PRESS RELEASE

REGULATED INFORMATION
12 November 2020, 07:00 CET

BIOCARTIS Q3 2020 BUSINESS UPDATE

Mechelen, Belgium, 12 November 2020 – 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 2020 and the outlook for the full year 2020.

Commenting on the Q3 2020 Business Update, Herman Verrelst, Chief Executive Officer of Biocartis, said: *"During Q3 2020, overall growth of cartridge volumes further recovered from the significant impact of the pandemic in Q2 2020. In the US, cartridge volumes in oncology were back at pre-pandemic levels and we picked up with growth again. Also in the US, we saw that our Idylla™ SARS-CoV-2 Test[1] is strengthening our footprint within our core customer base that is in need of a platform that delivers rapid response testing, both in oncology and in infectious diseases. With the recent CE-IVD marking of the Idylla™ SARS-CoV-2 Test we can now do the same for our European customers. Barring any pandemic-related deterioration of business conditions towards the end of the year, we are confident that we can deliver on our growth targets for the year. We had a setback with the termination of our collaboration with Genomic Health, but our partner strategy remains strong with two new partnerships initiated. The collaboration with GeneproDx marks our entry in the thyroid cancer domain with ThyroidPrint®, a proven test[2] aimed to help determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant, and as such may contribute to reducing unnecessary surgery. The new partnership with Endpoint Health and the successful market releases in Europe of the Idylla™ SARS-CoV-2 Test and SeptiCyte® RAPID[3] on Idylla™ again demonstrate the versatility of the Idylla™ platform as one single, fully automated solution for both oncology and infectious diseases testing, which is expected to drive further growth in Q4 2020 and beyond."*

Commercial highlights

- *Commercial cartridge volume* – During Q3 2020, overall commercial cartridge volumes recovered from the significant impact of the pandemic in Q2 2020 and grew 61% year-on-year. With year-to-date growth in commercial cartridge volume in Q3 2020 standing at 27%, Biocartis is on track to achieve the targeted 30% growth for FY2020. The US returned to the growth of commercial cartridge volumes in oncology, complemented by initial sales of the Idylla™ SARS-CoV-2 Test[1]. European markets showed consistent growth within oncology, fully in line with pre-pandemic expectations. In Rest of World (RoW[4]) markets, the year-on-year growth during Q3 2020 was moderate, while year-to-date growth is still stalling due to the continued impact of the pandemic.
- *Installed base* – During Q3 2020, the Idylla™ installed base continued to expand, with the US representing 50% of all new Idylla™ placements. The lingering impact of the pandemic continued to slow down the Idylla™ instrument growth in RoW markets.
- *Regulatory update RoW markets* – End of October 2020, the Taiwan FDA (TFDA) has accepted registrations for the Idylla™ platform and the Idylla™ EGFR Mutation Test (CE-IVD).

Test menu highlights

- *Oncology* – Advancements in the lung cancer domain were made during Q3 2020 with the publication of a large prospective lung cancer study[5] supported by AstraZeneca, showing that Idylla™ reduces EGFR mutation testing turnaround time by more than a week, allowing faster patient management decisions[6]. Furthermore, Biocartis received a EUR 1.2 million grant from VLAIO[7] for the development of the Idylla™ GeneFusion Assay.
- *Infectious diseases* – On 10 August 2020[8], Biocartis submitted a notification of intent to distribute and request for 'Emergency Use Authorization' (EUA) from the US FDA for the Idylla™ SARS-CoV-2 Test. EUA for this test is pending, but distribution continues per notification criteria in the US FDA's COVID-19 Policy[1]. Post the reporting period, on 10 November 2020, the CE-marked Idylla™ SARS-CoV-2 Test was successfully released to market in Europe. Biocartis also assumed further responsibility in responding to the COVID-19 pandemic by joining the COVID-19 Testing Industry Consortium led by Bristol-Myers Squibb Company[9] as announced on 1 October 2020. Finally, further progress was made on the SeptiCyte® RAPID[3] on Idylla™, resulting in the successful release of the CE-IVD marked version to the European market on 6 October 2020.

[1] Distribution of the Idylla™ SARS-CoV-2 Test was initiated in the US in Q3 2020 per US FDA Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), May 2020, Section IV.C. Commercial Manufacturer Development and Distribution of Diagnostic Tests Prior to EUA Submission
[2] ThyroidPrint® is a registered trademark owned by GeneproDx Chile SpA
[3] SeptiCyte® RAPID is a registered trademark owned by Immunexpress Pty Ltd. Developed by Biocartis' partner Immunexpress Pty Ltd ('Immunexpress'), a Seattle-based (US) molecular diagnostics company. The test is a host-response test that distinguishes sepsis from non-infectious systemic inflammation in patients suspected of sepsis and provides actionable results in about one hour. The market release announced on 6 October 2020 is part of Biocartis' exclusive commercialization of SeptiCyte® RAPID on Idylla™ in Europe. More info here. Available to select countries within the EU and European region. Availability to be checked with the local Biocartis representative
[4] RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan
[5] Hummel M. et al, "FACILITATE: a real-world multicenter prospective study investigating the utility of a rapid, fully automated RT-PCR assay vs reference methods (RM) for detecting epidermal growth factor receptor mutations (EGFRm) in NSCLC", ESMO Virtual Congress 2020 (19-21 September 2020), first published online on 14 September 2020
[6] It concerned a prospective, real-world data set study across 16 European sites in Belgium, France, Germany and Italy. The study aimed to prospectively test 100 paraffin-embedded biopsy or cytology tissue samples with ≥10% neoplastic cells per site, from patients with advanced NSCLC
[7] The Flanders Organization for Innovation & Entrepreneurship
[8] More info on the Biocartis website here
[9] As announced in a corporate statement on 1 October 2020. More info on the Biocartis website here

Partnerships highlights

- *Oncology partnerships:*
  - Partnership with GeneproDx – Post the reporting period, on 3 November 2020, Biocartis announced to have signed a license, development and commercialization agreement with GeneproDx, a molecular diagnostics company based in Santiago, Chile, for the development of GeneproDx's novel genomic test ThyroidPrint® on the Idylla™ platform. Under the terms of the agreement, GeneproDx will take the lead in the development of the Idylla™ ThyroidPrint® test, whereas Biocartis will be responsible for the distribution of the ThyroidPrint® on Idylla™ through its growing commercial infrastructure of Idylla™ instruments across the globe. ThyroidPrint® is a qRT-PCR[10] based mRNA-expression classifier[11] test that helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant[12]. A benign test result[13] allows physicians to recommend watchful waiting as an alternative to diagnostic surgery. This reduces exposing patients to surgical risks and permanent thyroid hormone supplementation. Moreover, it significantly reduces health costs associated with unnecessary surgery.
  - Partnership with Exact Sciences – Post the reporting period, on 29 October 2020, Biocartis and Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation) announced to have agreed to terminate their collaboration, which was focused on the development of the Oncotype DX Breast Recurrence Score® Test and the Oncotype DX Genomic Prostate Score® (GPS™) Test on the Idylla™ platform. As a result of COVID-19, the project had been suspended earlier during 2020, with the project plan and timing under evaluation. The decision to terminate the collaboration was driven by the uncertain timing of a product market release because of the pandemic and a decision by Exact Sciences to shift priorities to other initiatives. As part of a termination settlement, Genomic Health, Inc. agreed to pay USD 12 million to Biocartis and license certain rights and transfer certain assets to Biocartis. The impact of the termination to Biocartis' future growth is contained, as the collaboration was limited to the European market. As such, the termination will have no impact on Biocartis' growth ambitions in the US and in RoW markets, nor will it affect the financial performance in 2020 other than as a result of the settlement.
- *Infectious diseases partnership:*
  - Partnership with Endpoint Health – Post the reporting period, on 3 November 2020, Biocartis announced it has entered into a partnership agreement with Endpoint Health, a Palo Alto, CA (USA) based company developing personalized care solutions and targeted therapies for critically ill patients. The partnership targets the development and commercialization of a novel companion diagnostic (CDx) test[14] on the Idylla™ platform and as such will further strengthen Biocartis' CDx business and infectious disease test menu alongside its core oncology offering on Idylla™. Under the terms of the agreement, Endpoint Health will lead the development and registration of the Idylla™ Endpoint test in interventional trials across a range of interventions including targeted immunotherapy and coagulation therapy indications. The parties intend to collaborate on the commercialization of the Idylla™ Endpoint CDx test, building on the growing worldwide commercial infrastructure of Idylla™ instruments.

Financial highlights

- *Cash position* – End of Q3 2020, Biocartis' cash position amounted to EUR 137 million (unaudited figure).
- *Extraordinary Shareholders' Meeting* – During the extraordinary shareholders' meeting held on 25 September 2020, the shareholders of the Company approved all agenda items, including the renewal of the authorization to the Board of Directors to increase the share capital of the Company by up to 20% of the then current amount during a period of one year.

Outlook

Provided that (a) the current global resurgence of COVID-19 cases does not lead to (i) widespread lock-down measures and (ii) a significant restriction of cancer patients' access to diagnostic testing, and (b) the Emergency Use Authorization ('EUA') of the Idylla™ SARS-CoV-2 Test is timely granted, Biocartis' guidance for 2020 is as follows:

- *Commercial cartridge volume:* Targeting a year-over-year commercial volume growth around 30%, representing a volume of Idylla™ cartridges around 228k;
- *Idylla™ installed base:* Targeting an installed base growth around 300 new Idylla™ instrument placements;

[10] Quantitative Reverse Transcription PCR. PCR or Polymerase chain reaction is an efficient and cost-effective way to copy (amplify) small segments of DNA or RNA. As such, millions of copies of a section of DNA are made in just a few hours, allowing further analysis for clinicians to diagnose and monitor diseases using a minimal amount of sample, such as blood or tissue. Source: www.genome.gov, last consulted on 4 November 2020

[11] Based on RTqPCR analysis, combined with an advanced machine learning algorithm

[12] This means that the probability of the nodule being malignant drops from 25% to less than 5%, allowing follow-up to be recommended as an alternative to surgery. Info and source: https://thyroidprint.com/en/home-us/, last consulted on 4 November 2020

[13] NPV (Negative Predictive Value) > 95%

[14] A 'companion diagnostic' (CDx) test is a test used as a companion to a therapeutic drug that helps predict if a patient is likely to respond to a treatment or not

- *Idylla™ test menu outlook:*
  - ONCOLOGY MENU:
    - Colorectal cancer menu – Subject to further feedback from US FDA interaction, US FDA 510(k) submission of the Idylla™ MSI Test is expected in Q4 2020 and US FDA submission of the PMA (Pre-Market Approval) application for the Idylla™ RAS tests is now expected in H1 2021 (instead of end 2020 initially);
    - Lung cancer menu – RUO[15] launch of the Idylla™ GeneFusion Assay is expected in Q1 2021;
  - INFECTIOUS DISEASE PARTNER MENU:
    - The US FDA regulatory process, led by Immunexpress, is ongoing for the SeptiCyte® RAPID on Idylla™;
    - Emergency Use Authorization ('EUA') with the US FDA of the Idylla™ SARS-CoV-2 Test is pending.
- *Cash position*: Targeted cash position in the range of EUR 120 million by 2020 year-end, an increase of EUR 10m from previous guidance as a result of the settlement payment following the termination of the collaboration with Genomic Health, Inc. announced on 29 October 2020.

Financial calendar 2021

- Early 2021 Reporting on Guidance 2020
- 25 February 2021 2020 full year results
- 1 April 2021 Publication 2020 annual report
- 22 April 2021 Q1 2021 Business Update
- 14 May 2021 AGM Biocartis Group NV
- 2 September 2021 H1 2021 results
- 10 November 2021 Q3 2021 Business Update

This afternoon at 15:00h CET/14:00 BST/09:00 EST, Biocartis is hosting a virtual Capital Markets Day for financial analysts, institutional investors and financial media. Biocartis will provide an update on its longer-term Idylla™ test menu strategy in oncology as well as in infectious diseases as a response to several important market trends that are believed to have a potential favorable impact on the Company's business. The webcast will be held in English. A recording of the webcast and supporting presentation will be available on the Company's investor relations website shortly after.

--- END ---

More information:
Renate Degrave
Head of Corporate Communications & Investor Relations Biocartis
e-mail rdegrave@biocartis.com
tel +32 15 631 729
mobile +32 471 53 60 64
@Biocartis_ www.linkedin.com/Biocartis

About Biocartis

Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as for SARS-CoV-2 and sepsis. More information: www.biocartis.com. 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,

[15] RUO = Research Use Only, not for use in diagnostic procedures

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.