REGULATED INFORMATION

PRESS RELEASE

BIOCARTIS ANNOUNCES H1 2015 RESULTS AND STRENGTHENING OF MANAGEMENT TEAM

Key messages[1]**:**

- **32 Idylla™ commercial instruments sold in H1 2015. Guidance of 75 instruments sold in 2015 reiterated.**
- **Continued strong ramp up of global sales and distribution network, now covering 50 countries and nine new distribution contracts signed in H1 2015.**
- **Significant progress in test menu development:**
  - **CE-IVD mark for KRAS Mutation Test for colorectal cancer received in June 2015; and**
  - **Three new collaborations signed with development partners for further menu expansion in both oncology and infectious diseases.**
- **Menu outlook H2 2015:**
  - **Acceleration in market launch of IFV-RSV test to Q4 2015;**
  - **NRAS Research Use Only (RUO) Mutation Test launch expected in Q4 2015 (CE-IVD launch expected in H1 2016); and**
  - **Completion of EUA submission Rapid Ebola Virus Triage Test expected in Q4 2015.**
- **Solid cash position of EUR 128m at end of H1 2015, primarily driven by successful EUR 115m IPO in April 2015.**
- **Strengthening of management team with appointment of Hilde Windels as Deputy CEO and Ewoud Welten as CFO. Rudi Pauwels will continue to lead the Company as CEO.**

Biocartis will host a webcast presentation today at 14:00 CET to discuss the H1 2015 results and the strengthening of its management team. To access the live webcast, please visit Biocartis' website at https://investors.biocartis.com or by clicking here at least 15 minutes before the scheduled start time to download any necessary audio or plug-in software. The webcast presentation is also made available at https://investors.biocartis.com.

Mechelen, Belgium, **11 September 2015:** Biocartis (Euronext Brussels: **BCART**), an innovative molecular diagnostics company, today announced its operational highlights and financial results for the first half of 2015, prepared in accordance with the IAS 34 'Interim Financial Reporting' as adopted by the European Union. Furthermore, the Company is pleased to announce that is has strengthened its management team.

[1] Please find a glossary of important terms used in this press release in Biocartis' interim financial report 2015.

Commercial highlights

- **32 Idylla™ commercial instruments** sold in H1 2015, on track to realise the guided 75 Idylla™ instrument sales in 2015.
- **Idylla™ installed base** now **114** instruments at the end of H1 2015.
- **Nine new distribution contracts** signed in the first half with renowned distributors, covering 12 additional countries in Europe, Middle East and Asia Pacific, including minimum purchase obligations for over 100 Idylla™ instruments over the next three years.
- Continued expansion of **global sales and distribution network**, now covering more than 50 countries through direct and indirect sales channels:
  - Strengthened direct sales force, attracting key talent from industry, now covering 16 European countries.
  - Sales and marketing organization now 24 FTEs.

Menu highlights

During the first half of 2015, Biocartis has been strongly focused on expanding use of its current test menu and bringing to market new tests for Idylla™, its fully automated sample-to-result, real-time system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. In line with this, Biocartis has expanded it R&D team in H1 2015 to a total of 96 FTEs.

Biocartis is focused on addressing key unmet clinical needs in oncology and infectious diseases, which represent respectively the fastest growing and largest segments of the molecular diagnostic market worldwide.

Oncology

- During H1 2015, Biocartis continued to accelerate the **commercialisation of its Idylla™ BRAF Mutation Test** with, amongst others, the support from key opinion leaders. Post the period end, on 27 July 2015, Dr. Filip Janku, MD from MD Anderson (Houston, United States) published a research study on the analytical sensitivity and specificity of the Idylla™ BRAF Mutation Test. This research study showed that the Idylla™ BRAF Mutation Test is rapid and has high concordance with other routinely used but more complex BRAF mutation–detecting tests[2].
- In June 2015, Biocartis received **CE-IVD marking for its KRAS Mutation Test**, the world's first fully automated CE-IVD KRAS test for routine use to match novel guidelines that is capable of detecting an extended panel of 21 KRAS mutations with high sensitivity. It detects all clinically relevant driver mutations of the KRAS oncogene in tissue of colorectal cancers and provides results in an unprecedented timeframe of approximately two hours. The Idylla™ KRAS Test is the second test launched by Biocartis and is a cornerstone in a set of highly standardized and sensitive tests around metastatic colorectal cancer.
- Further progress is being made with **extended NRAS panels** currently in development for which CE-IVD marking is now expected in H1 2016. The NRAS test detects 19 mutations in the NRAS gene. When used in combination, the Idylla™ KRAS and NRAS tests enable testing an extended set of 40 clinically actionable RAS mutations. Next to the NRAS panel, Biocartis has progressed development of its NRAS/BRAF test (detecting BRAF codon 600 mutations in addition to the 19 NRAS mutations) as well as its NRAS/BRAF/EGFR492 (which also detects the EGFR S492R mutation) along the same timelines.
- Significant progress was also made in the field of **liquid biopsies**. In June 2015, Biocartis presented positive results of a research study in collaboration with Prof. Bart Neyns from the University Hospital Brussels at the American Society for Clinical Oncology, demonstrating that BRAF mutant tumour DNA levels circulating in blood of metastatic melanoma patients were associated with disease progression.
- In H1 2015, Biocartis successfully finalized a study on **microsatellite instability (MSI),** demonstrating the possibility of fully automated Polymerase Chain Reaction (PCR) detection of these mutational signatures found in colorectal cancers. Testing for MSI mutations is currently under-utilized, as these markers are currently only detectable with complex workflows using capillary electrophoresis. The ability to detect this important class of biomarkers in a user friendly manner is expected to boost

[2] The Idylla™ System and Idylla™ BRAF Mutation Test are currently not available in the USA.

adoption of MSI testing.

- Post the period end, on 17 July 2015, Biocartis signed a partnership agreement with ETPL (Exploit Technologies Pte. Ltd.), the commercialisation arm of the Agency for Science, Technology and Research (A*STAR, based in Singapore). A*STAR is Singapore's lead public sector agency that spearheads economic oriented research to advance scientific discovery and develop innovative technologies. Under the partnership, Biocartis has access to novel biomarkers (including those discovered within A*STAR's research institutes) from the Diagnostics Development Hub under ETPL. The aim of the partnership is to jointly develop of a range of proprietary tests for the Idylla™ platform with a main focus on **cancer biomarkers**.

Infectious diseases

- Biocartis has continued to make strong progress with its **Rapid Ebola Virus Triage Test** that it is developing in association with Janssen Diagnostics and the Institute for Tropical Medicine in Antwerp (Belgium) for its Idylla™ system. The formal Emergency Use Authorization' (EUA) submission process to the FDA for the Idylla™ platform and Rapid Ebola Virus Triage Test has been initiated and is expected to be completed in the beginning of Q4 2015.
- Biocartis also made strong progress with its **first respiratory panel test**, known as IFV-RSV. This test, which is being developed in collaboration with Janssen Diagnostics, is aimed at the detection of influenza A, influenza B, RSV (respiratory syncytial virus) A and RSV B in nasopharyngeal swabs from patients with influenza-like illness. CE-IVD marking of the IFV-RSV test is expected at the end of Q4 2015.
- In March 2015, Biocartis signed a worldwide license and collaboration agreement with Microbiome, a spin-off of the VU University Medical Center Amsterdam (the Netherlands), aimed at developing a test for the rapid detection of **bloodstream infections, such as sepsis**. This test is aimed to be used in conjunction with Biocartis' Idylla™-Enrich platform, a dedicated pre-enrichment platform for bloodstream infections that is under development by Biocartis.
- In addition, in May 2015 a strategic partnership was signed with Fast-track diagnostics (Luxembourg) aimed at the development of a broad range of Idylla™ **infectious disease tests** based on the new approach of **'syndromic multiplex testing'**, meaning the identification of a broader range of disease pathogens in a single test.

Financial highlights

- On 28 April 2015, Biocartis raised gross proceeds of EUR 115m in a 6.5x oversubscribed **successful Initial Public Offering** (IPO) on Euronext Brussels, underpinning the strong belief of institutional and retail investors in the potential of Biocartis. The IPO attracted a wide interest from a mix of long-term, specialist investors across continental Europe, the UK and the US. Total IPO costs amounted to EUR 9.2m.
- In H1 2015, Biocartis generated **total operating income** of EUR 7.2m compared to EUR 2.5m in H1 2014. Total product sales revenues amounted to EUR 1.7m of which EUR 1.3m is generated by Idylla™ system sales and EUR 0.4m by cartridge revenues. Upfront license and milestone revenues amounted to EUR 4.6m. Grant income amounted to EUR 0.6m and is mainly related to grants for R&D projects received from the Institute for the promotion of Innovation by Science and Technology in Flanders (IWT). After the reporting date, in July 2015, Biocartis was awarded a new IWT R&D grant for the development of novel molecular diagnostic solutions for bloodstream infections on the Idylla™ platform for a total amount of EUR 1.5m.
- As a result of the series F round financing (second tranche of EUR 21.5m was received in January 2015) and the IPO, Biocartis is able to report a **solid cash position** that amounts to EUR 128.5m per 30 June 2015.

Strengthening of team
Biocartis is pleased to announce it has strengthened its senior management team by the promotion of the current CFO to Deputy CEO and the appointment of a new CFO as of today.

Hilde Windels will assume the new title of Deputy CEO, a title that better fits the significant contribution she continues to make to the company. As Deputy CEO, Hilde will continue to work closely alongside the CEO, Rudi Pauwels, focusing on the day-to-day operational management of Biocartis. Rudi will continue to lead the company on a daily basis in its implementation of its mission, strategy and targets set by the Board of Directors, with a focus on the long-term future growth of the business.

Ewoud Welten will join Biocartis as CFO, a role previously assumed by Hilde Windels, from international investment bank Kempen & Co. He brings in extensive experience of the healthcare sector as a corporate financier in which position he managed numerous capital market transactions including IPOs, secondary fundraisings and M&A transactions. Ewoud will also have a key role in reinforcing Investor Relations (IR), together with Renate Degrave, who is joining from EY and will be heading Corporate Communications & IR.

In view of the next critical steps Biocartis has to take in becoming a world leader in molecular diagnostics, it has been decided to strengthen positions at its senior management level, besides the appointments of Hilde and Ewoud, to provide the company with the expertise needed for the execution of its strategy. Biocartis' senior management team going forward consists of the following members: Rudi Pauwels (CEO), Hilde Windels (Deputy CEO), Ewoud Welten (CFO), Ulrik Cordes (CCO), Caroline Collard (Marketing), Erwin Sablon (R&D and Alliance Management), Patrick Hofkens (General Counsel) and Susy Spruyt (Human Resources).

Commenting on the H1 2015 results and new appointments, Rudi Pauwels, Chief Executive Officer of Biocartis, said:

"*We are very pleased with the progress we made during the first six months of the year, both operationally and financially. Thanks to the efforts of all employees at Biocartis in the first half of 2015, we managed to successfully expand our installed base, resulting in 32 new Idylla™ instruments sold to various larger and smaller hospitals and distributors in and outside Europe in H1 2015, bringing our total installed base to 114 and thereby increasingly enabling more patients to benefit from the unique features our products offers."*

"I am especially proud of our IPO that was the largest Life Sciences transaction of 2015 on the European markets, ranking amongst the 10 largest IPOs the last 10 years on Euronext. On the one hand this IPO has been another milestone in realizing the vision of Biocartis, to transform the global diagnostics market by providing instant access to personalized medicine for all patients worldwide. However, it is also the start of a new era as a publicly listed company. We are committed to demonstrate that we can execute upon the promises that we have made to all participating investors."

"Our company is moving to a next stage of growth. This is why we have decided to strengthen our management team with, amongst others, the appointments of Hilde and Ewoud. Hilde plays a crucial leadership role within Biocartis and the new title of Deputy CEO better fits the significant contribution she continues to make in the day-to-day running of the company. We are delighted to welcome Ewoud to Biocartis. With a strong background in corporate finance, his extensive knowledge of capital markets will be of great value to the company as we continue our strong growth trajectory. As announced, we have also strengthened our management team through a number of other appointments. I wish everybody all the best in their new roles."

"Finally, I would like to mention that I am pleased that we can reiterate our guidance of selling 75 instruments in 2015. This in my view, once more underlines the potential of our Idylla™ platform."

Key figures for H1 2015

In EUR 1,000	**H1 2015**	**H1 2014**	**% change**
Revenue	**6,578**	**1,124**	**485%**
Other operating income	646	1,379	-53%
Total operating income	**7,224**	**2,503**	**189%**
Operating expenses	**-24,047**	**-18,066**	**33%**
Cost of goods sold	-1,158	-1,000	16%
Research and development expenses	-16,092	-12,768	26%
Marketing and distribution expenses	-3,219	-1,158	178%
General and administrative expenses	-3,578	-3,139	14%
Operational result	**-16,823**	**-15,563**	**8%**
Net financial result	-429	-512	-16%
Income tax	337	421	-20%
Loss from discontinued operations	-	4,092	
Net result	**-16,915**	**-19,746**	**-14%**
Cash flow from operating activities	-8,719	-16,808	-48%
Cash flow from investing activities	-1,679	-2,036	-18%
Cash flow from financing activities	127,977	-566	NM
Net cash flow	**117,579**	**-19,140**	**NM**
Cash and cash equivalents at the end of the period[1]	**128,477**	**9,585**	**NM**
Financial debt at the end of the period	13,364	13,585	-2%

[1] Including EUR 1.5m restricted cash

Income statement

During the first six months of 2015 total operating income increased to EUR 7.2m compared to EUR 2.5m in H1 2014. Revenues increased to EUR 6.6m as compared to EUR 1.1m in H1 2014. This EUR 5.5m increase is driven by increased collaboration revenues received under the license and development agreements with Janssen Pharmaceutica for an amount of EUR 4.6m and by an increase in product sales of EUR 0.9m. Other operating income decreased from EUR 1.4m to EUR 0.6m and mainly consists of R&D project support grants received from the IWT.

Operating expenses have increased with EUR 6.0m to EUR 24.0m in H1 2015 compared to EUR 18.1m in H1 2014. This increase in spending is first of all driven by an increase in research and development expenses for an amount of EUR 3.3m in view of the continued development and preparation for launch of new Idylla™ tests and further Idylla™ system developments. Secondly, this increase is driven by higher marketing and distribution expenses of EUR 2.1m as the result of an expanded sales and marketing team following the commercialization of the Idylla™ platform since September 2014.

General and administrative expenses increased from EUR 3.1m in H1 2014 to EUR 3.6m in H1 2015 and include non-capitalized expenses related to the IPO in April 2015 of EUR 1.1m. The remaining IPO costs of EUR 8.1m are allocated to equity. Biocartis' operational result consequently decreased from EUR -15.6m in H1 2014 to EUR -16.8m in H1 2015.

Biocartis' net financial result improved to a loss of EUR 0.4m in H1 2015 compared to EUR 0.5m in H1 2014. Taking into account positive income taxes for a net amount of EUR 0.3m in H1 2015 (EUR 0.4m in H1 2014) originating from R&D tax credits, the net loss for H1 2015 after taxes from continuing operations amounts to EUR 16.9m (EUR 15.7m in H1 2014).

Balance sheet

Property, plant and equipment decreased with EUR 0.3m to EUR 8.9m per 30 June 2015 from EUR 9.2m per 31 December 2014 driven by CAPEX in H1 2015 of EUR 1.6m and depreciations of EUR 1.9m. Per 30 June 2015, a financial participating of EUR 5.1m was included on the balance sheet as the result of the acquisition of a participation in MyCartis NV on 15 January 2015 following the exercise by Debiopharm Diagnostics SA of a put option in December 2014. Biocartis currently holds an 11.2% participation in MyCartis NV.

Inventory has increased from EUR 3.6m per 31 December 2014 to EUR 6.4m per 30 June 2015, caused by higher inventory levels in view of the further commercialization of the Idylla™ platform. Trade receivables have decreased significantly with EUR 12.7m to EUR 3.1m per 30 June 2015 because of the collection of receivables from Janssen Pharmaceutica. Trade payables decreased from EUR 4.3m per 31 December 2014 to EUR 3.9m per 30 June 2015. Deferred income has decreased to EUR 7.0m per 30 June 2015 from EUR 9.6m per 31 December 2014 because of the recognition of upfront payments from Janssen Pharmaceutica in relation to the strategic licensing, development and commercialization collaborations.

Driven by the second tranche of the series F round financing and the IPO, the cash position of the Group increased with EUR 117.6m from EUR 10.9m per 31 December 2014 to EUR 128.5m per 30 June 2015.

Cash flow statement

The cash flow from operating activities significantly improved in H1 2015 to EUR -8.7m compared to EUR -16.8m in H1 2014, as did the cash flow from investing activities, which amounted to EUR -1.7m in H1 2015 compared to EUR -2.0m in H1 2014. The cash flow from financing activities in H1 2015 amounted to EUR 128.0m, mainly thanks to the cash inflow from the IPO (EUR 107.0m) and the capital increase of the second tranche of the series F round (EUR 21.5m). The Group's net cash flow in H1 2015 amounted to EUR 117.6m.

Outlook 2015

- Driven by a total sale of 32 Idylla™ Instruments in H1 2015 and a promising outlook of product sales for H2 2015, Biocartis is comfortable to r**eiterate its guidance of recording a total of 75 Idylla™ Instruments** sold in 2015. Thereby, growing its installed base to over 150 in 2015.
- **Oncology:**
  - Expected **NRAS/BRAF/EGFR492 Research Use Only (RUO) test** launch at the end of 2015. CE-IVD marking of the two other NRAS tests is expected in H1 2016.
  - Following the significant progress made in the area of liquid biopsies, the launch of a **BRAF liquid biopsy test** (RUO) is anticipated by the end of 2015.
- **Infectious diseases:**
  - **CE-IVD marking of the IFV-RSV test** is expected at the end of Q4 2015. Furthermore, Janssen Diagnostics has agreed to appoint Biocartis as a worldwide co-exclusive distributor of the IFV-RSV test.
  - The 'Emergency Use Authorization' (EUA) submission process to the FDA for the Idylla™ platform and Rapid **Ebola** Virus Triage Test is expected to be completed in the beginning of Q4 2015.
- Finally, by the end of the year, Biocartis expects to have concluded the **outsourcing of the Idylla™ Instrument and Console production** to a Contract Manufacturing Organization, which will enable the realisation of significant cost efficiencies and required scaling of production capacity.

Webcast and presentation

The Biocartis management team will host a conference call and webcast during which the H1 2015 financial results will be presented, followed by a Q&A session. This event will be held today, 11 September 2015 at 14:00 CET. The conference call will be webcast live and may be accessed on the home page of the Biocartis website at www.biocartis.com or by clicking here. If you would like to participate in the Q&A, please dial +32 (0) 115 001 93 with confirmation code 26035912. Shortly after the call, a replay of the webcast and the presentation used in connection with the conference call webcast will be available on the website https://investors.biocartis.com under section Investor Overview/Latest news.

Auditor Statement

The condensed consolidated financial statements for the six month's period ended 30 June 2015 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 2014. 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 10 September 2015. The statutory auditor, Deloitte Bedrijfsrevisoren/Reviseurs d'Entreprises, represented by Gert Vanhees, has performed a limited review, which did not reveal any significant adjustments to the condensed consolidated financial statements. The interim financial report 2015 and the limited 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. Idylla™ addresses the growing demand for personalized medicine by allowing fast and effective treatment selection and treatment progress monitoring.

Biocartis launched the Idylla™ platform commercially in September 2014 together with its first assay to identify BRAF Mutations in metastatic melanoma. Its second assay, a KRAS Mutation panel for colorectal cancer has been launched in June 2015. 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. Further information can be found at: www.biocartis.com

About Idylla™ (www.idylla.com)

Idylla™, Biocartis' fully automated, real-time PCR based molecular diagnostics system, is designed to offer fast and easy access to clinical molecular diagnostic information, anywhere and anytime. The Idylla™ platform covers the entire process from sample to result in a time frame of 35 to 150 minutes with less than two minutes hands-on time. Idylla™ is applicable for a wide range of clinical sample types and can analyze both RNA and DNA. The fully integrated system enables clinical laboratories to perform a broad range of applications in oncology, infectious diseases and beyond. Idylla™ and the system's first assays, the Idylla™ BRAF Mutation Test for metastatic melanoma and Idylla™ KRAS Mutation Test for colorectal cancer have obtained CE-IVD marking.

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company or, as appropriate, the Company directors' 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 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

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