# BIOCARTIS GROUP NV FINANCIAL REPORT H1 2015











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#### 1 MESSAGE FROM THE CEO



Dear Stakeholder,

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.

Rudi Pauwels CEO

# 2 RESPONSIBILITY STATEMENT

The undersigned hereby declare that, to the best of their knowledge, the condensed consolidated interim financial statements for the six-months period ended 30 June 2015, which have been prepared in accordance with the IAS 34 'Interim Financial Reporting' as adopted by the European Union, give a true and fair view of the equity, the financial situation and the results of Biocartis Group NV and the companies that are included in the consolidation scope.

The undersigned also declare that, to the best of their knowledge, the interim financial report provides a true and fair review of the important events that have occurred during the first six months of the financial year and of the other legally required information.

In the name and for the account of the Board of Directors,

Rudi Pauwels Hilde Windels

CEO CFO

# 3 PRINCIPAL RISKS RELATED TO THE BUSINESS ACTIVITY

The principal risks related to Biocartis' business activities have been outlined in the April 2015 IPO Prospectus ('IPO Prospectus'), which is available on the internet at https://investors.biocartis.com. The principal risks have not materially changed from the ones outlined in the IPO Prospectus.

#### 4 BUSINESS REVIEW OF THE FIRST HALF OF 2015

# 1.1 Commercial highlights



During H1 2015, Biocartis sold **a total of 32 Idylla<sup>TM</sup> commercial instruments** to its customers, boding well for realizing the guided 75 Idylla<sup>TM</sup> instrument sales in 2015.

The **Idylla<sup>TM</sup>** installed base amounted to 114 instruments in different continents worldwide per 30 June 2015.

During the reporting period, Biocartis continued to move forward in establishing a strong global sales and distribution network that now covers more than 50 countries through direct and indirect sales channels.

A total of **nine new distribution contracts** were signed in H1 2015 with renowned distributors, covering 12 additional countries in Europe, Middle East and Asia Pacific. These new distribution contracts include minimum purchase obligations for over 100 ldylla<sup>TM</sup> instruments in the coming 3 years period.

Biocartis also continued to **strengthen its direct sales force** in H1 2015 by attracting key talent from the industry and which is now covering 16 European countries.

At the end of the reporting period, Biocartis' sales and marketing organization, including amongst others customer service and business development, amounted to 24 FTEs.

#### 1.2 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<sup>TM</sup>, 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<sup>TM</sup> 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<sup>TM</sup> BRAF Mutation Test. This research study showed that the Idylla<sup>TM</sup> BRAF Mutation Test is rapid and has high concordance with other routinely used

but more complex BRAF mutation-detecting tests<sup>1</sup>.

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<sup>TM</sup> 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<sup>™</sup> 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 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

 $<sup>^1</sup>$  The  $IdyIla^{TM}$  System and  $IdyIla^{TM}$  BRAF Test are currently not available in the USA.

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 detection of bloodstream rapid infections, such as sepsis. This test is aimed to be used in conjunction with Biocartis' Idylla™-Enrich platform, a dedicated preenrichment 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.

#### 1.3 Financial highlights



On 28 April 2015, Biocartis raised gross proceeds of EUR 115m in а 6.5x oversubscribed successful Initial Public Offering (IPO) Euronext on Brussels, underpinning the strong belief 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<sup>™</sup> 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<sup>™</sup> 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.

1.4 H1 2015 financial results

*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 development the continued preparation for launch of new Idylla<sup>TM</sup> tests and further Idylla<sup>™</sup> 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  $Idylla^{TM}$  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<sup>™</sup> 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 commercialization and 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.

# 5 CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS FOR THE PERIOD ENDED 30 JUNE 2015

# **5.1** CONDENSED CONSOLIDATED BALANCE SHEET

		As	of
In €000	<u>Notes</u>	30 June 2015	31 Dec 2014
Assets			
Non-current assets			
Intangible assets		9,218	9,652
Property plant and equipment	6.14	8,880	9,154
Financial participation	6.15	5,052	-
Other long term receivables		11	117
Deferred tax assets	6.11	1,474	947
		24,635	19,870
Current assets			
Inventory		6,415	3,583
Trade receivables	6.16	3,105	15,793
Other receivables	6.16	1,484	148
Other current assets	6.17	1,997	2,700
Cash and cash equivalents		128,477	10,919
		141,478	33,142
Total assets		166,113	53,012
Equity and liabilities			
Capital and reserves			
Legal share capital	6.18	405	222,268
Historical share capital adjustment	6.18	-221,232	-221,232
Share premium	6.18	522,067	166,592
Share based payment reserve	6.19	1,211	1,166
Accumulated deficit	6.18	-165,428	-148,513
Total equity attributable to owners of			
the Company		137,022	20,280
Non-current liabilities			
Financial debt		8,347	8,528
Deferred income	6.20	2,021	4,534
Accrued charges		2,486	1,955
		12,855	15,017
Current liabilities			
Financial debt		5,016	5,057
Trade payables		3,866	4,265
Deferred income	6.20	5,025	5,100
Other current liabilities		2,329	3,293
		16,236	17,714
Total equity and liabilities		166,113	53,012

# **5.2** CONDENSED CONSOLIDATED INCOME STATEMENT

		For the 6 months ended		
<u>In €000</u>	<u>Notes</u>	30 June 2015	30 June 2014	
Revenue				
Collaboration revenue	6.4	4,866	283	
Product sales revenue	6.4	1,663	829	
Service revenue	6.4	48	12	
		6,578	1,124	
Other operating income				
Grants and other income	6.5	646	1,379	
Total operating income		7,224	2,503	
Operating expenses				
Cost of goods sold	6.6	-1,158	-1,000	
Research and development expenses	6.7	-16,092	-12,768	
Marketing and distribution expenses	6.8	-3,219	-1,158	
General and administrative expenses	6.9	-3,578	-3,139	
		-24,047	-18,066	
Operating loss for the period		-16,823	-15,563	
Financial income		31	35	
Financial expense		-440	-495	
Foreign exchange gains/(losses), net		-20	-52	
Financial result, net		-429	-512	
Loss for the year before taxes from				
continuing operations		-17,252	-16,075	
Income taxes	6.11	337	421	
Loss for the year after taxes from		46045	45.654	
continuing operations		-16,915	-15,654	
Gain (loss) for the year after taxes from	6.12	_	-4,092	
discontinued operations	0.12		1,032	
Loss for the year		-16,915	-19,746	
attributable to owners of the Company		-16,915	-19,746	
attributable to non-controlling interest				
Earnings per share				
basic and diluted loss per share from continuing and discontinued operations	6.13	-0.50	-0.80	
basic and diluted loss per share from		-0.50	-0.63	
continuing operations		0.50	0.00	

# **5.3** CONDENSED CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE INCOME

		As of			
<u>In €000</u>	<u>Notes</u>	30 June 2015	30 June 2014		
Loss for the year		-16,915	-19,746		
Other comprehensive income (loss), not to be reclassified to profit or loss Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss		-	-		
Total comprehensive loss for the year		-16,915	-19,746		
Attributable to owners of the Company Attributable to non-controlling interest		-16,915 -	-19,746 -		

# **5.4** CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

Attributable to owners of the Company										
in €000	Notes	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 Share-based payment expense	6.19	-	-		- 87		-19,746	-19,746 87	-	-19,746 87
Balance as at 30 June 2014		926		175,946	1,110	-309	-165,377	12,296		12,296
Balance as at 31 December 2014		222,268	-221,232	166,592	1,166		-148,513	20,280		20,280
Loss for the period Share issue - tranche 2 of round F on 15 January 2015		-	-	-	-	-	-16,915	-16,915	-	-16,915
Share issue - contribution in kind of the participation in	6.18	20,488	-	1,025	-	-	-	21,513	-	21,513
Mycartis on 15 January 2015 Capital increase by incorporation of share premium on	6.18	4,812	-	241	-	-	-	5,052	-	5,052
15 January 2015 Capital decrease by conversion into share premium on	6.18	8	-	-8	-	-	-	-	-	-
13 April 2015	6.18	-247,271	-	247,271	_	-	-	-	_	_
Share issue -Initial Public Offering on 28 April 2015 Share issue - exercise of over-allotment warrant on 19	6.18	87	-	99,913	-	-	-	100,000	-	100,000
May 2015	6.18	13	-	14,987	-	-	-	15,000	-	15,000
Cost related to Initial Public Offering Share issue - exercise of stock options on 3 June 2015	6.18	-	-	-8,124	-	-	-	-8,124	-	-8,124
Share-based payment expense	6.18 6.19	-	-	171	- 45	-	-	171 45	-	171 45
Balance as at 30 June 2015		404	-221,232	522,067	1,211		-165,428	137,022		137,022

# **5.5** CONSOLIDATED CASH FLOW STATEMENT

		As of	
in €000	<u>Notes</u>	30 June 2015	30 June 2014
operating activities			
Loss for the period		-16,915	-19,746
Adjustments for			
Depreciation and amortization		2,417	2,096
Depreciation and amortization included in discontinued operations	6.12	-	81
Impairments		-	20
Tax income in profit and loss	6.11	-338	-421
Financial result, net		419	504
Net movement in retirement benefit		-	56
obligation Share based payment expense	6.19	45	87
Changes in working capital			
Net movement in inventories		-2,832	-1,574
Net movement in trade and other	6.16	12,160	3,450
receivables and other current assets	0.10	12,100	3,430
Net movement in trade payables & other current liabilities		-1,021	-931
Net movement in deferred income	6.20	-2,587	-349
Interests paid		-67	-81
Cash flow from operating activities		-8,719	-16,808
Investing activities			
Interest received		30	34
Purchases of property, plant & equipment	6.14	-1,620	-723
Purchases of intangible assets		-89	-492
Cash reclassified to assets held for sale			-855
Cash flow from investing activities		-1,679	-2,036
Financing activities			
Proceeds from issue of preference	6.18	21,513	-
shares F Proceeds from the issue of common			
shares, net of transaction costs	6.18	107,047	-
Repayment of borrowings		-576	-557
Bank charges		-7	-9
Cash flow from financing activities		127,977	-566
Net increase in cash and cash equivalents		117,579	-19,410
Cash and cash equivalents at the		10,919	29,047
beginning of the period		10,515	23,047
Effects of exchange rate changes on the balance of cash held in foreign		-20	-52
currencies		-20	-52
Cash and cash equivalents at the end of		128,477	9,585
the period			

# 6 NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

## **6.1** GENERAL INFORMATION

Biocartis Group NV (the "Company"), a company incorporated in Belgium with corporate address Generaal De Wittelaan 11 B, 2800 Mechelen in Belgium and its subsidiaries (together, the "Group") have developed an innovative and proprietary molecular diagnostics ("MDx") platform that offers accurate, highly-reliable molecular information from any biological sample, enabling fast and effective diagnostics treatment selection and treatment progress monitoring. The Company is using its CE-IVD marked Idylla<sup>TM</sup> platform to develop and market a broad set of high value clinical assays in the oncology and infectious diseases segments.

The Group's mission is to become a global, fully-integrated provider of novel molecular diagnostics solutions with industry-leading, high clinical value tests.

The Group has established subsidiaries in Mechelen (Belgium), Eindhoven (The Netherlands) and Lausanne (Switzerland).

The Group has so far been funded by a combination of private and public equity, upfront licensing fees and contract R&D income from collaborations, mainly from related parties. Several grants have been awarded to the Group to support its R&D activities.

The condensed consolidated interim financial statements have been authorized for issue on 10 September 2015 by the board of directors of the Company (the "Board of Directors").

# **6.2** SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies for preparing these condensed consolidated interim financial statements are explained below.

## 6.2.1 Statement of compliance and basis of preparation

These condensed consolidated interim financial statements for the six months ended 30 June 2015 have been prepared in accordance with IAS 34 'Interim financial reporting' as adopted by the EU. The statements should be read in conjunction with the annual financial statements for the year-ended 31 December 2014, which have been prepared in accordance with IFRS as adopted by the EU.

The accounting policies adapted in the preparation of the condensed consolidated interim financial statements are consistent with those applied in the special purpose preparation of the financial statements for the year ended 31 December 2014. New standards or interpretations applicable from 1 January 2015 have not had any impact on the condensed consolidated interim financial statements.

All amounts are presented in thousands of Euro, unless otherwise indicated, rounded to the nearest EUR '000.

These condensed consolidated interim financial statements have been subject to a limited review.

The following new standards and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2015:

- Improvements to IFRS (2011-2013) (applicable for annual periods beginning on or after 1 January 2015)
- IFRIC 21 Levies (applicable for annual periods beginning on or after 17 June 2014)

# 6.2.2 Segment reporting

The segment information is represented in a consistent manner with the internal reporting to the executive management, enabling decision making of allocating resources to the segment and evaluating financial performances of the segment.

At this moment, all of the Group's activities relate to "Idylla™" and as such there is only 1 operating segment. The reporting to the key decision makers is currently done at the global level.

In addition, all non-current assets of the Group are located in the country of domicile per 30 June 2015.

# **6.3** Critical accounting judgments and key sources of estimation uncertainty

In the application of the Company's accounting policies, which are described above, the Company is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

The following areas are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year:

Going concern: the interim results for the six months ended 30 June 2015 show a negative result, and the balance sheet includes a loss carried forward. The Board has examined the statements and accounting standards. Taking into account the solid cash position, and the fact that in April 2015 a successful IPO was completed, the Board is of the opinion that it can submit the interim financial statements on a going concern basis.

# **6.4** REVENUE

The Group's revenues are summarized in the table below:

	For the 6 months ended		
<u>In €000</u>	30 June 2015	30 June 2014	
Collaboration revenue			
R&D services	354	-	
Upfront license revenues	2,512	283	
Milestone revenues	2,000		
	4,866	283	
Product sales revenue			
System Sales	1,246	-	
Cartridge Sales	416	829	
	1,663	829	
Service revenue			
Service revenue	48	12	
	48	12	
Total	6,578	1,124	

#### 6.4.1 Collaboration revenue

License fees and milestone payments were generated under the Group's collaboration and development agreements with JPNV, an entity linked to a shareholder of the Group. This agreement was initially signed on 20 December 2010 and subsequently amended on 9 October 2014. Under this agreement, the Group commits to further develop its Idylla<sup>TM</sup> platform and parties agree upon a non-disclosed assay development collaboration. In return, the Group is entitled to non-refundable upfront payments, performance milestones and royalties on certain future assay sales.

#### 6.4.2 Product sales revenue

The product sales relate to  $Idylla^{TM}$  system sales (instruments and consoles) and test sales (cartridges) to customers and collaboration partners. The total product sales can be categorized in commercial sales and research and development sales.

	For the 6 months ended		
	30 June 2015	30 June 2014	
Commercial	1,272	-	
Research and development	391	829	
Total	1,663	829	

# 6.4.3 Revenues by region and major customers

	For the 6 months ended		
<u>ln €000</u>	30 June 2015	30 June 2014	
Country of domicile	57	-	
Belgium	57	-	
Total all foreign countries, of which	6,520	1,124	
United states of America	5,082	1,124	
Rest of the world	1,438		
Total	6,578	1,124	

Revenues in the above table are assigned according to the location of the group or parent company of the customer.

The Group has recognized revenues from one customer representing at least 10% of the total revenues. This customer accounts for  $\leq$  5.0 million of the revenues in the first half of 2015 (first half of 2014:  $\leq$  1.1 million).

# **6.5** OTHER OPERATING INCOME

	For the 6 months ended			
<u>In €000</u>	30 June 2015	30 June 2014		
R&D project support (IWT grants)	639	1,078		
Other project grants	-	297		
Other income	8	4		
Total	646	1,379		

# **6.6** COST OF GOODS SOLD

The Cost of goods sold in relation to the product sales is as follows:

	For the 6 months ended				
<u>In €000</u>	30 June 2015	30 June 2014			
Staff costs	-413	-480			
Material, lab consumables & small					
equipment	-536	-189			
Depreciation and amortization	-204	-305			
Other	-4	-25			
Total	-1,158	-1,000			

# **6.7** RESEARCH AND DEVELOPMENT EXPENSES

	For the 6 months ended	
<u>In €000</u>	30 June 2015	30 June 2014
Staff costs	-7,984	-6,631
Subcontracting	-2,696	-2,329
Laboratory expenses	-734	-403
Cartridge, instrument and consoles	-5	-22
Consultancy	-761	-580
Quality and regulatory	-	-39
Intellectual property	-447	-301
Facilities	-1,089	-456
Travel, training, office & other	-969	-731
Depreciation and amortization	-2,176	-1,557
Internally capitalized instruments	770	280
Total	-16,092	-12,768

Subcontracting includes expenses in relation to services provided by research and development providers such as services related to the development of the assay cartridge, instrument and console of the various diagnostic platforms, manufacturing equipment design and engineering services.

# **6.8** Marketing and Distribution expenses

	For the 6 months ended	
<u>In €000</u>	30 June 2015	30 June 2014
Staff costs	-1,706	-871
Subcontracting	-480	-41
Sales and marketing	-37	-12
Business development	-110	-34
Travel, training, office & other	-852	-195
Depreciation and amortization	-34	-4
Total	-3,219	-1,158

Sales and marketing expenses relate to costs of external market research, advertisement, and promotional activities related to the Group's products.

# **6.9** GENERAL AND ADMINISTRATIVE EXPENSES

	For the 6 mo	For the 6 months ended	
<u>In €000</u>	30 June 2015	30 June 2014	
Staff costs	-1,400	-1,401	
External advice	-1,018	-608	
Facilities	-165	-454	
ICT	-3	-57	
Travel, training, office and other	-988	-390	
Depreciation and amortization expenses	-4	-230	
Total	-3,578	-3,139	

External advice expenses include fees, service and consulting expenses related to legal, human resources, investor relations, accounting, audit and tax services. Other expenses include office, insurance and other miscellaneous expenses used in general and administrative activities.

# **6.10** Personnel expenses

For the 6		6 months ended	
<u>In €000</u>	30 June 2015	30 June 2014	
Staff costs	-11,503	-9,383	
Average number of full time equivalents	204	162	

# **6.11** TAXES

	For the 6 months ended	
<u>In €000</u>	30 June 2015	30 June 2014
Current income taxes	-190	-
Deferred income taxes	527	421
Total	337	421

Current income taxes for  $\leq$  0.2 million were recorded in the frame of the disposal of the Evalution<sup>TM</sup> branch in 2014. The deferred income taxes of  $\leq$  0.5 million relate to the R&D tax credit carry-forwards in Belgium for the first half of 2015.

The Group has tax losses available to carry forward of  $\in$  116.8 million per 30 June 2015 (31 December 2014:  $\in$  86.8 million). Due to uncertainty surrounding the Group's ability to realise taxable profits in the foreseeable future, the Group has not recognised any deferred tax assets on tax loss carry forwards.

# **6.12** DISCONTINUED OPERATIONS

The discontinued operations in the first half of 2014 relate to the results of the Evalution<sup>™</sup> business. The branch was contributed to the share capital of MyCartis NV per 1 July 2014.

	For the 6 months ended	
<u>In €000</u>	30 June 2015	30 June 2014
Revenue		
Collaboration revenue	-	133
Service revenue		1
	-	134
Other operating income		
Grants and other income	-	29
Operating expenses		
Research and development expenses	-	-3,368
Marketing and distribution expenses	-	-384
General and administrative expenses		-492
		-4,244
Operating loss for the period	-	-4,080
Foreign exchange gains/(losses), net	_	-11
Financial result, net		-11
Loss before taxes		-4,092
Taxes		
Net loss for the year from discontinuing		
operations	-	-4,092
		4.002
attributable to owners of the Company	-	-4,092
attributable to non-controlling interest	-	-

# **6.13** EARNINGS PER SHARE

The company has stock options plans that may be settled in common shares of the Company and which are considered anti-dilutive given that the Group's operations were loss making over the reporting period. As such, the basic and diluted earnings per share are equal.

	For the 6 months ended	
	30 June 2015	30 June 2014
Profit/loss for the period attributable to the owners of the Company (in €000)	-16,915	-19,746
Weighted average number of ordinary shares for basic loss per share (in number of shares)	33,557,321	24,690,864
basic loss per share (€)	-0.50	-0.80

# **6.14** Property, plant and equipment

The table below provides an overview of the investments per subcategory. Total additions amount to € 1.6 million in the first half of 2015 and mainly concern investments in cartridge molds (€ 0.5 million), 15 internally produced Idylla<sup>TM</sup> consoles (€ 0.1 million) and 50 internally produced Idylla<sup>TM</sup> instruments (€ 0.7 million) for internal use.

	As of
<u>In €000</u>	30 June 2015
Investments	
ICT equipment	95
Laboratory equipment	130
Manufacturing equipment	547
Internally produced systems	770
Furniture and fixtures	63
Leasehold improvements	35
Total	1,640

## **6.15** FINANCIAL PARTICIPATION

On 15 January 2015, the Group acquired a financial participation of 13.5% (per 30 June 2015: 11,2%) in MyCartis NV through a contribution in kind for an amount of € 5.1 million through the conversion of the share put option held by Debiopharm Diagnostics SA. The participation is accounted for at cost as the Group has no significant influence over MyCartis NV. No impairment has been recorded per 30 June 2015.

	As of	
<u>In €000</u>	30 June 2015	31 Dec 2014
Initial recognition amount	5,052	
Total	5,052	0

# **6.16** Trade and other receivables

Trade receivables have decreased from € 15.8 million per 31 December 2014 to € 3.1 million per 30 June 2015. The decrease of € 12.7 million results from the payment of JPNV receivables in 2015.

	As of	
<u>In €000</u>	30 June 2015	31 Dec 2014
Trade receivables	3,105	15,793
Allowance for doubtful receivables	<u>-</u>	
Total	3,105	15,793

The other receivables show an increase by € 1.3 million compared to 31 December 2014, which is explained by higher VAT receivables.

	As of	
<u>In €000</u>	30 June 2015	31 Dec 2014
VAT receivables	1,471	116
Other receivables	13	32
Total	1,484	148

# **6.17** OTHER CURRENT ASSETS

	As of	
<u>In €000</u>	30 June 2015	31 Dec 2014
Accrued grant income	986	2,168
Accrued other income	79	-
Deferred charges	932	533
Total	1,997	2,700

Other current assets include accrued grant income for € 1.0 million mainly related to Flemish government grants for IWT R&D projects and deferred charges of € 0.9 million.

# **6.18** EQUITY

## <u>Issued share capital</u>

The table below summarises the share capital and the outstanding shares of Biocartis Group NV.

		Biocartis Group NV	
	Number of	Number of	_
	common	preferred F	
	shares issued	shares issued	
	and	and	Share capital
	outstanding	outstanding	in '000€
At 31 December 2014	24,690,864	2,645,868	222,268
Share issue - tranche 2 of round F on 15 January			
2015	_	2,519,855	20,488
Share issue - contribution in kind of the		_,5 : 5,655	20, .00
participation in MyCartis on 15 January 2015	591,774	-	4,811
Capital increase by incorporation of share			
premium on 15 January 2015	-	-	8
Capital decrease by conversion into share			
premium on 13 April 2015	-	-	-247,271
Conversion preferred F shares into common	- 46	- 465 TOO	
shares on 28 April 2015	5,165,723	-5,165,723	-
Share issue -Initial Public Offering on 28 April 2015	8,695,652		87
Share issue - exercise of over-allotment warrant	0,093,032	-	07
on 19 May 2015	1,304,347	-	13
Share issue - exercise of stock options on 3 June	1,50 1,5 1,		.5
2015	21,000	-	-
At 30 June 2015	40,469,360		405

The following capital transactions took place at Biocartis Group NV from 1 January 2015 until 30 June 2015:

- On 15 January 2015, Biocartis Group NV raised € 21.5 million fully paid by an increase in share capital by € 20.5 million and an increase in share premium by € 1.0 million. This concerns the second tranche of the series F round.
- On 15 January 2015, Biocartis Group NV raised € 5.1 million through a contribution in kind of 2,253,262,501 shares in MyCartis NV following the execution of a put option held by Debiopharm Diagnostics SA. The share capital and share premium were increased by respectively € 4.8 million and € 0.2 million.
- On 15 January 2015, the share capital of Biocartis Group NV was raised by € 0.008 million by way of conversion of share premium into share capital.
- On 13 April 2015, the share capital of Biocartis Group NV was decreased by € 247.3 million by conversion into share premium.
- On 28 April 2015, Biocartis Group NV raised € 100.0 million following an Initial Public Offering, fully paid by an increase in share capital of € 0.1 million and an increase in share premium by € 99.9 million.

- On 19 May 2015, Biocartis Group NV raised € 15.0 million following the execution of the IPO over-allotment warrant. The amount was fully paid by an increase in share capital by € 0.013 million and by an increase in share premium by € 15.0 million.
- On 3 June 2015, Biocartis Group raised € 0.2 million following the execution of 21,000 stock options. The amount is fully paid by an increase in share capital by € 0.00021 million and an increase in share premium by € 0.2 million.

## **IPO** expenses

The Group has incurred € 9.2 million expenses in connection with the IPO consisting of underwriting fees, legal costs, investor relations costs, accounting and audit fees and share registration and other regulatory costs.

Underwriting fees and investor relations costs are fully attributable to the issuance of the new shares and were entirely deducted from the funds raised.

Legal costs, accounting and audit fees and share registration and other regulatory costs were incurred for both the issuance of new shares and the listing of the existing shares and were not fully deducted from equity. The Group deems that the best allocation is based on the ratio of new equity funding ( $\leq$  115.0 million) versus total equity funding ( $\leq$  296.4 million), being 38.8%. The 61.2% remaining portion of the costs incurred related to the listing of the existing shares are expensed. As such, in total  $\leq$  8.1 million was deducted from equity and  $\leq$  1.1 million was expensed.

#### **6.19** Share based compensation

#### **ESOP 2008**

The 2008 Plan is a non-dilutive stock option plan, implying that no new shares are issued upon the exercise of the respective stock options. In total 19,160 options were exercised in the first half of 2015 at CHF 4.14 exercise price and € 13.08 share price at the moment of the exercise of the options. A total of 75,172 options are still outstanding per 30 June 2015.

## ESOP 2013

The 2013 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options. In total 21,000 options were exercised in the first half of 2015, of which 1,000 options at € 8.1308 exercise price and 20,000 options at € 8.1309 exercise price, with € 13.79 average share price at the moment of the exercise of the options. A total of 699,340 options are outstanding per 30 June 2015. A total number of 279,660 stock options can still be granted under the 2013 Plan.

#### **ESOP 2015**

The 2015 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options. Biocartis Group NV is allowed to grant a maximum of 262,934 stock

options to selected staff members and directors. No stock options have been granted per 30 June 2015 under the 2015 plan.

#### **SOP WHC**

In execution of a decision of the board of directors of Biocartis S.A. of 24 April 2014, 100,000 options on shares of the Company were granted by the Company to Whitemarsh Capital LLC, a commercial partner of the Company that assists in brokering agreements for the Company with US governmental institutions for the payment of its products. In the first half of 2015, 33,000 options were forfeited. None of the remaining 67,000 options granted have been vested to this date and it is uncertain if this will occur in the near future. No share-based compensation was recorded as per 30 June 2015.

		SOP 2008	SOP 2013	SOP 2015	SOP WHC	Total
Total outstanding at 31 December						_
2014		94,362	720,340			814,702
Options granted	+	-	-	-	100,000	100,000
Options exercised	-	19,160	21,000	-	-	40,160
Options forfeited	-	-	-	-	33,000	33,000
Options cancelled	-					
Total outstanding at 30 June 2015		75,202	699,340		67,000	841,542

# Accounting for share based compensation

The shared-based compensation expense recognized in the income statement is given below:

	For the 6 months ended		
<u>In €000</u>	30 June 2015	30 June 2014	
Share based compensation	45	87	
Total	45	87	

#### **6.20** DEFERRED INCOME

	As of		
<u>In €000</u>	30 June 2015	31 Dec 2014	
Grants	-	75	
Partner income	7,046	9,559	
Total	7,046	9,634	
current	5,025	5,100	
Non-current	2,021	4,534	

Deferred partner income includes upfront payments received from JPNV in relation to the strategic licensing, development and commercialisation collaborations. This amount will be recognized as collaboration revenue in the following 2.5 years with a majority in 2015 and 2016.

Deferred	
partner	
income	

As per 31 December 2013	2,270
Invoiced	7,860
Recognized in profit or loss	-571
As per 31 December 2014	9,559
Recognized in profit or loss	-2,512
As per 30 June 2015	7,046

#### **6.21** OTHER DISCLOSURES

#### 6.21.1 Fair value

The fair value of the financial assets has been determined on the basis of the following methods and assumptions:

- The carrying value of the cash and cash equivalents and the current receivables approximate their value due to their short term character;
- Other current financial assets such as current other receivables are being evaluated on the basis of their credit risk and interest rate. Their fair value is not significantly different than its carrying value on 30 June 2015 and 31 December 2014.

The fair value of the financial liabilities has been determined on the basis of the following methods and assumptions:

- The carrying value of current liabilities approximates their fair value due to the short term character of these instruments;
- Loans and borrowings are evaluated based on their interest rates and maturity date. Most
  interest bearing debts have fixed interest rates and its fair value is subject to changes in
  interest rates and individual creditworthiness. The fair value measurement is classified as
  level 2.

## Fair value hierarchy

The Group uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

- Level 1: quoted (unadjusted) prices in active markets for identical assets and liabilities;
- Level 2: other techniques for which all inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly; and
- Level 3: techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data.

The Group has no financial instruments carried at fair value in the condensed consolidated balance sheet on 30 June 2015 and 31 December 2014.

	Carrying value		Fair value	
in '000 €	30 June 2015	31 Dec 2014	30 June 2015	31 Dec 2014
Financial assets				
Loans and receivables measured at amortised cost				
Trade and other receivables (current)	4,589	15,941	4,589	15,941
Other financial assets (non-current)	11	117	11	117
Other current assets	1,997	2,700	1,997	2,700
Total loans and other receivables	6,597	18,757	6,597	18,757
Cash & cash equivalents				
cash & cash equivalents	128,477	10,919	128,477	10,919
Total cash & cash equivalents	128,477	10,919	128,477	10,919
Financial liabilities measured at amortized cost				
Loans & Borrowings	13,364	13,585	13,933	14,077
Trade payables	3,866	4,265	3,866	4,265
Other liabilities and accrued charges	4,815	5,248	4,815	5,248
Total financial liabilities measured at amortized cost	22,045	23,098	22,614	23,590

# 6.21.2 Contingencies

For a description of outstanding contingencies, please refer to the annual report per 31 December 2014.

#### 6.21.3 Commitments

## 6.21.3.1 Capital commitments

The Group has € 4.2 million capital commitments mainly related to investments in the cartridge manufacturing facilities in Mechelen.

# 6.21.4 Related-party transactions

The table below provides an overview of the transactions with non-executive directors and shareholders during the period under review:

In €000	Sales of goods and services	Purchase of good and services	Interest cost
30 June 2015	5,285	-1,130	-235
30 June 2014	1,124	-18	-219
In €000	Trade receivables	Trade payables	Financial Debt
30 June 2015	2,306	81	6,942
31 December 2014	15,723	-	6,707

Transactions with related parties are made at arm's length. The main transactions are described below:

- Sales of goods and services and trade receivables mainly concern the collaboration and product sales towards Johnson & Johnson (or entities belonging to this Group) and Debiopharm.
- The interest cost and financial debt relate to the loan granted by PMV.

# **6.22** EVENTS AFTER THE BALANCE SHEET DATE

#### IWT NIMBLE grant

In July 2015, the Group has been awarded an R&D project grant from IWT (Institute for the promotion of Innovation by Science and Technology in Flanders) for the development of novel molecular diagnostic solutions for bloodstream infections on the Idylla<sup>TM</sup> platform. The grant amounts to € 1,461,565 and the project term is 12 months as of March, 2015.

#### Strategic collaboration with Exploit Technologies/A\*Star

In August 2015, the Group has signed a strategic collaboration agreement with Exploit Technologies/A\*Star, an organization representing 14 academic research centers in Singapore. The parties aim to jointly develop a range of multiplex tests on the Idylla<sup>TM</sup> platform. The initial focus will be on lung and liver cancer biomarkers.

#### 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.

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).

# 7 LIMITED REVIEW REPORT OF THE AUDITOR

Report on review of the condensed consolidated interim financial statements for the six-month period ended 30 June 2015

To the board of directors

In the context of our appointment as the company's statutory auditor, we report to you on the condensed consolidated interim financial statements. These condensed consolidated interim financial statements comprise the condensed consolidated balance sheet as at 30 June 2015, the condensed consolidated income statement, the condensed consolidated statement of other comprehensive income, the condensed consolidated statement of changes in equity and the condensed consolidated cash flow statement for the period of six months then ended, as well as selective notes 6.1 to 6.22.

## Report on the condensed consolidated interim financial statements

We have reviewed the condensed consolidated interim financial statements of Biocartis Group NV ("the company") and its subsidiaries (jointly "the group"), prepared in accordance with International Financial Reporting Standard IAS 34 – Interim Financial Reporting as adopted by the European Union.

The condensed consolidated balance sheet shows total assets of 166.113 (000) EUR and the condensed consolidated income statement shows a consolidated loss (group share) for the period then ended of 16.915 (000) EUR.

The board of directors of the company is responsible for the preparation and fair presentation of the condensed consolidated interim financial statements in accordance with IAS 34 – Interim Financial Reporting as adopted by the European Union. Our responsibility is to express a conclusion on these condensed consolidated interim financial statements based on our review.

# Scope of review

We conducted our review of the condensed consolidated interim financial statements in accordance with International Standard on Review Engagements (ISRE) 2410 – Review of interim financial information performed by the independent auditor of the entity. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit performed in accordance with the International Standards on Auditing (ISA) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion on the condensed consolidated interim financial statements.

Biocartis Group NV – condensed consolidated interim financial statements period ended 30 June 2015

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed consolidated interim financial statements of Biocartis Group NV have not been prepared, in all material respects, in accordance with IAS 34 – Interim Financial Reporting as adopted by the European Union.

Diegem, 10 September 2015

The statutory auditor

DELOITTE Bedrijfsrevisoren / Reviseurs d'Entreprises

BV o.v.v.e. CVBA / SC s.f.d. SCRL

Represented by Gert Vanhees

# 8 DISCLAIMER AND ADDITIONAL INFORMATION

#### General

Biocartis Group NV is a limited liability company organized under the laws of Belgium and has its registered office at Generaal De Wittelaan 11 bus B, 2800 Mechelen, Belgium.

As defined by Belgian law, Biocartis has to publish its financial report in the English and Dutch language. In case of difference in interpretation, the English version takes precedence.

An electronic version of the Half year financial report 2015 is available on the website of Biocartis at <a href="https://www.biocartis.com">www.biocartis.com</a>.

Other information on the website of Biocartis or on other websites is not a part of this Half-year Report.

#### **Contact Investor Relations**

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#### Listing

Biocartis is listed on Euronext Brussels under symbol BCART. Biocartis' ISIN code is BE0974281132.

#### Financial calendar

Q3 2015 Business Update: Thursday 19

November 2015

Full year 2015 financial results: Thursday 17

March 2016

#### Financial year

The financial year starts on 1 January and ends on 31 December.

#### **Auditor** information

Deloitte Bedrijfsrevisoren B.V. o.v.v.e. CVBA, represented by Gert Vanhees Berkenlaan 8b 1931 Diegem, Belgium

#### Forward-looking statements

Certain statements, beliefs and opinions in this report 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 report 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 even if actual results addition. developments are consistent with the forward-looking statements contained in this report, 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 report as a result of any

change in expectations or any change in events, conditions, assumptions circumstances on which these forwardlooking 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 report 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 report.

# 9 GLOSSARY

Assay

In the field of diagnostics, an assay is a process or method aimed at determining the presence or amount (quantitative assay) of a certain substance in a sample.

Serine/threonineprotein kinase B-raf (BRAF) BRAF is a protein that, in humans, is encoded by the BRAF gene. The BRAF protein is involved in sending signals within cells and in cell growth. Certain inherited BRAF mutations cause birth defects. Alternatively, other acquired mutations in adults may cause cancer.

Biomarker

A Biomarker is any molecular characteristic, feature or parameter that can be objectively measured through an assay and evaluated as an indicator of: (i) normal biologic processes; (ii) abnormal biologic processes; (iii) pathogenic processes; or (iv) pharmacologic responses to a therapeutic intervention or other action/intervention.

CE-mark

The CE-mark is a mandatory conformance mark on many products placed on the market in the European Union. With the CE-marking on a product, the manufacturer ensures that the product is in conformity with the essential requirements of the applicable European Union directives. The letters "CE" stand for "Conformité Européenne" ("European Conformity").

Deoxyribonucleic acid (DNA)

DNA is a nucleic acid molecule that contains the genetic instructions used in the development and functioning of living organisms.

Epidermal growth factor receptor (EGFR)

EGFR is a protein found on the surface of certain cells which can cause them to divide. It is found in abnormally high levels on the surface of many types of cancer cells.

Emergency Use Authorisation (EUA) This is an authorisation given by the FDA Commissioner pursuant to section 564 of the US Federal Food, Drug, and Cosmetic Act, as amended (the "FD&C Act"), which allows unapproved medical products or unapproved uses of approved medical products to be used in the United States in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear threat agents when there are no adequate, approved, and available alternatives.

Formalin fixed, paraffin embedded (FFPE)

FFPE tissues are samples, typically from suspected tumours, that are fixed or mixed with formalin to preserve the structural integrity of the sample. The sample is then embedded into a type of paraffin wax so that it can be sliced into very fine slices, 5-10 microns thick. Treating samples in this manner enables the samples to be stained with dyes to analyse abnormalities in tissue that is suspected of cancer.

US Food and Drug Administration (FDA) The FDA is a federal agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the regulation and supervision of, among other things, medical devices.

Influenza

Also known as "the flu" is a highly contagious respiratory tract infection caused by the family of influenza viruses.

In vitro diagnostics or In vitro diagnosis (IVD)

IVD is a diagnostic test outside of a living body in contrast to "in vivo", in which tests are conducted in a living body (for example an X-ray or CT-scan).

Kirsten rat sarcoma-2 virus oncogene (KRAS)

KRAS is a protein that, in humans, is encoded by the KRAS gene. Like other members of the Ras family, the KRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyse guanosine triphosphate), and is an early player in many signal transduction pathways. The protein product of the normal KRAS gene performs an essential function in normal tissue signalling, and the mutation of a KRAS gene is associated with the development of many cancers.

Molecular diagnostics (MDx)

MDx is a form of diagnostic testing used to detect specific sequences in DNA or RNA that may or may not be associated with disease. Clinical applications of MDx include infectious disease testing, oncology, pharmacogenomics and genetic disease screening.

Micro satellite instability (MSI)

MSI is a genetic hyper-mutability condition resulting from MMR that is functioning abnormally.

Multiplexing

The simultaneous detection of more than one analyte or biomarker from a single sample.

Neuroblastoma RAS viral (v-ras) oncogene (NRAS) NRAS is an protein that is encoded, in humans, by the NRAS gene. Like other members of the Ras family, the NRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyse guanosine triphosphate), and is an early player in many signal transduction pathways. The protein product of the normal NRAS gene performs an essential function in normal tissue signaling, and the mutation of a NRAS gene is associated with the development of many cancers.

Polymerase chain reaction (PCR)

The specific and exponential amplification of DNA sequences by consecutive thermal cycling steps. Real-time PCR is a form of PCR whereby the amplified sequences are made visible by means of fluorescent labelling in real time, i.e., as they become synthesized. Real-time PCR can be used to estimate the quantity of target DNA sequences in a multiplexed way. PCR and real-time PCR can also be used to detect and quantify RNA sequences after a DNA copy has been made from the RNA sequence by means of a reverse transcriptase enzyme.

Protein Polypeptide chain built from the 20 natural amino acids. Proteins are synthesized from a messenger RNA copy of a gene and can have many functions

in the cytoskeleton of the cell, enzymatic, messenger functions in cells and blood such as immune cytokines, DNA binding proteins that regulate expression, etc.

Respiratory Syncytial

Virus (RSV)

RSV is a major cause of lower respiratory tract infection that is a frequent

infection in children.

Research Use Only

(RUO)

This is a category of non-approved (i.e. no CE-marking and FDA approval) medical device products that can solely be used for research purposes. Many producers introduce their products first as RUO and/or IUO products, prior to

obtaining 510(k) clearance or PMA approval.

Sepsis Severe overall inflammatory response of the body to an infection.

