



PRESS RELEASE

REGULATED INFORMATION

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BIOCARTIS Q1 2018 BUSINESS UPDATE

Mechelen, Belgium, 26 April 2018 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today provides a business update for the first quarter of 2018 and an outlook for the remainder of the year.

Key messages

- Installed base: strong instrument placements in Q1 2018, US contributing to 40% of the total. On track to meet guidance for the full year.
- Cartridge volume: commercial cartridge volume in Q1 2018 increased with 70% compared to Q1 2017. On track to realize target of doubling volumes in 2018.
- Menu partnerships: Second companion diagnostics (CDx) agreement signed with Amgen. Partnership signed with Immunexpress to develop and commercialize Immunexpress' SeptiCyte™ test for use on the Idylla™ system.
- Cash position: Biocartis' cash position at the end of Q1 2018 amounted to EUR 102m (unaudited figure). No drawdowns were made on the Company's multiple purpose credit facility of EUR 27.5m as per end of Q1 2018.

Commenting on the Q1 business update, Herman Verrelst, Chief Executive Officer of Biocartis, said:

"Our performance in the first quarter paves the way for the realization of our 2018 targets. In particular, we saw great interest amongst top tier oncology hospitals in the US. Support from these hospitals and their key opinion leaders will be an important driver in realizing a broad market adoption of our system. We also established a US R&D center in New Jersey, which shows our dedication in the US market and will help realize efficiencies in the execution of existing and expected menu partnerships, another key driver for further market adoption. As we strengthen and grow the organization at all levels, we are also proposing a new board composition at our upcoming shareholders' meeting to include five new independent board members, each bringing new and complementary experience and expertise to our board. On behalf of the entire organization, I would like to thank all the outgoing board members for their valued contribution in the past years. I look forward to working with the new board in further laying the foundations for long-term growth."

Commercial update

- *Installed base* – Q1 2018 showed strong new Idylla™ placements in our European markets as well as in the US, the latter contributing to 40% of the total. Installed base growth is on track to meet guidance of exceeding 900 instruments placed by year-end.
- *Cartridge consumption* – Driven by amongst others increased instrument utilization in European markets, commercial Idylla™ cartridge consumption in Q1 2018 increased with 70% compared to Q1 2017 volumes. Driven by the expected number of instruments to be placed in H1 2018 as well as further ramp-up of instrument utilization on the existing installed base, cartridge volume growth is on track to meet guidance to double year-over-year.
- *US commercialization* – During Q1 2018, Biocartis and its US distribution partner Fisher HealthCare¹ attracted several new high profile customers across small, medium and large volume laboratories and hospitals, which have resulted in new instrument placements with significant volume potential. The ramp-up of US commercialization efforts in Q1 2018 will support placements growth in Q2 2018, resulting in a US installed base that will provide material commercial cartridge volumes in H2 2018. The value of the Idylla™ system for the US market continues to be demonstrated as communicated by Dr. Gregory Tsongalis, PhD, HCLD, CC during a webinar held on 15 March 2018: *"The complexity of management strategies for the cancer patient have made accurate and timely genomic assessment of tumor tissues imperative for optimal chances of good outcome. The Idylla™ system is a first of a kind, cartridge-based molecular test that has the potential to*

¹ Fisher HealthCare is part of Thermo Fisher Scientific Inc.

provide oncologists with rapid results for a select set of targeted and actionable mutations as a standalone test or while awaiting more comprehensive tumor genome profiling.”

- *Distribution markets RoW²* – Biocartis obtained additional market authorizations for its products in Singapore, Argentina, Brazil, Mexico, Malaysia, Uruguay and Canada in Q1 2018. Given the market constellation of Canada, Biocartis has decided to implement a direct sales approach for that market, supported by Biocartis' US direct sales team.

Menu and partnership update

- *Second CDx partnership Amgen* – On 9 January 2018, Biocartis announced a new 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.
- *Colorectal cancer (CRC) menu* – On 15 March 2018, Biocartis announced that a study abstract³ on the analytical and clinical validation of the liquid biopsy Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests⁴ was selected for oral presentation at the renowned AACR (American Association for Cancer Research) Annual Meeting in Chicago (US) held between 14-18 April 2018. Results demonstrated that the Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests⁵ provide a sensitive, reliable and fast solution for liquid biopsy RAS-BRAF ctDNA (circulating tumor) 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 for mCRC patients. Incorporating ctDNA testing in routine diagnostics could allow rapid detection of baseline RAS mutation status from a single blood draw.
- *Infectious disease partner menu* – 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™ system. The SeptiCyte™ LAB test, which recently received 510(k) clearance from the US FDA for use on a manual PCR instrument, and aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS) systemic inflammation in critically ill patients on their first day of their admission in the 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.

Organizational update

- *US R&D center* - On 1 March 2018, Biocartis announced the establishment of a R&D center in the US as the result of a transfer to Biocartis of R&D staff members and Idylla™ related assay development assets and tests of Janssen Pharmaceuticals ('Janssen'). With the establishment of this US R&D center, Biocartis supports the execution of its strategy to accelerate test menu expansion on the Idylla™ system through predominantly CDx collaborations and assay content partnerships.
- *New board composition proposed at upcoming AGM* – On 10 April 2018, Biocartis announced the agenda of its 2018 annual shareholders' meeting ('AGM') which included the proposal for a new board composition with four existing board members (Herman Verrelst - CEO, Peter Piot, Hilde Windels BVBA, represented by Hilde Windels, and Roald Borré) and the appointment of five new independent board members:
 - CRBA Management BVBA, represented by Christian Reinaudo (candidate chairman of the board);
 - Ann-Christine Sundell;
 - Harry Glorikian;
 - CLSCO BVBA, represented by Leo Steenbergen; and
 - Luc Gijsens BVBA, represented by Luc Gijsens.More information on the profiles of the proposed new board members can be found on the [Biocartis website](#). The proposed board composition will allow for a transition towards a board of directors consisting predominantly of independent directors.
- *New composition executive team* – In order to further streamline the governance structure of its organization Biocartis has reduced its number of formal executive managers to four persons: Herman Verrelst (chief executive officer), Ewoud Welten (chief financial officer), Hilde Eylenbosch (chief commercial officer) and Benoit Devogelaere (chief technology officer).

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

³ 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. Available online at <http://www.abstractsonline.com/pp8/#/1/4562>

⁴ These tests were developed under the collaboration with Merck KGaA, Darmstadt, Germany.

⁵ 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.

Financial update

- *EIB financing facility* – On 1 March 2018, Biocartis announced to have obtained an 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 programme Horizon 2020. This facility can be used to part-finance up to 50% of further investments in infectious diseases diagnostics solutions on the Idylla™ platform.
- *Cash position* - Biocartis' cash position at the end of Q1 2018 amounted to EUR 102m (unaudited figure). No drawdowns were made on the Company's multiple purpose credit facility of EUR 27.5m as per end of Q1 2018.

Outlook 2018

- *Menu expansion:*
 - Colorectal cancer: Launch of the Idylla™ MSI Assay (RUO⁶), aimed at the identification of MSI⁷ in all colorectal cancer patients as per recently updated guidelines in H2 2018; and submission of the Idylla™ RAS PMA (Pre-Market Approval⁸) documentation with the US FDA around year-end, subject to feedback from US FDA interactions.
 - Lung cancer: Launch of the Idylla™ ctEGFR Assay (RUO), a liquid biopsy version of the Idylla™ EGFR Mutation Test in H2 2018; and CE-marking of the solid biopsy Idylla™ BRAF Mutation Test, that will be validated for therapy selection in BRAF positive non-small cell lung cancer patients in H2 2018.
 - Breast cancer: Launch of the Idylla™ ctESR1 (RUO) Assay, a liquid biopsy test aimed at monitoring of metastatic breast cancer patients for resistance to hormone therapy, which is developed in collaboration with LifeArc in H2 2018.
- *Full year guidance reiterated* – Expected installed base growth with 250-275 Idylla™ instruments, doubling of cartridge volume in 2018 and realizing a targeted cash position in the range of EUR 50m – EUR 60m by year end, excluding drawdowns on the Company's multiple purpose credit facility.

Financial calendar 2018

- Annual General Meeting Biocartis Group NV 11 May 2018
- H1 2018 results 6 September 2018
- Q3 2018 Business Update 15 November 2018

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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™ system 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™ system 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

⁶ RUO = Research Use Only, not for use in diagnostic procedures.

⁷ Microsatellite instability (MSI) 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.

⁸ 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).

market worldwide. Today, Biocartis offers fourteen oncology assays and two infectious disease assays 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.

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