

Thursday, 5 September 2019, 07:00 CEST

## BIOCARTIS ANNOUNCES H1 2019 RESULTS

**Mechelen, Belgium, 5 September 2019** – 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 2019, prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union. Furthermore, the Company provides an updated outlook for the full year 2019.

### Key messages

- **Installed base:** Increased with 156 Idylla™ instruments in H1 2019, bringing the total to 1,129 as per 30 June 2019.
- **Cartridge volume:** Commercial cartridge volume amounted to 72k cartridges in H1 2019, representing a year-over-year increase of 24%. Commercial cartridge volume growth in H1 2019 was below expectations driven by a slower pick-up in US cartridge volumes.
- **Total operating income:** Increased year-over-year with 36% to EUR 17.3m driven by higher collaboration and product revenues.
- **Test menu:** Successful CE-marking of the Idylla™ MSI Test on 28 February 2019, further strengthening Biocartis' colorectal cancer (CRC) Idylla™ test menu.
- **Immuno-oncology menu:** Menu expansion into immuno-oncology through new partnerships with Bristol-Myers Squibb Company (NYSE: BMY), aimed at the registration of the Idylla™ MSI test as a companion diagnostic<sup>1</sup> for immuno-oncology therapies, and with Kite Pharma, Inc. (a Gilead Company), aimed at the development of Idylla™ assays that are supportive to Kite's therapies.
- **Commercial footprint:** Announcement of a commercialization agreement with Nichirei Biosciences Inc. for the Japanese market. Biocartis' commercial network now covers all major molecular diagnostics markets worldwide. Post the reporting period, on 5 September 2019, Biocartis and Fisher Healthcare announced to jointly terminate, with immediate effect, their distribution collaboration for the US market.
- **Cash position:** Cash and cash equivalents of EUR 209m as per end of H1 2019, driven by a successful equity capital raise of EUR 55.5m, a convertible bonds issue of EUR 150m and the repayment of the Company's subordinated loan of EUR 15m.

### Updated 2019 guidance

- **Installed base:** Guidance for full year installed base growth is now set in the range of 325-350 new Idylla™ instrument placements.
- **Cartridge volume:** Guidance for full year commercial Idylla™ cartridge volume growth is decreased and now set in the range of 30% - 35%.
- **Cash position:** Guidance for cash position now set in the range of EUR 170m-175m by year-end.

*Biocartis will host a conference call with live webcast presentation today at 14:00 CEST / 13:00 BST (UK) / 08:00 EDT (US) to discuss the H1 2019 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 (0)8445718892 (standard international), followed by the confirmation code 9075637.*

*The conference call and webcast will be conducted in English.*

*A replay of the webcast will be available on the [Biocartis investors' website](#) shortly thereafter.*

**Commenting on the H1 2019 results, Herman Verrelst, Chief Executive Officer Biocartis, said:** "During H1 2019, we realized continued commercial growth in Europe and our RoW<sup>2</sup> distributor markets and we maintain a good outlook for full year installed base growth. Despite the number of new high profile US customers that we attracted in the first half of this year, we encountered a delay in the actual US commercial cartridge volume ramp-up. While we take all actions to address this situation, our total cartridge volume growth for 2019 will be impacted. Good progress was made on other fronts. We added another CE-marked IVD test to our menu, further progressed work on US FDA filings and ventured into the immuno-oncology space, one of our strategic focus areas, with BMS and Kite as partners. Furthermore, with the closing of our commercialization deal for Japan, our commercial

<sup>1</sup> 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 26 August 2019

<sup>2</sup> RoW = Rest of World. RoW is defined as the world excluding Europe, US, China and Japan

*footprint is now covering all major markets worldwide. Finally, we significantly strengthened our financial position for the upcoming years thanks to a successful equity raise and a convertible bonds issuance. Overall, despite the delay incurred in US commercialization, we significantly strengthened our business in H1 2019 and feel confident about continuing our efforts for the remainder of the year, further supporting our ambitions towards building a leading global oncology business around the Idylla™ platform.”*

### **Commercial highlights**

- *Installed base* – The Idylla™ installed base increased with 156 instruments in H1 2019 driven by a continued growth across markets. The number of realized new placements in Europe and RoW<sup>2</sup> geographies exceeded expectations. On 26 February 2019, Biocartis announced that it has added its 1,000th Idylla™ instrument to its installed base, placed in the US with the Diagnostic Medicine Institute at Geisinger<sup>3</sup>. End of June 2019, the total installed base amounted to 1,129 Idylla™ instruments.
- *Commercial cartridge volume* – H1 2019 commercial cartridge volume amounted to 72k cartridges, representing a 24% year-over-year growth. Realized cartridge volume growth in H1 2019 was below expectations driven by a slower pick-up of US RUO<sup>4</sup> cartridge volumes.
- *European commercialization* – European direct markets performed well in H1 2019 with a continued growth in cartridge volumes and an installed base growth that exceeded expectations. This was mainly driven by an increased usage of Idylla™ in first line testing in amongst others the UK, France and Italy, as well as a strong overall contribution from pharma collaborations.
- *US commercialization* – During H1 2019, the US customer base was further expanded with new high profile customers. While efforts were made to accelerate the Idylla™ implementation timeline of instruments at these new customers, cartridge volume pick-up was below expectations due to a more gradual increase of cartridge orders after the Idylla™ instrument implementation. The latter is related to a variety of reasons including education on amended standard operational procedures and a gradual switch from current testing methodologies to Idylla™. A number of US customers is currently completing Idylla™ implementation which is expected to drive cartridge volume ramp-up over the course of H2 2019. We expect to accelerate further growth of the US customer base once the operational transition from Fisher Healthcare (see paragraph post-period events below) is completed and the expansion of the Biocartis US direct sales team is further progressed.
- *Distribution markets RoW<sup>2</sup>*– Biocartis’ RoW distribution markets realized a solid performance in H1 2019 with new instrument placements exceeding expectations and significant continued cartridge volume growth. This was driven by a strong customer base expansion in Canada, Asia, Eastern Europe and North Africa and new market authorizations for products in amongst others Colombia and Thailand.
- *China commercialization*: Completion of the closing of the joint venture with Wondfo (‘China JV’) in Q1 2019 resulted in the first capital contribution by both partners and subsequently the payment by the China JV of a license fee to Biocartis.
- *Japan commercialization*: On 7 January 2019, Biocartis announced the signing of an agreement with Nichirei Biosciences Inc., a leading supplier of biological and diagnostics products in Japan, for the product registrations and distribution of the Idylla™ platform in Japan. Upon successful registration, Nichirei Biosciences’ sales force is expected to commercialize the Idylla™ platform across its network of approximately 2,000 pathology laboratories. During H1 2019, Biocartis and Nichirei Biosciences further progressed registration preparations for the Idylla™ instrumentation and assays for the Japanese market.

### **Menu and partnership highlights**

- *Colorectal cancer menu:*
  - CE-marking Idylla™ MSI Test – On 28 February 2019, Biocartis announced the CE-marking of its fully automated Idylla™ MSI Test. MSI testing is currently recommended for all colorectal and endometrial cancers<sup>5</sup> but is still underused since current methods are highly complex. The Idylla™ MSI Test has been developed to overcome these drawbacks. The test provides information on the MSI status<sup>6</sup> (i.e. Microsatellite Instability-High (MSI-H) or Microsatellite Stable (MSS)) of colorectal cancer (CRC) tumors within approximately 150 minutes from just one slice of FFPE<sup>7</sup> tumor tissue, without the need for a reference sample. The Idylla™ MSI Test<sup>8</sup> shows high concordance (>97%) and lower failure rates compared to

<sup>3</sup> Source: [www.geisinger.org](http://www.geisinger.org), last consulted on 26 August 2019

<sup>4</sup> All Idylla™ assays sold in the US are for Research Use Only (RUO), not for use in diagnostic procedures

<sup>5</sup> Source: ASCO guidelines, [www.asco.org/endorsements/HereditaryCRC](http://www.asco.org/endorsements/HereditaryCRC)

<sup>6</sup> Clinical Performance Study showed 99.7% concordance for MSI testing vs Promega (unpublished data); De Craene et al. (2018) Journal of Clinical Oncology 36:15 suppl, e15639; De Craene et al. (2017) Annals of Oncology 28 (suppl\_5): v209-v268; Maertens et al. (2017) Annals of Oncology 28 (suppl\_5): v22-v42

<sup>7</sup> FFPE = formalin fixed, paraffin embedded

<sup>8</sup> The Idylla™ MSI Test uses a new set of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A & SULF2 genes, which were exclusively licensed to Biocartis in 2013 from VIB, the life sciences research institute in Flanders (Belgium), and originated from the research of the group of Prof. Diether Lambrechts (VIB-KU Leuven, Belgium). These MSI biomarkers are tumor-specific, show a high frequency in colorectal and endometrial cancers and are stable across different ethnicities ensuring excellent specificity of the assay

- standard methods. The unique aspects of the Idylla™ MSI Test could enable a broader penetration of MSI testing, and make this test a key addition to Biocartis' Idylla™ CRC test menu.
- US FDA submission of MSI assay – During H1 2019, further progress was made in the preparation of the regulatory US FDA submission documentation of the Idylla™ MSI Assay, which is expected in 2020, subject to further feedback from the US FDA.
  - US FDA submission of RAS tests – During H1 2019, further progress was made in the preparation of the regulatory US FDA submission documentation of the Idylla™ RAS PMA<sup>9</sup>, which is expected in 2020, subject to further feedback from US FDA.
  - *Lung cancer menu:*
    - ctEGFR – During H1 2019, further progress was made in the development of the liquid biopsy version of the Idylla™ EGFR Mutation Test. This test is planned for RUO<sup>10</sup> launch in Q4 2019 and is an important addition to Biocartis' lung cancer menu for liquid biopsy EGFR testing. Liquid biopsy EGFR testing is included in the guidelines<sup>11</sup> for situations where no tumor tissue is available for EGFR testing.
    - GeneFusion – During H1 2019, further progress was made in the development of the Idylla™ GeneFusion Panel. This assay is expected to be launched in 2020 and covers, together with the Idylla™ EGFR Mutation Test (CE-IVD), the majority of actionable lung cancer mutations.
  - *Immuno-oncology menu:*
    - Partnership BMS – On 12 March 2019, Biocartis announced the signing of a collaboration agreement with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company, focused on MSI testing in connection with immuno-oncology therapies. Bristol-Myers Squibb's Opdivo® (nivolumab) plus low-dose Yervoy®<sup>12</sup> (ipilimumab) is the first immuno-oncology combination treatment approved by the US FDA for MSI-High or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with certain chemotherapies<sup>13</sup>. The collaboration agreement allows for joint developments and registrations of the Idylla™ MSI test for use in a variety of indications, commercial settings and geographies. The first focus under the agreement is expected to be the registration in the US of the Idylla™ MSI assay as a companion diagnostic<sup>14</sup> (CDx) device in mCRC.
    - Partnership Kite – On 1 June 2019, Biocartis announced a master development and commercialization agreement with Kite Pharma, Inc., a Gilead Company (NASDAQ: GILD), a pharmaceutical company engaged in the development of innovative cancer cell therapies. The collaboration aims at the development of molecular-based assays on the Idylla™ platform that are supportive to Kite's therapies.
  - *Breast cancer menu:*
    - Partnership Genomic Health Inc. - During H1 2019, the development of an Idylla™ version of the Oncotype DXi IVD Breast Recurrence Score® Test was further progressed. Moreover, preparations were initiated for Idylla™ instrument placements at early access sites for the validation studies in Europe, beginning in France and Germany. Importantly, on 20 June 2019, Genomic Health announced that the German Federal Joint Committee (G-BA) issued a positive reimbursement decision for the Oncotype DX Breast Recurrence Score® Test. This decision makes the Oncotype DX® the only multigene test reimbursed by statutory sick funds with wide national coverage in Germany, for use in all patients with primary node-negative, hormone receptor-positive, HER2-negative early-stage breast cancer when a decision for or against chemotherapy cannot be made based on clinical and pathological parameters alone<sup>15</sup>.
  - *Covance partnership:* On 23 April 2019, Biocartis announced the global strategic commercialization agreement with Covance, LabCorp's Drug Development business, aimed at offering the Idylla™ platform and its existing Idylla™ oncology assay menu to Covance's customer base globally to support customer needs for clinical trials and, when appropriate, to validate and implement companion diagnostic applications.
  - *Idylla™ publications:* During H1 2019, approx. 30 abstracts, posters and publications were published on the Idylla™ platform and its assays, of which 12 in the US. Several were selected for publication at large scientific conferences, including:
    - Idylla™ MSI performance study at ASCO – On 16 May 2019, a multi-centered study<sup>16</sup> on the performance of the Idylla™ MSI Test (CE IVD) in comparison with the Promega MSI test ('Promega MSI Test') was selected

<sup>9</sup> PMA = Pre-Market Approval

<sup>10</sup> RUO = Research Use Only, not for use in diagnostic procedures

<sup>11</sup> Source: D. Plancharde et al., 'Metastatic non-small cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up', published online 3 October 2018; updated 26 January 2019

<sup>12</sup> 3 mg/kg Opdivo® plus 1 mg/kg Yervoy®

<sup>13</sup> Treatment with fluoropyrimidine, oxaliplatin and irinotecan

<sup>14</sup> 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 16 August 2019

<sup>15</sup> The G-BA decision will become effective following its publication by the Ministry of Health in the Federal Gazette (Bundesanzeiger). Source: Genomic Health website, <https://newsroom.genomichealth.com/news-releases/news-release-details/german-federal-joint-committee-g-ba-issues-exclusive-nationwide>, last consulted on 26 August 2019

<sup>16</sup> Pauwels P. et al, 'The Idylla™ MSI Test multi-center concordance study: microsatellite instability detection in colorectal cancer samples', first published at ASCO Annual Meeting of the American Society of Clinical Oncology, 30 May – 4 June 2019, Chicago (IL), US

for publication at the renowned ASCO (American Society of Clinical Oncology) Annual Meeting. This [study](#) showed high performance and a low invalid rate of the Idylla™ MSI Test, as such demonstrating the possibility of rapid, fully automated MSI testing with Idylla™.

- USCAP Idylla™ studies – A total of six Idylla™ studies were presented by four different US customers at the United States and Canadian Academy of Pathology ('USCAP') Annual Meeting in Maryland, US: (1) Dartmouth Hitchcock Medical Center (a CRC focused prospective study and a melanoma focused study with comparison to NGS), (2) Medical College of Wisconsin (a CRC focused study with comparison to PCR<sup>17</sup> and IHC<sup>18</sup> for Microsatellite Instability Status and a multiple cancers focused study using challenging FFPE samples not suitable for conventional sanger and NGS testing), (3) Memorial Sloan Kettering Cancer Center (a hairy cell leukemia focused study using different sample types including stained smear slides, blood and bone marrow without pre-extraction) and (4) Wake Forest Baptist Health (a melanoma focused study using pigmented melanomas). The posters of the referenced studies can be found [here](#).

### Organizational and operational highlights

- *Management team* – In light of the Company's further international growth, expansion of its partner network and associated scaling of the organization, several changes to the Company's management team were effectuated:
  - Appointment Chief Operating Officer – Piet Houwen joined Biocartis as its Chief Operating Officer in April 2019.
  - Appointment Global Head Pharma Collaborations and Partnering – Dirk Zimmermann joined Biocartis in May 2019 as Global Head of Pharma Collaborations and Partnering.
  - Changes in the Chief Commercial Officer role – Biocartis and Hilde Eylenbosch, the Company's Chief Commercial Officer, have agreed to terminate their collaboration as per the end of April 2019. The tasks of the CCO have been temporarily reallocated to the Company's CEO and senior commercial management.
- *Cartridge manufacturing* – During H1 2019, progress was made in the production transfer to the new cartridge manufacturing line and commercial manufacturing of the Idylla™ KRAS Mutation Test was started on this line.

### Financial highlights

- *Total operating income* – Total operating income increased year-over-year with 36% to EUR 17.3m driven by increased collaboration and product revenues. Collaboration revenues increased from EUR 3.6m in H1 2018 to EUR 6.8m in H1 2019, a growth of 93%. Product revenues amounted to EUR 10.0m in H1 2019, a year-over-year increase of 17%.
- *OPEX* – Total operating expenses (including cost of sales) increased from EUR 33.9m in H1 2018 to EUR 44.0m in H1 2019, an increase of 30%. This was amongst others driven by increased costs of sales due to higher commercial product volumes, increased R&D expenses due to the addition of menu partnerships, increased marketing & sales expenses due to the expansion of the US sales force and increased general & administrative expenses due to overall organizational growth as well as a general cost allocation that is shifting more towards a commercial stage organizational structure.
- *Equity raise* – On 23 January 2019, Biocartis announced that it successfully raised an amount of EUR 55.5m in gross proceeds by means of an over-subscribed private placement via an accelerated bookbuild offering.
- *Convertible bonds issue* – On 2 May 2019, Biocartis announced the issue of EUR 150 million senior unsecured convertible bonds due 9 May 2024. An application will be made for the convertible bonds to be listed and admitted to trading on the regulated market of Euronext Brussels by no later than 1 December 2019.
- *Repayment subordinated loan* – In June 2019, Biocartis exercised an early repayment option under its subordinated loan to optimize interest payment obligations. That loan had a nominal amount of EUR 15m, carried a 7% interest rate, had an initial duration of 5 years and was due July 2021. The cash out related to the early repayment amounted to EUR 18.5m based on the nominal amount of the loan and capitalized interest.
- *Net cash flow and cash position* - Total net cash flow in H1 2019 amounted to EUR 145.8m versus EUR -21.4m in H1 2018. Biocartis' cash position as per end June 2019 amounted to EUR 209m.
- *Additional details* – See 'key figures for H1 2019' below for more details on the H1 2019 financials.

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<sup>17</sup> Polymerase Chain Reaction

<sup>18</sup> Immunohistochemistry

## Post-period events

- *AACC* – On 5 August 2019, Biocartis announced that a study<sup>19</sup> poster on the performance of the Idylla™ NRAS-BRAF Mutation Assay (RUO) was presented by Dr. Gregory Tsongalis, PhD. (Director, Laboratory for Clinical Genomics and Advanced Technology of the Dartmouth-Hitchcock Medical Center) at the 71st AACC (American Association for Clinical Chemistry) Annual Scientific Meeting that took place between 4-8 August in Anaheim, CA (US). The study concluded that the Idylla™ system offers rapid and accurate testing of NRAS and BRAF mutations in melanoma directly from FFPE tissue, and that its simplicity and ease of use compared to other available molecular techniques make it suitable for small centers that lack specifically trained staff and infrastructure.
- *Termination distribution agreement Fisher Healthcare* – On 5 September 2019, Biocartis and Fisher Healthcare announced that they jointly agreed to terminate, with immediate effect, their distribution collaboration for the US market. Going forward, Biocartis' US direct sales team will drive US commercialization and will be further expanded according to market needs.

## News flow H2 2019

- *Menu expansion:*
  - Colorectal cancer menu – Regulatory submission of the Idylla™ MSI Assay documentation with the US FDA and a PMA<sup>20</sup> submission of the Idylla™ RAS tests documentation, subject to further feedback from US FDA, expected in 2020;
  - Lung cancer menu – Launch of a liquid biopsy version of the Idylla™ EGFR Mutation Assay (RUO<sup>21</sup>) expected in Q4 2019. Further development of the Idylla™ GeneFusion Panel towards expected launch in 2020; and
  - Breast cancer menu – Placement of Idylla™ instruments at European sites expected in Q4 2019 as a preparation for the clinical validation studies of the Idylla™ Oncotype DXi IVD Breast Recurrence Score™ test.
- *Full year 2019 guidance updated:* Expected full year installed base growth in the range of 325-350 Idylla™ instruments, full year increase in commercial Idylla™ cartridge volume in the range of 30%-35% and a targeted cash position in the range of EUR 170m -175m by year end.

## Key figures for H1 2019

The tables below show an overview of the key figures and a breakdown of operating income for H1 2019. Consolidated financial statements including notes are included in Biocartis' financial report for H1 2019 that can be downloaded from the Company's website [here](#).

Key figures (EUR 1,000)	H1 2019	H1 2018	% Change
<b>Total operating income</b>	<b>17,298</b>	<b>12,741</b>	<b>36%</b>
Cost of sales	-8,742	-6,890	27%
Research and development expenses	-20,031	-16,029	25%
Marketing and sales expenses	-8,811	-7,152	23%
General and administrative expenses	-6,399	-3,809	68%
<b>Operating expenses</b>	<b>-43,983</b>	<b>-33,880</b>	<b>30%</b>
<b>Operational result</b>	<b>-26,685</b>	<b>-21,139</b>	<b>26%</b>
Net financial result	-2,822	-691	308%
Share in the result of associated companies	-181	0	
Income tax	18	70	-74%

<sup>19</sup> M. Rabie Al-Turkmani et al., 'Evaluation of a Cartridge-Based System for Rapid Detection of BRAF and NRAS Mutations in Melanoma', Dartmouth-Hitchcock Medical Center and Geisel School of Medicine at Dartmouth, first published at the 71st AACC Annual scientific meeting & clinical lab expo, 4-8 August 2019, Anaheim (CA), US, available on <https://www.abstractsonline.com/pp8/#!/6831/presentation/566>

<sup>20</sup> PMA = Pre-Market Approval

<sup>21</sup> Research Use Only, not for use in diagnostic procedures

<b>Net result</b>	<b>-29,670</b>	<b>-21,760</b>	<b>36%</b>
Cash flow from operating activities	-28,357	-20,335	39%
Cash flow from investing activities	-5,267	-2,301	129%
Cash flow from financing activities	179,465	1,251	na
<b>Net cash flow<sup>1</sup></b>	<b>145,841</b>	<b>-21,385</b>	<b>na</b>
<b>Cash and cash equivalents<sup>2</sup></b>	<b>209,200</b>	<b>91,269</b>	<b>129%</b>
Financial debt	166,731	38,145	372%

<sup>1</sup> Excludes effects of exchange rate changes on the balance of cash held in foreign currencies

<sup>2</sup> Including EUR 1.2m of restricted cash (as a guarantee for KBC lease financing)

<b>Operating income (EUR 1,000)</b>	<b>H1 2019</b>	<b>H1 2018</b>	<b>% Change</b>
<b>Collaboration revenue</b>	<b>6,816</b>	<b>3,535</b>	<b>93%</b>
Idylla™ System sales	2,499	1,952	28%
Idylla™ Cartridge sales	7,481	6,603	13%
<b>Product sales revenue</b>	<b>9,980</b>	<b>8,555</b>	<b>17%</b>
Service revenue	351	251	40%
<b>Total revenue</b>	<b>17,147</b>	<b>12,341</b>	<b>39%</b>
Grants and other income	151	400	-62%
<b>Total operating income</b>	<b>17,298</b>	<b>12,741</b>	<b>36%</b>

<b>Product sales revenue (EUR 1,000)</b>	<b>H1 2019</b>	<b>H1 2018</b>	<b>% Change</b>
Commercial revenue	9,551	7,950	20%
Research & Development revenue	429	605	-29%
<b>Total product sales revenue</b>	<b>9,980</b>	<b>8,555</b>	<b>17%</b>

#### *Income statement*

Collaboration revenues in H1 2019 increased year-over-year to EUR 6.8m driven by a strong growth in R&D services and license revenues, partially offset by the absence of milestone payments. R&D services, consisting of invoiced services to pharma and content partners, increased from EUR 2.6m in H1 2018 to EUR 4.4m in H1 2019 as a consequence of new partnerships closed in H2 2018 and H1 2019. License revenues increased from EUR 75k in H1 2018 to EUR 2.4m in H1 2019 and included a EUR 2m revenue recognition of a EUR 4m license payment from the China joint venture that was received in H1 2019 following the formal closing of that joint venture. No milestones revenues were recorded in H1 2019 versus EUR 0.8m of milestones in H1 2018.

Product sales revenues increased year-over-year with 17% to EUR 10.0m driven by an increase in cartridge sales and instrument revenues. Cartridge sales increased from EUR 6.6m in H1 2018 to EUR 7.5m in H1 2019, a year-over-year increase of 13%. Instrument revenues amounted to EUR 2.5m in H1 2019, a year-over-year increase of 28% as the consequence of the increase in installed base in H1 2019 and of an increased revenue contribution from instruments placed at clients under leasing contracts in previous periods. Year-over-year, commercial product

revenues increased with approx. 20% whereas R&D product revenues decreased with 29%.

Service revenues increased year-over-year with 40% to EUR 0.4m. Grants and other income amounted to EUR 0.2m in H1 2019. Consequently, total operating income amounted to EUR 17.3m versus EUR 12.7m in H1 2018, a year-over-year increase of 36%.

Total operating expenses (including cost of sales) amounted to EUR 44.0m in H1 2019 versus EUR 33.9m in H1 2018, an increase of 30%. Cost of sales increased year-over-year with 27% to EUR 8.7m in H1 2019 driven by higher cartridge as well as instrument volumes. Expenses for R&D amounted to EUR 20.0m in H1 2019, a year-over-year increase of 25% that was predominantly driven by higher staffing costs and allocated depreciation expenses (see comment below on adoption IFRS 16). Expenses for sales and marketing increased year-over-year with 23% and amounted to EUR 8.8m. This increase was mainly driven by higher staffing costs, as a consequence of an expansion of Biocartis' US sales team and higher expenses for consultancy and subcontracting. G&A expenses increased year-over-year with 68% to EUR 6.4m due to overall organizational growth as well as a general cost allocation that is shifting more towards a commercial stage organizational structure. The above resulted in an operational result for H1 2019 equal to EUR -26.7m compared to EUR -21.1m in H1 2018. Following a net financial result for the period of EUR -2.8m, of which EUR 1.1 m is related to accrued interest of the outstanding convertible bond and EUR 1.0m related to interest and repayment of the Company's subordinated loan, the net result for H1 2019 equaled to EUR -29.7m compared to EUR -21.8m in H1 2018.

#### *Balance sheet*

As required, Biocartis has adopted the new IFRS 16 standard for lease accounting with date of initial application on 1 January 2019. This standard introduces a single lessee accounting model and requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, eliminating the distinction between operating and finance leases. The first time adoption of IFRS 16 has an impact on the Group's balance sheet as well as results in a reclassification of operational expenses in the Group's income statement. Concretely, as of 1 January 2019, Biocartis also recognizes its operational leasing contracts (i.e. for buildings, company cars and office furniture) on its balance sheet in addition to the Group's financial leasing contracts (i.e. for manufacturing equipment). This resulted in a one-off increase in property, plant and equipment and lease liabilities of EUR 14.3m on 1 January 2019. Furthermore, as property, plant and equipment is depreciated over time, the income statement recognizes depreciation charges and financing expenses for all the recognized leases versus previously the recognition of lease payments as e.g. building rent or facility & office expenses.

Property, plant and equipment increased in H1 2019 to EUR 43.7m as per end of June 2019 from EUR 30.4m at the end of 2018, an increase of EUR 13.3m. This increase was driven by a EUR 15.3m impact of IFRS 16 (as per 30 June 2019), EUR 2.8m of actual capital expenditures (mainly related to capitalization of instrumentation placed at clients under leasing or rental contracts) and a depreciation charge of around EUR 4.9m. Investments in associates and joint ventures was added to the balance sheet in H1 2019 in relation to the closing of the China joint venture and amounts to EUR 2.6m as per end of June 2019.

Inventory increased in H1 2019 to EUR 15.4m (versus EUR 11.9m per end 2018), predominantly driven by an increase in finished products of both cartridges and Idylla™ instrumentation. Trade and other receivables decreased in H1 2019 with EUR 1.14m due to lower trade receivables. On the other side of the balance sheet, trade payables decreased with EUR 2.8m to EUR 5.2m. Deferred income decreased with EUR 0.6m and accrued charges decreased with EUR 1.5m, the latter mainly driven by the first time adoption of IFRS 16.

The Group's cash and cash equivalents end of H1 2019 amounted to EUR 209.2m compared to EUR 63.5m end of 2018. Total financial debt end of H1 2019 amounted to EUR 166.7m, representing an increase of EUR 131.4m compared to end of 2018. This was the result of the issuance of a convertible bond, an increase in lease liabilities in the context of the first time adoption of IFRS 16 and the repayment of the Company's subordinated loan. Please note that the IFRS accounting treatment of the Company's convertible bond has resulted in an allocation of the EUR 150m nominal amount to financial debt (EUR 134m) and equity (EUR 12m, adjusted for related transaction costs) as per the end of H1 2019.

#### *Cash flow statement*

The cash flow from operating activities in H1 2019 amounted to EUR -28.4m compared to EUR -20.3m in H1 2018. This increase is the result of a higher operating loss for the period, an increase in investments in working capital as well as higher interest and other financial expenses for H1 2019. The cash flow from investing activities in H1

2019 amounted to EUR –5.3m (compared to EUR -2.3m in H1 2018) and consisted of the initial capital contribution made to the China joint venture and capitalized Idylla™ systems. The cash flow from financing activities in H1 2019 amounted to EUR 179.5m (compared to EUR 1.3m in H1 2018) which was driven by the issuance of the convertible bonds (net proceeds of EUR 145.5m) and by the capital raise (net proceeds of EUR 53.4m), partially offset by the repayments of borrowings (predominantly the Company's subordinated loan) of EUR 19.4m. Because of the aforementioned, the net cash flow of H1 2019 amounted to EUR 145.8m compared to EUR –21.4m in H1 2018.

#### **Financial calendar**

- Special Shareholders' Meeting – 27 September 2019
- Q3 2019 business update – 14 November 2019
- 2019 full year results – 27 February 2020
- Publication 2019 annual report – 2 April 2020

#### **Webcast and presentation**

Biocartis will host a conference call with live webcast, during which the H1 2019 results will be presented, followed by a Q&A session. This event will be held today, 5 September 2019 at 14:00 CEST / 13:00 BST (UK) / 08:00 EDT (USA). Access the webcast by clicking [here](#). If you would like to participate in the Q&A, please dial +44 (0) 8445718892 (standard international), followed by the confirmation code 9075637. A replay of the webcast will be available on the [Biocartis investors' website](#) shortly after.

#### **Auditor Statement**

The condensed consolidated financial statements for the six-months' period ended 30 June 2019 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 2018. 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 Gert Vanhees, has performed a review, which did not reveal any significant adjustments to the condensed consolidated financial statements. The interim financial report 2019 and the review opinion of the auditor are available on [www.biocartis.com](http://www.biocartis.com).

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#### **More information:**

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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 in oncology. This 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](http://www.biocartis.com). Press Photo Library available [here](#). Follow us on [Twitter](#): @Biocartis\_.

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### **Forward-looking statements**

*Certain statements, beliefs and opinions in this press release 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 press release 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 press release, 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 press release 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 press release 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 press release.*