

BIOCARTIS ANNOUNCES H1 2020 RESULTS

Mechelen, Belgium, 3 September 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces its business highlights and financial results for the first half of 2020, prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union. Furthermore, the Company reinstates its outlook for the full year 2020.

Commenting on the H1 2020 results, Herman Verrelst, Chief Executive Officer of Biocartis, reacted:

"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. RoW¹ 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."

KEY MESSAGES

- **Commercial cartridge volume:**
 - 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.
- **Installed base:**
 - 101 new Idylla™ instruments placed versus 156 in H1 2019;
 - Total installed base of 1,411 end H1 2020;
 - 50% of the new placements in Europe. Pace of new placements in the US and RoW slowed down due to highly restricted access to customers.
- **New Idylla™ pandemic response test menu in H2 2020:**
 - 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 SeptiCyte® RAPID² on Idylla™ from Immunexpress Pty Ltd³ ('Immunexpress').
- **Expanded oncology partnerships:**
 - Partnership with AstraZeneca expanded with a study on liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay (RUO⁴);
 - New project with Bristol Myers Squibb Company (BMS) aimed at pursuing the registration of the Idylla™ MSI Test as a companion diagnostic⁵ (CDx) test in metastatic colorectal cancer (mCRC) in China.
- **Financials:**
 - 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.

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

² Developed in collaboration with Immunexpress. More info [here](#)

³ Immunexpress is a molecular diagnostic company focused on improving outcomes for suspected sepsis patients

⁴ RUO = Research Use Only, not for use in diagnostic procedures

⁵ An IVD companion diagnostic device is an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. Source: US FDA, last consulted on 6 August 2020

COVID-19 impact and 2020 outlook

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 temporary slowdown in the Idylla™ core oncology business. Furthermore, the unique combined offering of the Idylla™ SARS-CoV-2 Test and the SeptiCyt® RAPID (CE-IVD) test on Idylla™ should fuel additional demand for Idylla™ instruments in the hospital intensive care units⁶ (ICUs). Provided 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 US FDA Emergency Use Authorization ('EUA'), Biocartis is 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; and
- Targeting a cash position in the range of EUR 110m by year-end 2020.

Biocartis will host a conference call with live webcast presentation today at 15:00 CET / 14:00 BST (UK) / 09:00 EDT (US) to discuss the H1 2020 results. Click [here](#) to access the live webcast. To participate in the questions and answers session, please dial 5-10 minutes prior to the start time the number +44 8445718892 (standard international), followed by the confirmation code 6661855. The conference call and webcast will be conducted in English. A replay of the webcast will be available on the [Biocartis investors' website](#) shortly after.

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 Q1 2020, commercial cartridge volumes in Q2 2020 were 20% lower than last year as a direct consequence of the pandemic, which also limited 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™ instruments placements. The negative impact of the pandemic was most notable at the start of Q2 2020, but the strength of the European customer base led 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., Ltd⁷ 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 cancer⁸ (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™ ctEGFR Mutation Assay (RUO) could provide further benefits to tissue-based EGFR molecular testing.

⁶ The Idylla™ SARS-CoV-2 Test and the SeptiCyt® RAPID (CE-IVD) test on Idylla™ are intended for use in microbiology labs

⁷ Wondfo®, SHE: 300482, a fast growing diagnostics leader in China

⁸ More info on https://investors.biocartis.com/sites/default/files/press-releases/2020/200304_pr_bms_china_eng_final.pdf

- *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 mCRC⁹ 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® RAPID¹⁰ 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 Authority¹¹ ('BARDA')¹² for the SeptiCyte® RAPID¹³ test on Idylla™.
- *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 posters¹⁴ were issued, all demonstrating strong data of Idylla™ tests. The studies included, amongst others, a [new US multicenter study](#)¹⁵ 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 ASCO¹⁶, [five Idylla™ abstracts and posters](#)¹⁷ 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 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.

⁹ mCRC = metastatic colorectal cancer

¹⁰ 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

¹¹ 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

¹² More info [here](#)

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¹⁴ 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 bronchial cancer: comparative prospective study by NGS and Idylla platform technologies. *Annales de Pathologie.* Feb 2020; (9) Bocciaelli 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) Gralewski 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) Périaux 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 BEAmpling. *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/aaqaa044. Online ahead of print. See also www.biocartis.com/publications

¹⁵ 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/aaqaa044. Online ahead of print.

¹⁶ American Society of Clinical Oncology meeting, took place between 8-10 August 2020

¹⁷ 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 Gralewski 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

Post-period events

The following events took place since 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® RAPID¹⁸ 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 data¹⁹ indicate that sepsis is the most frequently observed complication in COVID-19²⁰. 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, as described in the menu outlook below. 'Emergency Use Authorization' (US) and CE-marking (Europe) of the Idylla™ SARS-CoV-2 Test is pending.
- *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 partnership²¹ between LifeArc and Biocartis. Under the new agreement, LifeArc 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.

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 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.

Key figures for H1 2020

The tables below show an overview of the key figures and a breakdown of operating income for H1 2020 and H1 2019. Consolidated financial statements and accompanying notes are included in Biocartis' half-year 2020 report that is available [here](#) on the Company's website.

Key figures (EUR 1,000)	H1 2020	H1 2019	% Change
Total operating income	17,606	17,298	2%
Cost of goods sold	-9,233	-8,742	6%
Research and development expenses	-20,303	-20,031	1%
Sales and marketing expenses	-7,931	-8,811	-10%
General and administrative expenses	-6,491	-6,399	1%
Operating expenses	-43,958	-43,983	0%
Operating result	-26,352	-26,685	-1%

¹⁸ Developed in collaboration with Immunexpress. More info [here](#)
¹⁹ 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)

²⁰ 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])

²¹ 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. 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

Net financial result	-5,129	-2,822	82%
Share in the result of associated companies	-195	-181	8%
Income tax	118	18	556%
Net result	-31,558	-29,670	6%
Cash flow from operating activities	-24,526	-28,357	-14%
Cash flow from investing activities	-1,028	-5,267	-80%
Cash flow from financing activities	-3,456	179,465	-102%
Net cash flow¹	-29,010	145,841	-120%
Cash and cash equivalents²	149,674	209,200	-28%
Financial debt	165,258	166,578	-1%

¹ Excludes the effect of exchange rate differences on the cash balances held in foreign currencies

² Including EUR 1.2m of restricted cash in H1 2020 and H1 2019

Operating income (EUR 1,000)	H1 2020	H1 2019	% Change
Collaboration revenue	4,746	6,816	-30%
Idylla™ system sales	1,837	2,499	-26%
Idylla™ cartridge sales	9,584	7,481	28%
Product sales revenue	11,421	9,980	14%
Service revenue	530	351	51%
Total revenue	16,697	17,147	-3%
Grants and other income	909	151	502%
Total operating income	17,606	17,298	2%

Product sales revenue (EUR 1,000)	H1 2020	H1 2019	% Change
Commercial revenue	10,491	9,551	10%
Research & development revenue	930	429	117%
Total product sales revenue	11,421	9,980	14%

Outlook

- *Commercial cartridge volume:* Targeting a year-over-year commercial volume growth in the range of 30%, representing a volume of Idylla™ cartridges in the range of 228k.
- *Idylla™ installed base:* Targeting an installed base growth in the range of 300-350 new Idylla™ instrument placements.
- *Idylla™ test menu outlook:* COVID-19 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 (instead of end 2020 initially);
 - Lung cancer menu – Minor delay of the RUO launch of the Idylla™ GeneFusion Assay to Q1 2021 (instead of end 2020 initially);
 - Breast cancer menu – The plan for the Idylla™ IVD Oncotype DX Breast Recurrence Score® test is under evaluation and 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.

Financial calendar 2020

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

Auditor Statement

The condensed consolidated financial statements for the six-months' period ended 30 June 2020 have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union. They do not include all the information required for the full annual financial statements and should therefore be read in conjunction with the financial statements for the year ended 31 December 2019. The condensed consolidated financial statements are presented in thousands of Euros (unless stated otherwise). The condensed consolidated financial statements have been approved for issue by the Board of Directors. The statutory auditor, Deloitte Bedrijfsrevisoren/Reviseurs d'Entreprises, represented by Nico Houthaeve, has performed a review, which did not reveal any significant adjustments to the condensed consolidated financial statements. The interim financial report 2020 and the review opinion of the auditor are available on www.biocartis.com.

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About Biocartis

Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer. More information: www.biocartis.com. Follow us on [Twitter](https://twitter.com/Biocartis): @Biocartis_.

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