PRESS RELEASE

REGULATED INFORMATION

Thursday, 6 September 2018, 07:00 CEST

BIOCARTIS ANNOUNCES H1 2018 RESULTS

Mechelen, Belgium, **6 September 2018 –** 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 2018, prepared in accordance with the IAS 34 Interim Financial Reporting as adopted by the European Union. Furthermore, the Company provides it updated outlook for the full year 2018.

Key messages H1 2018 results

- **Installed base:** Increased with 149 Idylla™ instruments in H1 2018, bringing the total close to 800 as per 30 June 2018.
- **Cartridge consumption:** Commercial consumption more than doubled year-over-year in H1 2018 and amounted to approximately 58k cartridges.
- **Total operating income:** Increased year-over-year with 83% to EUR 12.7m driven by higher product and collaboration revenues.
- **MSI testing**: Accelerated development of the Idylla™ MSI Assay (RUO[1]) in H1 2018, resulting in a successful launch on 17 July 2018, following amongst others the publication of several studies that demonstrated its superior performance compared to reference methods.
- **Partnership tests:** Second CDx (Companion Diagnostics) partnership signed with Amgen for the development of Idylla™ CDx biomarker tests for a novel oncology compound and partnership signed with Immunexpress aimed at the development and commercialization of Immunexpress' SeptiCyte™ test for use on the Idylla™ platform.
- **China strategy:** Finalization in H1 2018 of the Company's China strategy, resulting in a joint venture announcement on 3 September 2018 with Wondfo, a fast growing diagnostics leader in China, for the commercialization of the Idylla™ platform and MDx oncology products in mainland China.
- **Cash position:** Cash and cash equivalents of EUR 91.3m as per end H1 2018. No drawdowns were made on the Company's multiple purpose credit facility of EUR 27.5m as per end of H1 2018.

Updated 2018 guidance

- **Installed base:** Guidance on instrument placements for 2018 now set at the top end of the targeted 250 - 275 range, bringing the forecasted installed base to around 925 Idylla™ instruments by year-end.
- **Cartridge consumption:** Guidance to double year-over-year commercial cartridge consumption in 2018 reiterated.
- **Cash position:** Targeted year-end cash position narrowed to around EUR 50-55m, excluding drawdowns on the Company's multiple purpose credit facility.

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 2018 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)330 336 9125 (standard international), followed by the confirmation code 3161692.
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 2018 results, Herman Verrelst, Chief Executive Officer Biocartis, said: *"Our European direct and RoW[2] markets showed good momentum in H1 2018, Europe even exceeding our expectations. Furthermore, I am pleased that in H1 2018 we could significantly strengthen our commercial presence in the US by attracting amongst others top tier customers who fueled a strong US installed base growth. This demonstrates the attractiveness of the Idylla™ platform for the US market, paving the way for further market adoption. All of this allowed us to grow our installed base to close to 800 instruments and to realize a doubling of cartridge volumes year-over-year. In addition to that, the expansion of existing and addition of new test menu collaborations in H1 2018 will allow us to further build on this momentum, as such collaborations have shown to be an accelerator in the market adoption of Idylla™. It is in this context that we have further redirected internal resources in H1 2018*

[1] RUO = Research Use Only, not for use in diagnostic procedures.
[2] RoW = Rest of the World. RoW is defined as the world excluding Europe, US, China and Japan.

to facilitate such partnerships. Finally, driven by strong demand from customers, we accelerated the development of our unique MSI test and managed to successfully launch this product in July 2018, an important kick-starter for the second half of this year!"

Commercial highlights

- *Installed base* – The Idylla™ installed base increased with 149 instruments in H1 2018 driven by higher than expected growth in Europe and strong placements in the US, the latter contributing to approximately 1/3 of overall growth. End of June 2018, the total installed base amounted to 796 Idylla™ instruments.
- *Commercial cartridge volume:* H1 2018 commercial volume increased to approximately 58k cartridges, which is more than a doubling of the H1 2017 volume (approximately 27k cartridges). Europe followed by RoW contributed most to the growth in commercial cartridge volume.
- *European commercialization* – The H1 2018 performance of European direct markets exceeded expectations driven by amongst others an increased usage of Idylla™ in first line testing in amongst others the UK, France and Germany as well as a strong overall contribution from pharma collaborations.
- *US commercialization* - During H1 2018, Biocartis significantly expanded the US customer base with new high profile customers across small, medium and large volume laboratories and hospitals, including some of the top 10 oncology hospitals in the US[3]. This has resulted in strong instrument placements with a promising volume potential and an initial ramp-up of cartridge volumes. Pending validation efforts at existing US customers, combined with an ongoing expansion of Biocartis' US sales team is expected to fuel further growth of both the US installed base and cartridge volume growth in H2 2018. In H2 2018, the market adoption of Idylla™ in the US will be further supported by Biocartis' presence at the leading Association for Molecular Pathology (AMP) conference in November 2018. Here, Biocartis will amongst others host a workshop with testimonials from Maria E. Arcila, MD (Director Diagnostic Molecular Pathology Laboratory) and Khedoudja Nafa, PharmD PhD (Molecular Geneticist) of Memorial Sloan Kettering Cancer Center, a leading cancer treatment and research hospital in the US, and during which several Idylla™ performance studies by US KOLs[4] will be presented.
- *Distribution markets RoW* – Biocartis obtained additional market authorizations for its products in Argentina, Brazil, Canada, Malaysia, Mexico, Singapore and Uruguay in H1 2018. A promising growth in cartridge volumes was observed across key RoW markets driven by increased commercialization efforts of both distribution and pharma partners.

Partnership menu highlights

- *CDx business* - On 9 January 2018, Biocartis announced its second CDx development agreement with Amgen, a leading biotechnology company (NASDAQ: AMGN), aimed at the development of Idylla™ CDx biomarker tests for a novel oncology compound to be used in the treatment of certain solid tumors.
- *Undisclosed feasibility projects* – In H1 2018, Biocartis advanced promising undisclosed pharma-sponsored feasibility projects aimed at the development of new Idylla™ assays that are to be used for monitoring purposes, of which one focused on the field of immuno-oncology.
- *Partnership Genomic Health* – On 3 June 2018, Biocartis' partner Genomic Health, Inc. (NASDAQ: GHDX) announced the results of its long-awaited TAILORx[5] study, the largest ever breast cancer treatment trial, which provided definitive evidence that the Oncotype DX Breast Recurrence Score test identified 70 percent of early-stage breast cancer patients who receive no benefit from chemotherapy, and can be effectively treated with endocrine therapy alone. Additionally, the trial established that chemotherapy may provide life-saving benefit to 30 percent of patients. These results are expected to be an important driver in the market adoption of the future Idylla™ Oncotype DX® test in Europe. During H1 2018, Genomic Health and Biocartis reached an important milestone in the development of the Idylla™ IVD Oncotype DX Breast Cancer test by demonstrating full feasibility of that test on the Idylla™ platform. Furthermore, early access sites to conduct validation studies for the test were selected with the aim to launch in the second half of 2019, beginning in France and Germany.
- *Infectious diseases partnership* - On 24 January 2018, Biocartis and Immunexpress Pty Ltd ('Immunexpress'), a host response molecular diagnostic company, announced a partnership agreement aimed at the development and commercialization of Immunexpress' SeptiCyte™ test for use on the Idylla™ platform. The SeptiCyte™ LAB test recently received 510(k) clearance from the US FDA for use on a manual PCR[6] instrument, and aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS) systemic inflammation in critically ill

[3] Source: US NEWS Top 10 hospital ranking, https://www.usnews.com/info/blogs/press-room/articles/2017-08-08/us-news-announces-2017-18-best-hospitals, last consulted on 9 August 2018.
[4] Key Opinion Leaders.
[5] Trial Assigning Individualized Options for Treatment (Rx), or TAILORx. Source: Genomic Health website, last consulted on 3 August 2018, http://newsroom.genomichealth.com/releasedetail.cfm?ReleaseID=1069104.
[6] Polymerase Chain Reaction.

patients on their first day of their admission in the ICU (intensive care unit). Under the partnership, parties will co-develop the SeptiCyte™ Idylla™ test, whereas Immunexpress will take the lead in the commercialization, with an initial focus on the US and the European markets.

Menu highlights

- *Review external performance studies* – On 27 June 2018, Biocartis announced the publication of a study in the Journal of Clinical Pathology[7] that reviewed 18 Idylla™ performance studies[8], showing a strong performance of Idylla™ compared to reference methods commonly used in clinical practice today to determine biomarker status (BRAF, NRAS, KRAS and EGFR mutations) that drive frequently occurring cancers (i.e. melanoma, colorectal, lung, thyroid and pancreatic cancer[9]). Results showed that out of the nearly 2,500 Idylla™ tests, 98.1% of the tests generated a valid result. The study also showed an excellent concordance rate of 94.8% between Idylla™ and the reference methods. The data generated by the studies demonstrated as such the high accuracy of the Idylla™ platform to test for actionable BRAF, NRAS, KRAS and EGFR mutations in different cancers, underlining the cost-effectiveness of Idylla™ testing compared to other molecular methods.
- *Colorectal cancer menu* – A total of three performance studies of Idylla™ CRC tests were published in H1 2018:
  - *ctRAS testing at AACR* - On 15 March 2018, Biocartis announced that a study abstract[10] on the analytical and clinical validation of its liquid biopsy Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests[11] was selected for oral presentation at the renowned AACR (American Association for Cancer Research) Annual Meeting in Chicago, IL (US). Results demonstrated that the Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests[12] provide a sensitive, reliable and fast solution for liquid biopsy RAS-BRAF ctDNA (circulating tumor DNA) testing, and that RAS-BRAF mutation status can be adequately determined using blood plasma from metastatic colorectal cancer (mCRC) patients with liver metastases. RAS-BRAF mutation analysis is mandatory by all major international guidelines[13] for mCRC patients.
  - *MSI testing at ASCO* - On 17 May 2018, Biocartis announced that two studies conducted in cooperation with the Flemish Institute for Biotechnology (VIB) regarding the performance of its exclusively licensed novel set of biomarkers for microsatellite instability (MSI[14]) that are included in the Idylla™ MSI Assay (the 'MSI Biomarkers'), were selected for publication at the ASCO (American Society of Clinical Oncology) Annual Meeting, which took place between 1-5 June 2018 in Chicago, IL (US). The first study[15] used the prototype Idylla™ MSI Assay in finalized design and shows superior performance of the MSI assay compared to reference methods. The second study[16] underlined the potential of Biocartis' MSI Biomarkers to be used as a companion diagnostic to predict immunotherapy outcome in MSI-High endometrial and colorectal tumors. Biocartis launched its Idylla™ MSI Assay (RUO) on 17 July 2018, early than initially planned.
- *Lung cancer menu* – On 28 May 2018, Biocartis announced the publication of a study[17] in the Journal of Clinical Pathology demonstrating that the Idylla™ EGFR Mutation Test (CE-IVD) was able to rescue 80% of the EGFR samples whose assessment was unsuccessful with Next Generation Sequencing (NGS). The study concluded that the Idylla™ EGFR Mutation Test is a viable alternative to NGS for rapid treatment decisions[18] in patients with acute deterioration, in particular when testing is performed on a less than optimal tumor tissue sample, which frequently yields insufficient amounts of DNA for proper NGS analysis. There was a 100% concordance

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[7] The review study was performed by Dr. Arnaud Uguen (MD, PhD, Department of Pathology of the Brest University Hospital, Brest, France) and Dr. Giancarlo Troncone (MD, PhD, Professor of Anatomic Pathology, University of Naples Federico II, Naples, Italy).

[8] The Medline and Google Scholar databases were searched to retrieve studies addressing the Idylla™ system performance in comparison to other diagnostic methods. Only original papers were taken into account, excluding congress abstracts. Data analyzed included the number and types of samples, the specific Idylla™ cartridges used and the non-Idylla™ reference method. Special care was also taken to record discordant cases, focusing on the underlying reasons of disagreements between Idylla™ and non-Idylla™ methods.

[9] Overall, five studies were dedicated to colorectal cancer, four to lung cancer, four to melanoma, one to thyroid cancer, one to pancreatic cancer and three to different tumors including the aforementioned types as well as a few examples of other tumors. The studies included the following Idylla™ test cartridges used: Idylla™ BRAF Mutation Test (CE-IVD), Idylla™ NRAS-BRAF-EGFRS492R Mutation Assay (RUO or Research Use Only), Idylla™ NRAS-BRAF Mutation Test (CE-IVD), Idylla™ KRAS Mutation Test (CE-IVD), Idylla™ NRAS Mutation Test (CE-IVD), Idylla™ EGFR Mutation Assay (RUO).

[10] B Jacobs, B Claes, P Laurent-Puig, JP Bachet, S Tejpar, G Maertens, E Sablon, "Analytical and clinical validation of the Idylla™ ctKRAS and ctNRAS-BRAF Liquid biopsy tests", first presented at the 2018 AACR Annual Meeting in Chicago, US, 14-18 April 2018.

[11] These tests were developed under the collaboration with Merck KGaA, Darmstadt, Germany.

[12] The Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test are CE-marked IVD's in Europe and not for sale in the US. Please check availability with the local Biocartis sales representative.

[13] http://www.amp.org/committees/clinical_practice/CRCOpenComment.cfm; ESMO (ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016); NCCN (NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016); ASCO (Allegra C.J. et al. Extended RAS gene mutation testing in metastatic Colorectal Carcinoma to predict response to antiepidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. Journal of Clinical Oncology 2016; 34(2):179-85) and CAP/AMP/ASCO

[14] Microsatellite instability or MSI is the result of inactivation of the body's so-called DNA mismatch repair (MMR) system. Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, contributing to tumor growth and evolution. Current MSI testing methods rely on manual, lengthy and complex procedures involving amongst others obtaining and testing of a second reference sample.

[15] B. De Craene et al., "Detection of microsatellite instability (MSI) in colorectal cancer samples with a novel set of highly sensitive markers by means of the Idylla™ MSI Assay prototype", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, IL (US).

[16] H. Zhao et al., "A novel set of 7 homopolymer indels for detection of MSI is associated with tumor mutation burden and total indel load in endometrial and colorectal cancers", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, US. The methodology used for detection of the seven biomarkers, TMB (tumor mutation burden,) and indel load, was whole-exome sequencing.

[17] De Luca et al, University of Naples Federico II, "The Idylla™ Assay and Next Generation Sequencing: an integrated EGFR mutational testing algorithm", Journal of Clinical Pathology, to consult online on http://jcp.bmj.com/content/jclinpath/early/2018/05/24/jclinpath-2018-205197.full.pdf?ijkey=V8eBoaMDpKZ7t9N&keytype=ref,

[18] To be taken by a multidisciplinary team.

with NGS for the valid results, where Idylla™ confirmed the EGFR mutational status. For a large portion (20/25 or 80%) of the cases whose NGS assessment was invalid, Idylla™ was able to process the sample and adequately produced a result.
- *Breast cancer menu* – See under 'Menu partnership highlights' – partnership Genomic Health.

Organizational and operational highlights
- *New board composition* – Following the annual shareholders' meeting (AGM) held on Friday 11 May 2018, five new independent board members were appointed and three board members whose mandate expired at the closing of the AGM, were re-appointed. The new board composition allows for a transition towards a board of directors consisting predominantly of independent directors and consists of: CRBA Management BVBA (represented by Christian Reinaudo), chairman of the board, Ann-Christine Sundell, Scientia II LLC (represented by Harry Glorikian), CLSCO BVBA (represented by Leo Steenbergen), Luc Gijsens BVBA (represented by Luc Gijsens), Peter Piot[19], Hilde Windels BVBA (represented by Hilde Windels[20]), Roald Borré[21] and Herman Verrelst (CEO of Biocartis).
- *US R&D center* - On 1 March 2018, Biocartis announced to have established an R&D center in the US as the result of a transfer of R&D staff members and Idylla™ related assay development assets and tests of Janssen Diagnostics (a division of Janssen Pharmaceuticals, Inc.). With the establishment of this US R&D center, Biocartis supports the execution of its strategy to accelerate test menu expansion on the Idylla™ platform through predominantly CDx collaborations and assay content partnerships.
- *Cartridge manufacturing* – Strong progress was made during H1 2018 in the validation of Biocartis' second cartridge manufacturing line that should provide for an additional annual cartridge capacity of over 1 million Idylla™ cartridges. The aim is to start commercial cartridge production on this line by year-end.

Financial highlights
- *Total operating income* – Total operating income increased year-over-year with 83% to EUR 12.7m driven by increased product and collaboration revenues. Product revenues increased year-over-year from EUR 5.1m to EUR 8.6m, an increase of 68%, which was predominantly driven by cartridge revenues that more than doubled. Collaboration revenues increased from EUR 0.8m in H1 2017 to EUR 3.6m in H1 2018, a year-over-year increase of close to five times.
- *OPEX* – Total operating expenses (including cost of sales) amounted to EUR 33.9m in H1 2018 versus EUR 30.7m in H1 2017, an increase of around 10% that was mainly driven by higher costs of sales. Operating expenses excluding costs of sales in H1 2018 amounted to EUR 27.0m versus EUR 27.4m in H1 2017, a decrease of approx. 2% predominantly due to lower expenses for research & development that was partially offset by higher expenses for sales & marketing and general & administrative expenses.
- *Net cash flow* - Total net cash flow in H1 2018 amounted to EUR -21.4m versus EUR -24.2m in H1 2017, a year-over-year improvement of approximately 12%.
- *Cash position* - Biocartis' cash position as per end June 2018 amounted to EUR 91.3m compared to EUR 112.8m as per 31 December 2017. In addition, the Company has EUR 27.5m of multiple purpose credit lines at its disposal on which no drawdowns were made as per end of H1 2018.
- *EIB financing facility* – On 1 March 2018, Biocartis announced to have obtained a EUR 24m debt financing facility from the European Investment Bank. The financing facility is supported by InnovFin – EU Finance for Innovators' Infectious Diseases Finance Facility, with the financial backing of the European Union under its research and innovation program Horizon 2020. It can be used to part-finance up to 50% of further investments in infectious diseases diagnostics solutions.
- *Additional details* – See 'key figures for H1 2018' below for more details on the H1 2018 financials.

Post-period events
- *Launch Idylla™ MSI Assay* – On 17 July 2018, Biocartis launched its innovative Idylla™ MSI Assay (RUO) that provides information on the MSI status[22] (i.e. MSI-High or Microsatellite stable) of a tumor within approximately 150 minutes from just one slice of FFPE[23] tumor tissue, without requiring a reference sample. This fully automated Idylla™ MSI Assay includes a novel set of seven exclusively licensed MSI biomarkers, consisting of

[19] Independent director.
[20] Non-executive director.
[21] Non-executive director.
[22] Maertens G. et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42; De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268; De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639)>.
[23] Formalin fixed, paraffin embedded.

short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2 genes. Several multi-center studies[22] comparing the standard methods[24] with the Idylla™ MSI Assay showed a >95% concordance between results. Furthermore, compared to standard methods, the Idylla™ MSI Assay has a significantly lower failure rate[22] provides automated result reporting and includes MSI-specific pan-tumor biomarkers, independent of ethnicity[22]. Once validated for diagnostic use, the test is expected to significantly strengthen Biocartis' colorectal cancer test menu and since MSI is an independent factor that may predict a patient's response to certain immunotherapies[25], it provides Biocartis with further opportunities to enter into the field of immuno-oncology.

- *RAS performance study at AACC* – On 31 July 2018, Biocartis announced that a study abstract[26] on the performance of the Idylla™ KRAS and NRAS-BRAF-EGFR492 Mutation Assays compared with Next Generation Sequencing (NGS) using colorectal cancer (CRC) tissue samples was selected for oral presentation at the 70th AACC (American Association for Clinical Chemistry) Annual Scientific Meeting in Chicago, IL (US). In the study, 44 archived FFPE colorectal cancer (CRC) tissue samples previously analyzed by NGS[27] were tested on Idylla™. The Idylla™ platform successfully detected all of the target KRAS, NRAS and BRAF mutations previously identified by the NGS method, resulting in an Idylla™ sensitivity of 100%. Analysis of the control samples[28] demonstrated agreement for all sample results with 100% reproducibility. The study concluded that the Idylla™ platform offers reliable and sensitive testing of mutations in KRAS, NRAS and BRAF directly from FFPE tumor tissue sections, and that it may complement NGS and other molecular testing systems at larger diagnostic centers by providing significantly faster turnaround times through its simplicity and ease of use.
- *Agreement with Hospital del Mar* – On 28 August 2018, Biocartis announced that it has obtained exclusive worldwide license rights for highly innovative EGFR ectodomain mutations that have shown to determine response to targeted therapy for patients with metastatic colorectal cancer (mCRC)[29]. The new agreement is a conversion of two existing agreements with Hospital Del Mar (Barcelona, Spain) and inventors Dr. Bardelli and Dr. Arena from the University of Torino (Torino, Italy) in relation to two patent families of EGFR ectodomain mutations. Biocartis is now entitled to sublicense the licensed rights to third parties.
- *China strategy* – On 3 September 2018, Biocartis and Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, announced entering into a joint venture aimed at the commercialization of the fully automated molecular diagnostics (MDx) Idylla™ platform in mainland China, within the field of oncology. The joint venture will be 50% owned by Biocartis and 50% owned by Wondfo. The initial activities of the joint venture are focused on the local manufacturing, commercialization and registration with the Chinese Regulatory Authorities (CFDA) of the existing products in the Idylla™ MDx oncology test menu for amongst others colorectal and lung cancer. This is a first important step in unlocking Idylla™'s commercial potential in China that will provide a broader cancer patient population with access to personalized medicines.

Menu news flow H2 2018

- *Colorectal cancer menu* – Driven by amongst others pre-submission discussions with the US FDA, the submission of the Idylla™ RAS PMA (Pre-Market Approval) documentation with the US FDA is now set for Q1 2019, subject to further feedback from US FDA interactions;
- During H1 2018, Biocartis has further re-prioritized resources across the portfolio of development projects to further optimize the ramp-up of cartridge volumes and execution of pharma and test content partnerships, impacting test menu news flow:
  - *MSI testing* – Driven by strong demand from existing and new customers, Biocartis has accelerated the RUO launch of the Idylla™ MSI Test as well as aims to bring forward its CE-marking;
  - *Lung cancer* – Introduction of a liquid biopsy version of the Idylla™ EGFR Mutation Test is now set for H1 2019. Furthermore, Biocartis will no longer seek CE-marking of the existing solid biopsy Idylla™ BRAF Mutation Test for lung cancer, but intends to add such BRAF mutations in a larger lung cancer panel covering multiple genes with predictive markers for lung cancer; and
  - *Breast cancer* - Launch of the Idylla™ ctESR1 (RUO) Assay, a liquid biopsy test aimed at monitoring of

[24] Including IHC and Promega MSI analysis system 1.2.
[25] ESMO (ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016); NCCN (NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016); ASCO (Allegra C.J. et al. Extended RAS gene mutation testing in metastatic Colorectal Carcinoma to predict response to antiepidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. Journal of Clinical Oncology 2016; 34(2):179-85) and CAP/AMP/ASCO.
[26] M. Rabie Al-Turkmani et al., "Rapid Somatic Mutation Testing in Colorectal Cancer Using a Fully Automated System and Single-Use Cartridge: A Comparison with Next-Generation Sequencing", first presented at 70th AACC Annual Scientific Meeting in Chicago, IL (US).
[27] Using the Ion AmpliSeq 50-gene Cancer Hotspot Panel v2 (Thermo Fisher Scientific).
[28] Horizon mutated samples.
[29] ESMO (ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016); NCCN (NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016); ASCO (Allegra C.J. et al. Extended RAS gene mutation testing in metastatic Colorectal Carcinoma to predict response to antiepidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. Journal of Clinical Oncology 2016; 34(2):179-85) and CAP/AMP/ASCO.

metastatic breast cancer patients for resistance to hormone therapy, which is developed in collaboration with LifeArc[30], is now set for 2019. This will allow the market introduction of that test to benefit from marketing synergies of a more orchestrated launch of the initial breast cancer test menu that is under development.

Key figures for H1 2018

The tables below show an overview of the key figures and a breakdown of operating income for H1 2018. Consolidated financial statements including notes are included in Biocartis' financial report for H1 2018 that can be downloaded from the Company's website here.

Key figures *(EUR 1,000)*	**H1 2018**	**H1 2017**	**% Change**
Total operating income	**12,741**	**6,978**	**83%**
Cost of sales	-6,890	-3,278	110%
Research and development expenses	-16,029	-19,320	-17%
Marketing and distribution expenses	-7,152	-5,308	35%
General and administrative expenses	-3,809	-2,781	37%
Operating expenses	**-33,880**	**-30,687**	**10%**
Operational result	**-21,139**	**-23,709**	**-11%**
Net financial result	-691	-729	-5%
Income tax	70	456	-85%
Net result	**-21,760**	**-23,982**	**-9%**
Cash flow from operating activities	-20,335	-22,172	-8%
Cash flow from investing activities	-2,301	-1,531	50%
Cash flow from financing activities	1,251	-479	-361%
Net cash flow[1]	**-21,385**	**-24,182**	**-12%**
Cash and cash equivalents[2]	**91,269**	**59,042**	**55%**
Financial debt	38,145	35,388	8%

[1] Excludes effects of exchange rate changes on the balance of cash held in foreign currencies
[2] Including EUR 1.2m of restricted cash (as a guarantee for KBC lease financing)

[30] LifeArc is an independent UK based life science medical research charity and aims to move promising medical research forward into patient treatments and diagnostics and has been involved in helping deliver a number of therapies including Keytruda® (pembrolizumab, marketed by MSD) which is an important immunotherapy treatment for various cancers.

Operating income *(EUR 1,000)*	H1 2018	H1 2017	% Change
Collaboration revenue	**3,535**	**716**	**394%**
Idylla™ System sales	1,952	1,821	+7%
Idylla™ Cartridge sales	6,603	3,270	102%
Product sales revenue	**8,555**	**5,092**	**68%**
Service revenue	251	104	141%
Total revenue	**12,341**	**5,912**	**109%**
Grants and other income	400	1,066	-62%
Total operating income	**12,741**	**6,978**	**83%**

Product sales revenue (EUR 1,000)	H1 2018	H1 2017	% Change
Commercial revenue	7,950	5,024	58%
Research & Development revenue	605	66	811%
Total product sales revenue	**8,555**	**5,091**	**68%**

Income statement

Collaboration revenues in H1 2018 increased year-over-year with close to five times to EUR 3.6m driven by a strong growth in R&D services and milestone revenues as the consequence of new partnerships closed in H2 2017 and H1 2018. R&D services, consisting of invoiced services to pharma and content partners, increased from EUR 45k in H1 2017 to EUR 2.6m in H1 2018. Milestone revenues amounted EUR 0.8m in H1 2018 (versus no milestone revenues in H1 2017) and consisted of realized assay development milestones. Product sales revenues increased year-over-year with 68% to EUR 8.6m driven by a doubling of cartridge sales from EUR 3.3m in H1 2017 to EUR 6.6m in H1 2018. Instrument revenues amounted to EUR 2.0m in H1 2018, a year-over-year increase of 7% as the consequence of the increase in installed base in H1 2018 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. 58% and R&D product revenues with about 8 times, the latter as the consequence of the increased number of content partnerships. Grants and other income amounted to EUR 0.4m in H1 2018 which resulted in a total operating income of EUR 12.7m versus EUR 7.0m in H1 2017, a year-over-year increase of 83%.

Total operating expenses (including cost of sales) amounted to EUR 33.9m in H1 2018 versus EUR 30.7m in H1 2017, an increase of 10% as the consequence of higher cost of sales. Cost of sales increased year-over-year with 110% to EUR 6.9m in H1 2018 driven by higher cartridge as well as instrument volumes. Operating expenses excluding cost of sales amounted 27.0m in H1 2018, a year-over-year decrease of 2% as higher expenses for marketing and distribution and G&A were offset by a decrease in R&D expenses. Expenses for R&D amounted to EUR 16.0m in H1 2018, a year-over-year decrease of 17% that was predominantly driven by lower platform and cartridge prototype costs, allocated depreciation expenses and staffing costs. Expenses for marketing and distribution increased year-over-year with 35% and amounted to EUR 7.2m. This increase was mainly driven by higher staffing costs as the consequence of an expansion of Biocartis' sales team, of which most for the US market. G&A expenses increased year-over-year with 37% to EUR 3.8m as the consequence of higher staffing costs (including non-cash share based payment expenses), external advice and facility costs.

The above resulted in an operational result for H1 2018 equal to EUR –21.1m compared to EUR -23.7m in H1 2017, an improvement of 11%. Following a net financial result for the period of EUR –0.7m, the net result for H1 2018 equaled to EUR –21.8m compared to EUR -24.0m in H1 2017.

Balance sheet

Property, plant and equipment increased in H1 2018 to EUR 29.5m as per end of June 2018 from 26.2m at the end of 2017 (increase of EUR 3.3m) driven by capital expenditures in H1 2018 of EUR 5.1m (predominantly related to investments for cartridge manufacturing expansion and capitalized Idylla™ systems) and a depreciation charge of around EUR 1.8m. Inventory increased in H1 2018 to EUR 10.6m (versus EUR 9.1m per end 2017), predominantly driven by an increase in finished products of both cartridges and Idylla™ instrumentation. Trade and other receivables increased in H1 2018 with EUR 0.9m due to predominantly higher VAT receivables. On the other side of the balance sheet, trade payables increased in H1 2018 with EUR 0.9m and deferred income decreased with EUR 0.7m.

The Company's cash and cash equivalents end of H1 2018 amounted to EUR 91.3m compared to EUR 112.8m end of 2017. Total financial debt end of H1 2018 amounted to EUR 38.1m, representing an increase of approx. EUR 2.8m compared to end of 2017. This was the result of an increase in lease financing in the context of the ongoing cartridge manufacturing expansion, as well as the addition of capitalized interest to the Company's subordinated loan.

Cash flow statement

The cash flow from operating activities in H1 2018 amounted to EUR –20.3m compared to EUR –22.2m in H1 2017 (an improvement of 8%), primarily driven by an improved result for the period which was partially offset by higher investments in working capital. The cash flow from investing activities in H1 2018 amounted to EUR –2.3m (compared to EUR –1.5m in H1 2017) and is mainly related to capitalized Idylla™ systems placed with customers under (reagent) rental agreements and Idylla™ systems used for internal needs. The EUR 3.2m investments for cartridge manufacturing expansion in H1 2018 are excluded from the cash flow from investing activities since these invoices were directly financed through our leasing partner. The cash flow from financing activities in H1 2018 amounted to EUR 1.3m (compared to EUR -0.5m in H1 2017) and predominantly relates to proceeds from warrants exercises that are partially offset by repayments of borrowings. Because of the aforementioned, the net cash flow of H1 2018 amounted to EUR –21.4m compared to EUR –24.2m in H1 2017, representing an improvement of 12% year-over-year.

Financial calendar 2018

- Q3 2018 business update – 15 November 2018
- 2018 full year results – 28 February 2019
- Capital Markets Day – 28 February 2019
- Publication 2018 annual report – 4 April 2019

Webcast and presentation

Biocartis will host a conference call with live webcast, during which the H1 2018 results will be presented, followed by a Q&A session. This event will be held today, 6 September 2018 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)330 336 9125 (standard international), followed by the confirmation code 3161692. 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-month's period ended 30 June 2018 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 2017. 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 on 30 August 2018. 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 2018 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 launched the Idylla™ platform in September 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers fifteen oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

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. 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.