



PRESS RELEASE

REGULATED INFORMATION

BIOCARTIS ANNOUNCES 2015 RESULTS AND 2016 GUIDANCE

Key messages 2015 results

- **Idylla™ installed base:** Successful initial market adoption of the Idylla™ platform in 2015 by adding 83 Idylla™ instruments to the installed base, exceeding the 2015 guidance of 75 and bringing the installed base of Idylla™ instruments to over 160 at the end of 2015.
- **Menu expansion:** Significant progress made in further building the Idylla™ menu in our core areas of oncology and infectious diseases, with three new tests in oncology and a first infectious disease test launched in 2015.
- **Financials:** Total operating income increased in 2015 to EUR 15.0m compared to EUR 10.4m in 2014. Biocartis' cash position as per 31 December 2015 amounted to EUR 104.1m (compared to EUR 11.9m per 31 December 2014).

Guidance 2016

- Installed base of Idylla™ instruments end of 2016 of over 300 by adding 150-175 instrument placements;
- Launch of at least four new tests; and
- Cash position end of 2016 of in the range of EUR 45m to EUR 55m

Biocartis will host a webcast presentation today at 14:00 CET to discuss the 2015 results, 2016 guidance and update on its menu of Idylla™ tests. The live webcast may be accessed on the [Biocartis website](#) or by clicking [here](#). To participate in the questions and answers session, please dial 5-10 minutes prior to the start time the number +44 (0)20 3427 1914 (standard international), followed by the confirmation code 1026764. The webcast and conference call will be conducted in English. A replay of the webcast will be available on the [Biocartis website](#) shortly after.

Mechelen, Belgium, 17 March 2016 - Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: **BCART**), today announced its operational highlights and financial results for 2015, prepared in accordance with IFRS as adopted by the European Union. Furthermore, the Company today provides its guidance for 2016 and an update on its menu of Idylla™ tests.

Commercial highlights

Following launch in September 2014, 2015 was the first full commercialisation year of Biocartis' molecular diagnostics platform Idylla™ that is being sold via direct representations in key European countries and via distribution partners in geographies accepting CE-mark.

- *Installed base:* In 2015, Biocartis added a total of 83 instruments to its installed base with customers worldwide. Consequently, the Company exceeded its target of 75 instruments for 2015. Based on the 82 instruments sold in 2014, Biocartis' installed base amounted to 165 as per 31 December 2015, underlining a successful initial market adoption of the Idylla™ platform.
- *Commercial footprint:* Biocartis strengthened its commercial footprint in 2015 by adding 39 countries. This was realised by expanding the direct sales force in Europe to 14 commercial representatives and the signing of 21 distribution agreements. At the end of 2015, Biocartis' commercial footprint covered over 55 countries worldwide.
- *Sales & Marketing:* By the end of 2015, Biocartis' sales and marketing organization amounted to 32 people, an increase of 12 compared to 2014, to support ramp-up in commercialisation via its own sales force and distribution partners.

Highlights menu Idylla™ tests

During 2015, Biocartis further advanced the development of new tests for its Idylla™ platform with a focus on

addressing clinical unmet needs in oncology and infectious diseases, being respectively the fastest growing and largest segment of the worldwide molecular diagnostics market. Biocartis aims to launch a minimum of four Idylla™ tests per year.

Oncology menu

Biocartis' initial focus within oncology is to develop a core menu consisting of four solid biopsy and four liquid biopsy tests for melanoma, colon and lung cancer. The majority of this core menu is expected to be on the market by the end of 2016:

- *Solid biopsy menu:* Biocartis launched two new solid biopsy tests for metastatic colorectal cancer (mCRC): the CE-marked Idylla™ KRAS Mutation Test (June 2015) and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay (December 2015, Research Use Only). Together, these tests provide for a complete mCRC mutation analysis of 39 KRAS and NRAS mutations, from two slices of so-called formalin-fixed paraffin embedded (FFPE) tumour tissue, at high sensitivity. For the first time in the molecular pathology field, these tests allow to perform a complete RAS analysis on a same-day basis, opening up the route towards faster and more accurate treatment selection, based on a single patient visit.
- *Liquid biopsy menu:* In December 2015, Biocartis launched the Idylla™ ctBRAF Mutation Assay (Research Use Only), the world's first and only fully automated liquid biopsy test that can potentially act as a substitute for tissue biopsy testing in melanoma, colorectal and lung cancers, as well as conditions such as hairy cell leukaemia and histiocytosis¹. The commercial market for liquid biopsy testing, that allows for diagnostic testing based on circulating tumour (ct) DNA fragments in the blood, has grown significantly in 2015. This has, amongst others, driven Biocartis' decision to accelerate the development of liquid biopsy versions of its solid biopsy tests.
- *Performance studies:* During 2015, multiple studies to analyse performance of the Idylla™ BRAF and RAS products were conducted, generating over 3,000 test results. In general, these studies demonstrated high concordance with reference methodologies and higher sensitivity and specificity of the Idylla™ tests compared to competing In Vitro Diagnostic (IVD) solutions. Furthermore, these studies underlined Idylla™'s capability of offering very rapid turnaround times, based on a fully automated sample-to-result solution. More information on these studies can be found on the Biocartis website.

Infectious disease menu

Biocartis' focus within infectious diseases is on offering highly sensitive syndromic panel tests for, amongst others, respiratory diseases:

- *Idylla™ Respiratory (IFV-RSV) Panel:* In November 2015, the first infectious disease test on the Idylla™ platform was launched. The CE-marked Idylla™ Respiratory (IFV-RSV) Panel has been developed by Janssen Diagnostics. This test is intended for the detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV) from nasopharyngeal swabs (NPS²) of adult and paediatric patients. The Panel combines, in one single product, the speed of rapid tests (turnaround time of as little as 50 minutes with less than one minute hands-on time) with the quality and sensitivity standards of central lab tests.
- *MERS test:* During Q3 2015, Biocartis and Fast-track diagnostics initiated the development of a test aimed at detecting MERS-CoV. MERS-CoV is a type of coronavirus that was first identified in Saudi Arabia in 2012 and is the cause of Middle East Respiratory Syndrome (MERS). A large outbreak of this disease occurred in South-Korea in 2015 and approximately 36% of patients with MERS reported to date have died³. The MERS test will further complement Biocartis' offering of respiratory tests.
- *Ebola test:* Biocartis submitted the required documentation for an emergency use authorisation (EUA) application to the US Federal Drug Administration (FDA) of its Rapid Ebola Virus Triage Test, which Biocartis is developing in association with Janssen Diagnostics and the Institute for Tropical Medicine in Antwerp (Belgium).

Collaborations

To ensure a rapid expansion of the test menu, Biocartis has an active partnership strategy to develop tests in collaboration with external strategic partners. Biocartis signed the following collaborations in 2015:

- 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.

¹ Histiocytosis is a general name for a group of disorders or "syndromes" that involve an abnormal increase in the number of immune cells that are called histiocytes. Source: <https://www.nlm.nih.gov/medlineplus/ency/article/000068.htm>, December 2015.

² The test is compatible with both dry NPS swabs as well as with a viral transport medium.

³ Source: World Health Organization, Fact sheet N°401.

- Fast-track diagnostics (a Luxembourg company commercialising real-time PCR kits for infectious diseases); aimed at the development of a broad range of Idylla™ infectious disease tests based on the approach of 'syndromic multiplex testing', meaning the identification of a broader range of disease pathogens in one single test.
- A*STAR⁴ (Singapore's lead public sector agency that spearheads economic oriented research to advance scientific discovery and develop innovative technologies); aimed at the joint development of a range of proprietary tests for the Idylla™ platform, with a main focus on cancer biomarkers.
- Merck KGaA (Merck), a leading science and technology company in healthcare, life science and performance materials, signed a collaboration agreement with Biocartis for the development and commercialization of a new liquid biopsy RAS biomarker test for patients with metastatic colorectal cancer (mCRC). The aim of the collaboration is to support clinical practice in performing integrated liquid biopsy RAS biomarker tests, independently of the laboratories' volume of testing or level of expertise. Both parties plan to implement the Idylla™ liquid biopsy RAS test in numerous medical centres across the world⁵. The test is expected to be available for Research Use Only (RUO) in Q3 2016 and is shortly thereafter planned to be submitted for a CE mark.
- Amgen Inc (Amgen), one of the world's leading biotechnology companies, signed a collaboration agreement to offer Biocartis' new RAS biomarker tests (i.e. the Idylla™ KRAS Mutation Test and Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay) to hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain⁶ and Turkey. The aim of the collaboration is to accelerate access to RAS biomarker information in the selected countries.

Financial highlights

From a financial point of view, 2015 was a year marked by successfully securing funding, as well as initiating the transition process from revenues driven by R&D activities, towards revenues driven by partnerships and commercial product sales:

- *Operating income:* Biocartis increased its total operating income from EUR 10.4m in 2014 to EUR 15.0m in 2015, an increase of 44%. This increase was primarily attributable to an increase in collaboration revenues of EUR 6.5m to EUR 9.7m in 2015. Total product revenues equalled EUR 3.6m in 2015.
- *Equity raisings:* In 2015, Biocartis raised a total of EUR 136.5m through the second tranche of its F-round financing of EUR 21.5m in January 2015 and the gross proceeds of EUR 115.0m following a 6.5x oversubscribed successful Initial Public Offering (IPO) on Euronext Brussels in April 2015. The IPO attracted a wide interest from a mix of long-term, specialist investors across continental Europe and the UK and from qualified institutional buyers in the US.
- *Financial debt:* Biocartis attracted a new financing facility of EUR 5m in Q4 2015 to fund investments in manufacturing. As per 31 December 2015, EUR 1.8m was drawn under this new facility. Following repayment of the Senter Novem loan in October 2015 and ongoing repayments under the KBC Lease facilities, the total outstanding amount of financial debt as of 31 December 2015 amounted to EUR 10.8m.
- *Cash burn:* Driven by positive movements in working capital of approx. EUR 11.5m primarily from net movements in inventories, receivables and payables, Biocartis' cash flow from operating activities and investing activities amounted to EUR -32.8m in 2015.
- *Cash position:* Based on a cash position of EUR 10.9m as of 31 December 2014, a negative cash flow from operating and investment activities of EUR 32.8m and a positive cash flow from financing activities of EUR 125.9m, Biocartis' cash position amounted to EUR 104.1m as per 31 December 2015.

Operational highlights

The operational focus in 2015 was on further strengthening the organisation to support and enable the envisaged test menu expansion and related commercial roll-out of the Idylla™ platform:

- *Manufacturing:* During 2015, Biocartis outsourced the manufacturing of its Idylla™ Instrument and Idylla™ Console to a renowned Contract Manufacturing Organization. This enabled cost efficiencies and scaling of production capacity. Furthermore, in Q4 2015 Biocartis ordered the equipment and tools for a second manufacturing line that should provide an additional annual cartridge capacity of over 1 million Idylla™ cartridges as of H2 2017.
- *Strengthening management team:* In view of the next critical steps Biocartis has to take in becoming a world leader in molecular diagnostics, Biocartis strengthened positions at its senior management level in September

⁴ 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).

⁵ Excluding the U.S., China and Japan.

⁶ Added to the collaboration in December 2015.

2015, to provide the company with the expertise needed for the execution of its strategy.

- *Employee base:* Biocartis' employee base included 270 FTEs as per 31 December 2015, compared to 189 FTEs as per 31 December 2014.

Commenting on the 2015 results, Rudi Pauwels, Chief Executive Officer of Biocartis, said:

"2015 was a year of great success for Biocartis. I am extremely proud to say that we delivered on the promises that were made during the time of our IPO. Furthermore, I am also pleased to say that we realised a promising initial market adoption of Idylla™. Besides this being a key value driver for our company, it also has a positive impact on society, as Idylla™ offers accurate and fast diagnostic information - where and when clinicians and patients meet.

Backed-up by a solid cash position and a strengthened organisation with dedicated employees, we are confident to continue to deliver on our promises in 2016, both operationally and commercially. In a rapidly changing healthcare landscape, where molecular information is increasingly used to detect and stage disease earlier and more accurately, our Idylla™ technology in combination with our Idylla™ oncology tests are increasingly showing their complementary use in diagnostics, as a companion to new, promising treatments such as immuno-oncology. As such, in 2016 we will aim to have our core menu for oncology on the market and by doing so, expect further leverage of our Idylla™ technology."

Key figures for 2015

The tables below show an overview of the key figures and a breakdown of operating income for 2015. A consolidated income statement, balance sheet, cash flow statement and statement of changes in equity of Biocartis Group NV is presented in the paragraph 'Financial information' at the end of this press release.

Key figures (EUR 1,000)	2015	2014	% Change
Total operating income	14,951	10,367	44%
Cost of goods sold	-2,642	-4,251	-38%
Research and development expenses	-36,554	-25,014	46%
Marketing and distribution expenses	-8,747	-3,095	183%
General and administrative expenses	-6,662	-7,180	-7%
Operating expenses	-54,606	-39,540	38%
Operational result	-39,655	-29,173	36%
Net financial result	-790	-961	-18%
Income tax	648	947	-32%
Result from discontinued operations	-	19,472	-100%
Net result	-39,797	-9,715	310%
Cash flow from operating activities	-23,357	-35,884	-35%
Cash flow from investing activities	-9,414	5,052	-286%
Cash flow from financing activities	125,943	12,727	890%
Net cash flow	93,173	-18,105	-615%
Cash and cash equivalents¹	104,088	10,919	853%
Financial debt	10,814	13,585	-20%

¹ Including EUR 1.5m of restricted cash (as a guarantee for bank and lease financing)

Breakdown operating income (EUR 1,000)	2015	2014	% Change
Collaboration revenue	9,686	3,174	205%
Product sales revenue	3,593	5,260	-32%

Service revenue	54	44	22%
Total revenue	13,334	8,478	57%
Grants and other income	1,617	1,889	-14%
Total operating income	14,951	10,367	44%

Income statement

Biocartis' total operating income increased from EUR 10.4m in 2014 to EUR 15.0m in 2015, an increase of 44%. This increase was primarily attributable to a EUR 6.5m increase in collaboration revenues bringing the total to EUR 9.7m in 2015. Collaboration revenues consisted of revenue recognition from upfront payments that Biocartis received under its license and development agreements with Janssen Pharmaceutica in the amount of EUR 5m, a total of EUR 4m of milestone payments that Biocartis received from Janssen Pharmaceutica in relation to the further commercialisation of the Idylla™ platform, as well as EUR 0.7m of revenues from R&D services.

Total product sales revenues in 2015 amounted to EUR 3.6m, representing a decrease of EUR 1.7m compared to 2014. This is the result of a one-off direct sale of 80 Idylla™ instruments towards Janssen Pharmaceutica in 2014 and lower product sales from R&D activities that were only partially off-set by higher commercial product sales. Idylla™ instrument sales consequently decreased from EUR 3.7m in 2014 to EUR 2.3m in 2015. Other operating income in 2015 amounted to EUR 1.6m and consisted of grants that Biocartis received from the IWT (Institute for Innovation by Science and Technology in Flanders), mainly for R&D in the field of sepsis and liquid biopsy technologies.

Total operating expenses in 2015 increased from EUR 39.5m in 2014 to EUR 54.6m in 2015, primarily driven by higher expenses in R&D as well as in marketing and distribution.

R&D expenses increased from EUR 25.0m in 2014 to EUR 36.6m in 2015 (increase of EUR 11.6m) as the consequence of an expansion of the R&D team with 38 FTE, increased R&D activities for test and platform development and additional required support from service providers. Marketing and distribution expenses increased from EUR 3.1m in 2014 to EUR 8.7m in 2015 (increase of EUR 5.6m) as the result of an expansion of the marketing & distribution team with 12 FTE, additional external sales force support and increased marketing activities to support the global roll-out of the Idylla™ platform. G&A expenses decreased from EUR 7.2m in 2014 to EUR 6.7m in 2015. This decrease is the combined result of exceptional expenses that Biocartis incurred in 2014 for its group restructuring and a costs increase because of the expansion of G&A staff with 10 FTE in 2015. Cost of goods sold decreased, predominantly as the result of lower product sales from R&D activities and a decrease in manufacturing costs for instrumentation and cartridges.

The operational result in 2015 amounted to a loss of EUR 39.7m compared to a loss of EUR 29.2m in 2014. Net financial result improved from EUR -1.0m in 2014 to EUR -0.8m in 2015.

The above has resulted in a net result from continued operations in 2015 of EUR 39.8m, compared to a loss of EUR 29.2m in 2014. In this respect it is important to note that in 2014, Biocartis realised a one-off gain from discontinued operations of EUR 19.5m.

Balance sheet

In 2015, property, plant & equipment increased with EUR 5.1m from EUR 9.2m in 2014 to EUR 14.2m as the result of EUR 9.2m of additions, predominantly capex for manufacturing equipment, and depreciation of EUR 4.2m.

Per 31 December 2015, a financial participation 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 a 9.53% participation in MyCartis NV.

Inventory increased from EUR 3.6m per 31 December 2014, to EUR 5.8m end of 2015, caused by higher inventory levels in view of the further commercialization of the Idylla™ platform. Trade receivables have decreased significantly with EUR 9.9m to EUR 5.9m per 31 December 2015, because of the collection of receivables of approx. EUR 12.0m from Janssen Pharmaceutica. Trade payables increased from EUR 4.3m per 31 December 2014, to EUR 13.9m per 31 December 2015, mainly driven by prepayment invoices for operating and

capital commitments in relation to manufacturing expansion. Deferred income has decreased to EUR 5.2m per 31 December 2015, from EUR 9.6m per 31 December 2014, because of recognised upfront payments from Janssen Pharmaceutica in relation to the strategic licensing, development and commercialization collaborations.

Total financial debt decreased from EUR 13.6m as of 31 December 2014, to EUR 10.8m per 31 December 2015. This has primarily been the result of the full repayment of the Senter Novem loan of EUR 4.1m, repayments on existing lease facilities of EUR 1.1m and a new financing facility of EUR 5.0m that was obtained from a financial institution end of 2015 under which EUR 1.8m was drawn per 31 December 2015.

Driven by the second tranche of the series F financing round of EUR 21.5m in January 2015 and the gross proceeds of EUR 115.0m of the IPO in April 2015, the cash position of the Group increased with EUR 93.2m from EUR 10.9m per 31 December 2014 to EUR 104.1m per 31 December 2015.

Cash flow statement

The cash flow from operating activities improved in 2015 to EUR -23.4m compared to EUR -35.9m in 2014, as the result of positive changes in working capital, a higher loss for 2015 as well as an exceptional gain in 2014 on the disposal of MyCartis NV of EUR -26.6m.

The cash flow from investing activities in 2015 amounted to EUR -9.4m compared to EUR 5.1m in 2014, as the result of higher investments in property, plant & equipment, as well as a one-off gain in 2014 of EUR 7.5m as the result of a divestment into MyCartis NV.

The cash flow from financing activities amounted in 2015 to EUR 125.9m, compared to EUR 12.7m in 2014, driven predominantly by the proceeds of the second tranche of the series F financing round and the IPO as well as net payments of borrowings.

Outlook 2016

- *Installed base:* Target of growing the total installed base to over 300 Idylla™ instrument by adding 150-175 instrument placements, driven by the availability of a core oncology menu by the end of 2016.
- *Test launches:* aim to launch at least four new tests in 2016 to further expand the test menu for Idylla™. The following test launches are expected:
 - Solid biopsy Lung Cancer Panel (Research Use Only, Q2 2016);
 - Rapid Ebola Virus Triage Test (Based on US FDA emergency use authorisation, Q2 2016);
 - Two liquid biopsy tests for colon cancer, being liquid biopsy versions of the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay (Research Use Only, H2 2016); and
 - Idylla™ MERS Test (Middle East Respiratory Syndrome, H2 2016).
- *Regulatory upgrades:* the following regulatory upgrades are expected of existing Idylla™ tests:
 - CE-marking of the Idylla™ NRAS and NRAS/BRAF solid biopsy tests (H2 2016); and
 - US FDA approval (510k file) for the Idylla™ Respiratory (IFV-RSV) Panel and the Idylla™ Instrument a,d Idylla™ Console (expected around year-end).
- *Cash position:* Biocartis targets a cash position by the end of 2016 in the range of EUR 45m to EUR 55m.

Update test menu

Biocartis continuously monitors market developments and feedback from key opinion leaders, its Scientific Advisory Board and customers to optimize its Idylla™ menu of tests. Especially recent developments in the field of oncology have resulted in several menu optimisations as summarised below.

Oncology menu

- Increased focus on development of *fully automated liquid biopsy solutions*, including development of CE-IVD tests in collaboration with pharmaceutical companies, as these non-invasive tests are ideally placed to open up the route to faster and better treatment selection and treatment monitoring;
- Broadening of the scope of the *Idylla™ MSI⁷ Test*, with an aim to capture the expected value of MSI for predicting response to certain immunotherapies as shown by recent data; and

⁷ MSI or Microsatellite Instability is the condition of genetic hyper mutability that results from impaired DNA mismatch repair (MMR). MSI is a known prognostic factor in colorectal cancer and can also be found in a range of other cancer types.

- Development of *Idylla™ NGS Prep Panels* that will function as a gateway to link the Idylla™ platform to next-generation sequencing (NGS), a rising technology which allows detailed information analysis across multiple genes. The first Idylla™ NGS Prep Panel is expected to be launched in 2017.

Infectious diseases menu

- The *Idylla™ Sepsis Test* and its workflow automation have been further improved in 2015. Initial launch of the Idylla™ Sepsis Test is now scheduled for 2018. Sepsis remains a high unmet need as it is a life-threatening illness and the third most common cause of hospital mortality⁸;
- Increased focus on development of *highly multiplexed syndromic panels* (e.g. Respiratory Mixed panel, Meningitis, Tropical Fever and Immunocompromised panels); and
- *Higher volume/lower priced tests* to be launched at a later point in time to complete our Idylla™ test offering.

Additional background on the summarised menu update will be provided during today's webcast presentation at 14:00CET.

Financial calendar 2016

- Publication of the 2015 Annual Report: 12 April 2016
- Q1 2016 Business Update: 12 May 2016
- Annual General Meeting Biocartis Group: 13 May 2016
- Half year results H1 2016: 6 September 2016
- Q3 Business Update 2016: 17 November 2016

Webcast and presentation

The Biocartis management team will host a conference call and webcast, during which the 2015 results, 2016 outlook and test menu update will be presented, followed by a Q&A session. This event will be held today, 17 March 2016 at 14:00 CET. The conference call will be webcast live and may be accessed on www.biocartis.com or by clicking [here](#). If you would like to participate in the Q&A, please dial +44 (0)20 3427 1914 (standard international) with confirmation code 1026764. Shortly after the call, a replay of the webcast and presentation will be available on www.biocartis.com.

For more information, please contact:

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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 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. More information: www.biocartis.com.

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 release regarding past trends or activities are not guarantees of future performance and

⁸ Kochanek KD, Xu J, Murphy SL, Miniño AM, Kung HC. 2011. Deaths: final data for 2009. Natl. Vital Stat. Rep. 60(3):1–116.

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 update 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. 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.

Financial information

The consolidated financial statements have been prepared in accordance with IFRS, as adopted by the EU. The financial information included in this press release is an extract from the full IFRS consolidated financial statements, which will be published on 12 April 2016. The statutory auditor, Deloitte Bedrijfsrevisoren/Reviseurs d'Entreprises, represented by Gert Vanhees, has substantially completed the audit procedures on the IFRS consolidated statements as of and for the year ended 31 December 2015, and has confirmed that the consolidated balance sheet, the consolidated statements of comprehensive income, cash flow and changes in shareholders' equity, included in this press release, are consistent in all material aspects with the consolidated accounts from which they have been derived.

Consolidated Statement of Comprehensive Income

In €000	Years ended 31 December,	
	2015	2014
Revenue		
Collaboration revenue	9,686	3,174
Product sales revenue	3,593	5,260
Service revenue	54	44
	13,334	8,478
Other operating income		
Grants and other income	1,617	1,889
Total operating income	14,951	10,367
Operating expenses		
Cost of goods sold	-2,642	-4,251
Research and development expenses	-36,554	-25,014
Marketing and distribution expenses	-8,747	-3,095
General and administrative expenses	-6,662	-7,180
	-54,606	-39,540
Operating loss for the period	-39,655	-29,173
Financial income	107	60
Financial expense	-819	-933
Foreign exchange gains/(losses), net	-78	-88
Financial result, net	-790	-961
Loss for the year before taxes from continuing operations	-40,445	-30,134
Income taxes	648	947
Loss for the year after taxes from continuing operations	-39,797	-29,187
Gain (loss) for the year after taxes from discontinued operations	0	19,472
Loss for the year	-39,797	-9,715
attributable to owners of the Company	-39,797	-9,118
attributable to non-controlling interest		-598
Earnings per share		
basic and diluted loss per share from continuing and discontinued operations	-1.07	-0.36
basic and diluted loss per share from continuing operations	-1.07	-1.14

Consolidated Balance Sheet

In €000	As of 31 December,	
	2015	2014
Assets		
Non-current assets		
Intangible assets	8,987	9,652
Property plant and equipment	14,245	9,154
Participating interests	5,052	0
Other long term receivables	11	117
Deferred tax assets	1,986	947
	<u>30,281</u>	<u>19,870</u>
Current assets		
Inventory	5,837	3,583
Trade receivables	5,852	15,793
Other receivables	1,063	148
Other current assets	1,258	2,700
Cash and cash equivalents	104,087	10,919
	<u>118,097</u>	<u>33,142</u>
Total assets	<u>148,378</u>	<u>53,012</u>
Equity and liabilities		
Capital and reserves		
Legal share capital	405	222,268
Historical share capital adjustment	-221,232	-221,232
Share premium	522,708	166,592
Share based payment reserve	1,345	1,166
Accumulated deficit	-188,310	-148,513
Total equity attributable to owners of the Company	114,916	20,280
Non-current liabilities		
Financial debt	2,662	8,528
Deferred income	1,342	4,534
Accrued charges	1,580	1,955
	<u>5,585</u>	<u>15,017</u>
Current liabilities		
Financial debt	8,152	5,057
Trade payables	13,927	4,265
Deferred income	3,812	5,100
Other current liabilities	1,986	3,293
	<u>27,877</u>	<u>17,714</u>
Total equity and liabilities	<u>148,378</u>	<u>53,012</u>

Consolidated Cash Flow Statement

in €000	Years ended 31 December,	
	2015	2014
operating activities		
Loss for the period	-39,797	-9,715
Adjustments for		
Depreciation and amortization	5,021	4,437
Depreciation and amortization included in discontinued operations	0	81
Impairments	73	37
Tax income in profit and loss	-1,039	-947
Financial result, net	688	897
Net movement in retirement benefit obligation	0	108
Gain on disposal MyCartis NV	0	-26,624
Share based payment expense	179	143
Changes in working capital		
Net movement in inventories	-2,254	-2,524
Net movement in trade and other receivables and other current assets	10,574	-2,736
Net movement in trade payables & other current liabilities	7,981	1,860
Net movement in deferred income	-4,479	-746
Interests paid	-304	-155
Cash flow from operating activities	-23,357	-35,884
Investing activities		
Interest received	106	60
Purchases of property, plant & equipment	-9,241	-1,927
Purchases of intangible assets	-371	-840
Proceeds from sale and lease back of property, plant and equipment	18	0
Proceeds from the sale of fixed assets	74	0
Disposal shares in other companies	0	245
Acquisition of a subsidiary	0	7,514
Cash flow from investing activities	-9,414	5,052
Financing activities		
Proceeds from borrowings	1,817	0
Proceeds from issue of preference shares F	21,513	21,244
Disposal of Mycartis NV to capital owners of the parent	0	-5,138
Proceeds from the issue of common shares, net of transaction costs	107,688	0
Repayment of borrowings	-5,057	-3,378
Bank charges	-18	-1
Cash flow from financing activities	125,943	12,727
Net increase / (decrease) in cash and cash equivalents	93,173	-18,105
Cash and cash equivalents at the beginning of the period	10,919	29,047
Effects of exchange rate changes on the balance of cash held in foreign currencies	-4	-23
Cash and cash equivalents at the end of the period	104,088	10,919
Supplementary cash flow disclosures		
new finance leases	1,216	0

Consolidated Statement of Changes in Shareholder Equity

in €000	Legal share capital	Historical share capital adjustment	Share premium	Share based payment reserve	Gains and losses on defined benefit plans	Accumulated deficit	Total equity attributable to the owners of the Company	Non-controlling interest	Total equity
Balance as at 31 December 2013	926		175,946	1,023	-309	-145,631	31,955		31,955
Loss for the period						-9,118	-9,118	-598	-9,716
Non-controlling interest of 20% in Mycartis NV						6,057	6,057	1,443	7,500
Capital increase by incorporation of share premium	30,488		-30,488						
Disposal of interest in Mycartis NV through capital decrease	-30,488				309	178	-30,000	-845	-30,845
Issue of preference shares	110		21,403				21,513		21,513
Cost related to capital increase			-269				-269		-269
Share-based payment expense				143			143		143
Change in reporting entity	221,232	-221,232							-
Balance as at 31 December 2014	222,268	-221,232	166,592	1,166		-148,513	20,280		20,280
Loss for the period						-39,797	-39,797		-39,797
Share issue - tranche 2 of round F on 15 January 2015	20,488		1,025				21,513		21,513
Share issue - contribution in kind of the participation in Mycartis on 15 January 2015	4,812		241				5,052		5,052
Capital increase by incorporation of share premium on 15 January 2015	8		-8				-		-
Capital decrease by conversion into share premium on 13 April 2015	-247,272		247,272				-		-
Share issue -Initial Public Offering on 28 April 2015	87		99,913				100,000		100,000
Share issue - exercise of over-allotment warrant on 19 May 2015	13		14,987				15,000		15,000
Cost related to Initial Public Offering			-8,124				-8,124		-8,124
Share issue - exercise of stock options on 3 June 2015	0		171				171		171
Share issue - exercise of stock options on 6 October 2015	0		313				313		313
Share issue - exercise of stock options on 23 December 2015	0		295				295		295
Costs related to capital increase			33				33		33
Share-based payment expense				179			179		179
Balance as at 31 December 2015	405	-221,232	522,708	1,345		-188,310	114,916		114,916