PRESS RELEASE

REGULATED INFORMATION

Thursday, 16 November 2017, 07:00 CET

BIOCARTIS Q3 2017 BUSINESS UPDATE

Mechelen, Belgium, **16 November 2017 –** Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today provides a business update for the third quarter of 2017, post-period events and an outlook for the remainder of the year.

Key messages

- **Cartridge volume**: Commercial cartridge volume first nine months of 2017 increased about threefold year-over-year.
- **US commercialization**: In Q3 2017, Biocartis initiated the commercialization of the Idylla™ platform on the US market.
- **Strategic collaboration Genomic Health**: Exclusive agreement signed with Genomic Health to develop an IVD version of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform.
- **2017 guidance reiterated.**

Commenting on the business update, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"I am pleased to present today the first business update in my capacity as CEO. Q3 was a quarter in which Biocartis made impressive progress on all fronts. The start of commercialization in the US is a crucial next step in the commercial roll-out of our Idylla™ platform, and a key revenue driver in the mid-term. I look forward to work with our partner Thermo Fisher Scientific[1] to make Idylla™ the go-to platform for clinical oncology molecular diagnostics (MDx) in the US. The new collaborations with Genomic Health and A*STAR further demonstrate our ability to enter into collaborations with renowned development partners. I see it as a major validation that Genomic Health has chosen our Idylla™ platform to increase global patient access to standard-of-care testing with the Oncotype DX Breast Recurrence Score® test. Adding additional partnerships with pharma and biotech companies, for amongst others Companion Diagnostics (CDx) development, as well as attracting additional exclusive biomarker content for our tests, will assist Biocartis in its mission to make personalized medicine an everyday reality."*

Commercial and regulatory update

- *Installed base* – Idylla™ installed base expansion was further continued in Q3 2017, on track to meet guidance of increasing the installed base to over 640 instruments by year-end.
- *Cartridge consumption* – Driven by the ongoing Idylla™ installed base growth and test menu expansion, Biocartis' commercial Idylla™ cartridge consumption for the first nine months of 2017 increased about threefold year-over-year.
- *US commercialization* – In Q3 2017, Biocartis initiated the commercialization of the Idylla™ platform in the US market, the largest single market for oncology MDx testing in the world[2], and successfully installed the first Idylla™ instruments with US customers. It also continued the training of the sales force of the Company's US distribution partner Fisher Healthcare[1] which has now entered into full commercialization mode.
- *Distribution markets RoW[3]* – Biocartis signed new distribution agreements for markets in Eastern Europe and Asia and obtained additional market authorizations for its products in the Middle East and Asia in Q3 2017. Driven by hurdles in obtaining local market authorizations, uptake in several RoW markets was slower than expected. To offset this, Biocartis increased its efforts in obtaining required market authorizations for key distribution markets in H2 2017.
- *Regulatory* – In July 2017, the US FDA[4] published a final list of devices that it has exempted from 510(k) premarket notification requirements. The product codes applicable to the Biocartis Idylla™ Instrument and Idylla™ Console are included on this list. This exemption is expected to accelerate the rollout of the Idylla™ platform in the US.

[1] The agreement was signed with Fisher HealthCare, part of Thermo Fisher Scientific Inc.
[2] MarketsandMarkets, 2017.
[3] RoW = Rest of the World. RoW is defined as the world excluding Europe, US, China and Japan.
[4] US Food and Drug Administration.

Menu update

- *Breast cancer menu* – Breast cancer is the most common cancer among women worldwide: one in eight women is diagnosed with breast cancer in her lifetime[5]. In June 2017, Biocartis initiated the development of the first test for its breast cancer menu in partnership with LifeArc[6]. This test is aimed at monitoring of metastatic breast cancer patients for resistance to hormone therapy. During Q3 2017, Biocartis started the development of two additional breast cancer tests following the signing of new partnerships with Genomic Health (NASDAQ: GHDX) and A*STAR (Singapore's Agency for Science, Technology and Research):
  - Strategic Collaboration Genomic Health – On 13 September 2017, Biocartis and Genomic Health, the world's leading provider of genomic-based diagnostic tests, announced an exclusive agreement to develop an IVD version of the Oncotype DX Breast Recurrence Score® test on the Idylla™ platform that can be performed locally by laboratory partners and in hospitals around the world. The Oncotype DX Breast Recurrence Score® test, the only test proven to predict chemotherapy benefit, is included in all major cancer guidelines worldwide and is currently considered a standard test for early-stage breast cancer. The strategic collaboration will provide Genomic Health with exclusive worldwide rights to develop and commercialize its Oncotype DX Breast Recurrence Score® test on the Idylla™ platform, with the option to expand the collaboration to include additional tests in oncology and urology. The development timeline of the Oncotype DX IVD test aims at providing initial access to patients in Europe, beginning with France and Germany, in 2019. As part of the agreement, Genomic Health has made a payment of approximately USD 3.3m to Biocartis. Additional payments to Biocartis will be made as certain developmental and commercial milestones will be achieved in the future. Upon commercialization, Genomic Health will make royalty payments to Biocartis based on net sales.
  - Partnership A*STAR – The extended partnership with A*STAR is focused on the development of IVD tests for the Idylla™ platform. The first assay selected for development under the partnership is a fully automated solid biopsy assay, aimed at supporting optimal therapy selection decisions for breast cancer patients. Under the terms of the agreement, parties will co-invest in the development of jointly selected tests. For each selected test, Biocartis will be responsible for the commercialization of the tests under its own label, while A*STAR will act as a development partner through Singapore's Diagnostics Development Hub.

  The Idylla™ breast cancer menu is the first cancer subtype menu on the Idylla™ platform that is to be fully developed with partners.
- *Colorectal cancer (CRC) menu* – During Q3 2017, Biocartis successfully finalized the validation studies for the CE-marking of the Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test that it develops in collaboration with the leading science and technology company Merck KGaA[7] (ETR: MRK). Furthermore, Biocartis advanced the development of the Idylla™ MSI (microsatellite instability[8]) Assay. At the renowned European Society for Medical Oncology (ESMO) congress in September 2017, two studies on the performance of the exclusively licensed novel set of biomarkers for MSI that are to be included in the Idylla™ MSI Test (the 'MSI Biomarkers') were presented. Both studies, of which one was performed in collaboration with Merck KGaA[7], show strong performance of Biocartis' MSI Biomarkers for the detection of MSI status in gastric and colorectal cancer samples. The Idylla™ MSI Assay is another important addition to the CRC test menu, and could also become of relevance within the immuno-oncology field as MSI is believed to be the sole independent factor that may predict a patient's response to certain immunotherapies[9].
- *Lung cancer menu* – In Q3 2017, Biocartis further improved the product profile and specifications of the Idylla™ ctEGFR Mutation Assay, a liquid biopsy version of the solid biopsy Idylla™ EGFR Mutation Test that was CE-marked in June 2017. Consequently, the launch of the Idylla™ ctEGFR Mutation Assay is now set for 2018.
- *Infectious disease menu* – On 5 September 2017, the US FDA granted 510(k) clearance[10] for the Idylla™ Respiratory (IFV-RSV) Panel, developed by Biocartis' strategic partner Janssen Diagnostics, LLC ('Janssen'). The Idylla™ Respiratory (IFV-RSV) Panel is intended for the detection of various strains of Influenza Virus

[5] Source: World Health Organization, www.breastcancer.org, last consulted on 6 November 2017.
[6] On 15 June 2017, MRC Technology changed its name in LifeArc. LifeArc is an independent life science medical research charity that 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.
[7] Merck KGaA, Darmstadt, Germany.
[8] Microsatellite instability is the result of errors in the body's so-called DNA mismatch repair (MMR) system. Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, resulting potentially in tumor growth.
[9] Recent data have shown that advanced CRC patients with an MSI-high status respond particularly well to certain immunotherapies (Xiao Y et al. (2015) The microsatellite instable subset of colorectal cancer is a particularly good candidate for checkpoint blockade immunotherapy. Cancer Discov. 5, 16-18; and, Le et al. (2015) PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. N Engl J Med 372, 2509-2520).
[10] Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k).

(IFV) and Respiratory Syncytial Virus (RSV). This is the first FDA cleared test on the Idylla™ platform, marking another important milestone and adding yet another layer of validation to the quality of Biocartis' product offering.

Organizational and operational update

- *New CEO* – On 1 September 2017, Herman Verrelst started as new CEO of Biocartis. Herman is a seasoned executive with a proven international commercial track-record in molecular diagnostics. He held the position of Vice President and General Manager of the Genomics and Clinical Applications Division of Agilent Technologies Inc. (NYSE: A) prior to joining Biocartis.
- *Cartridge manufacturing* – Strong progress was made during Q3 2017 in the construction of a second cartridge manufacturing line that should provide for an additional annual cartridge capacity of 1 million Idylla™ cartridges. Biocartis and its manufacturing partners aim to have this line operational by the end of 2017, after which line validation can be initiated, aiming to start commercial production in the second half of 2018.

Financial update

- *Multiple purpose credit facility* – End of Q3 2017, Biocartis reached agreement with KBC and BNP Paribas Fortis to replace the Company's EUR 25m multiple purpose credit facility (partially guaranteed by the Flemish Government) with a new multiple purpose credit facility of EUR 27.5m (not covered by a government guarantee). The new multiple purpose credit facility consists of a EUR 18.5m rollover credit line and a EUR 9m working capital credit line, and has lower overall financing costs compared to the previous facility.
- *Cash position* - Biocartis' cash position at the end of Q3 2017 amounted to approximately EUR 56m (unaudited figure). The Company's cash position at the end of Q3 2017 includes take-up of EUR 10m on the above mentioned credit lines.

Menu outlook 2017

- CE-marking Idylla™ ctKRAS Mutation Test and Idylla™ ctNRAS-BRAF Mutation Test as part of the partnership with Merck KGaA[7] (Q4 2017).

Post-period events

- US commercialization: On 15 November 2017, Biocartis announced that performance data of Idylla™ was presented during the Biocartis workshop at the annual Association for Molecular Pathology (AMP) meeting. Two US key opinion leaders from renowned oncology centers[11] discussed key challenges that molecular diagnostic (MDx) testing is still facing in the US, especially around long turnaround times. Results from an internal study at the Dartmouth Hitchcock Medical Center, comparing the performance of the Idylla™ KRAS, NRAS and BRAF tests to their internal Standard of Care methods (in this case a Next-Generation Sequencing (NGS) technology), indicated full concordance in terms of sensitivity, specificity and predictive value[12].

Financial calendar 2018

- 2017 full year results – 1 March 2018
- Publication 2017 annual report – 5 April 2018

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[11] Dr. Kanwal Raghav, MD, MBBS (Gastrointestinal Medical Oncology, MD Anderson Cancer Center, Houston, Texas, US) and Dr. Gregory J. Tsongalis, BS, MS, PhD (Professor of Pathology, Dartmouth Hitchcock Medical Center, New Hampshire, US.
[12] The study was performed on 53 archived formalin-fixed paraffin-embedded (FFPE) colorectal cancer samples in the Dartmouth Hitchcock Medical Center. Compared to the NGS technology, Idylla™ scored 100% on sensitivity, specificity and positive & negative predictive value. Study results were first presented at the Biocartis Corporate Workshop held at the Association for Molecular Pathology (AMP) 2017 Annual Meeting, 15 November 2017, US.

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 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 has ten oncology tests and two infectious disease tests in its product menu. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

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