre-pandemic guidance with 31% growth in commercial cartridge volumes and the placement of 335 new Idylla™ instruments. As per year-end, the total Idylla™ installed base amounted to 1,581 Idylla™ instruments<sup>21</sup>.

While being disruptive, the COVID-19 pandemic also created an increased demand for molecular diagnostic testing. Since 2017, Biocartis has mainly focused its efforts on developing and commercializing oncology tests, which resulted in a solid on-market menu of proprietary Idylla™ oncology tests in colorectal cancer, lung cancer and melanoma, and ongoing developments in breast and thyroid cancer.

The current pandemic market conditions now also bring opportunities to grow in infectious diseases and as such accelerate the expansion of our installed base, offering this market the advantage of Idylla™'s speed and simplicity, together with the dual use for oncology testing.

### PARTNER AND BUSINESS PROJECT IMPACT

On 29 October 2020, Biocartis and Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation) announced to have agreed to terminate their collaboration which was focused on the development of the Oncotype DX Breast Recurrence Score® Test and the Oncotype DX Genomic Prostate Score® (GPS™) Test on the Idylla™ platform. As a result of COVID-19, the project had been suspended earlier during 2020, with the project plan and timing under evaluation. The decision to terminate the agreement was driven by the uncertain timing of a product market release because of the pandemic and a decision by Exact Sciences

to shift priorities to other initiatives. As part of a termination settlement, Genomic Health, Inc. agreed to pay USD 12m to Biocartis and licensed certain rights and transferred certain assets to Biocartis.

Motivated by a strong demand from partners and customers, Biocartis gave priority to the development of the Idylla™ SARS-CoV-2 Test and re-allocated resources accordingly. Consequently, Biocartis delayed the US FDA submission of the PMA (Pre-Market Approval) application for the Idylla™ RAS tests.

### SUPPLIER IMPACT

During 2020, Biocartis worked more closely than ever with its suppliers to assess and monitor the risks related to the impact of the pandemic on the supply of goods directly related to the production of our cartridges:

- ✎ Supplies were monitored closely and discussed in a COVID-19 Steering Committee on a daily basis. There were no shortfalls of supply related to the pandemic, but the pandemic has led to a more proactive supplier strategy including the allocation of volumes per supplier, a closer follow-up communication and the listing and activation of additional suppliers for core materials.
- ✎ Biocartis performed additional risk assessments encompassing any COVID-19 related risks.

## **ENVIRONMENTAL IMPACT**

The main environmental impact of COVID-19 on Biocartis' activities resulted from restricted travel by our sales teams (sales related travel), general management (business development and investor roadshow travel) as well as employees (commuting to the workplace). In general, the more established culture of virtual meetings is expected to have a lasting impact on the need to travel. The pandemic crisis equally put a strain on our co-workers having to adopt new ways of working. Biocartis supported its employees through the development of processes to improve office and home working and is carefully analyzing the needs of its employees in terms of a balanced office and home working regime, evaluating certain permanent changes to the working environment post-pandemic. It is therefore expected that Biocartis will continue to decrease its commuting and office floor space related emissions post the pandemic (see below).

Our staff in production continued to work 100% on site during the pandemic, leading to an increase in the use of COVID-19 safety equipment, which increased the amount of healthcare waste (non-measured).

## SOCIAL IMPACT

Since the start of the pandemic mid-March 2020, Biocartis assumed responsibility in meeting the high need for diagnostic testing and set up several actions to ensure business continuity while supporting its employees during these challenging times. These measures that contributed to business continuity and helped avoid any pandemic related unemployment, included:

- ✕ The set-up of a COVID-19 Crisis Team that gathered daily to ensure amongst others:
  - ✕ Safe working conditions for employees that needed to be on site (including production and technical teams) in full compliance with applicable regulations such as social distancing
  - ✕ All safety and travel guidelines remained up to date
  - ✕ Supply chain and production continuity
- ✕ The set-up of internal communications channels to disseminate specific COVID-19 related information such as an updated travel policy and strict rules on social distancing, cleaning and hygienic rule at the workplace
- ✕ Weekly staff meetings led by the CEO, COO and HR in the period between March-June, and monthly updates as from Summer, with the focus to keep everyone committed and fully updated
- ✕ IT program tools were updated and renewed for virtual working
- ✕ A COVID-19 communications campaign was set up, including topics such as wellbeing webinars to guide employees and people managers through these challenging times. Attention was also given to ergonomic tips for home working and tips and tricks for COVID-19 hygienic rules
- ✕ Switch to a fully virtual HR recruitment, onboarding and training program
- ✕ Supporting the leadership team to keep a virtual connection with their teams through virtual tool manuals and trainings
- ✕ Close collaboration with the external company doctor
- ✕ Employee survey in September 2020 showed, amongst others, that most employees are proud to be working for a company that helps to deliver a (diagnostic) solution, but attention was needed to improve the work-life balance, especially mental wellbeing.

*In terms of wellbeing, Biocartis saw the pandemic as an opportunity to further develop its wellbeing strategy in 2020 and beyond. This strategy is aimed at increasing our agility and resilience as an organization. Several actions were already rolled out in 2020 to reinforce the mental 'muscle' of our employees, including webinars and virtual wellbeing sessions on mental resilience. Additionally, a renewed Wellbeing Action Plan will be rolled out in 2021, with a focus on Workplace Transformation combining the best of both office and home working, and the introduction of mental wellbeing tools such as regular webinars and articles, practical tips and tricks and e-learning modules.*

