

# Financial report H1 2016

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Biocartis Group NV

# Content

1. Message from the CEO .....	2
2. Responsibility statement.....	3
3. Principal risks related to the business activities.....	3
4. Business review of the first half of 2016.....	3
5. Condensed consolidated interim financial statements for the period ended 30 June 2015.....	9
6. Notes to the condensed consolidated interim financial statements.....	15
7. Limited review report of the auditor .....	32
8. Disclaimer and additional information .....	33
9. Glossary .....	34



## 1. Message from the CEO

Dear Shareholder,

I am pleased to present to you our financial report for the first six months of 2016. For Biocartis, 2016 is a year where we are working hard to show that our efforts in installed base growth and diagnostic test menu expansion are gradually being translated into increasing cartridge demand from customers - which is the ultimate value driver of Biocartis' 'razor-razorblade' approach.

Our H1 2016 achievements, both commercially and operationally, show first evidence that this approach is succeeding, as we are building on our mission to exponentially increase the number of patients helped by our solutions. With the launch of our Idylla™ EGFR Mutation Test<sup>1</sup> for lung cancer in June, we added a very important element to our core menu for oncology. With this new test, together with the 106 Idylla™ instruments we added to our installed base the past six months and the new tests we expect to launch in the remainder of this year, the fundament is there to continue our growth path in the 2nd half of the year.

Finally, we managed to strengthen our financial position with a new non-dilutive financing of EUR 55m, announced in July 2016. This financing will further support us in our ambitious growth trajectory, aimed at making high quality molecular diagnostic solutions available everywhere and every time healthcare workers and patients interact and need to make clinical and therapeutic decisions.

Rudi Pauwels  
Founder and CEO Biocartis

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<sup>1</sup> Research Use Only.

## 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 2016, 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,

Ewoud Welten  
CFO

Rudi Pauwels  
CEO

## 3. Principal risks related to the business activities

The principal risks related to Biocartis' business activities have been outlined in Biocartis' 2015 Annual Report, p. 18-24, available on the [Biocartis website](#).

In summary, the principal risks and uncertainties faced by Biocartis relate to strategic and commercial risks, operational risks, regulatory risks and financial risks.

The principal risks have not materially changed from the ones outlined in the 2015 Annual Report.

## 4. Business review of the first half of 2016

### 4.1. Commercial highlights

Biocartis commercialises its proprietary molecular diagnostics platform Idylla™ via direct representations in key European countries and via distribution partners in other geographies.

- *Installed base:* A total of 106 Idylla™ instruments were added to the installed base in H1 2016, bringing the total to over 270 instruments as per 30 June 2016. A key driver behind the new installations was the expansion of the oncology menu by end 2015, which doubled from two to four tests with the launch of the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay and the Idylla™ ctBRAF Mutation Assay. Furthermore, the launch of the Idylla™ EGFR Mutation Assay on 21 June 2016 was another important element behind the installed base growth in H1 2016 as many clients had been waiting for this breakthrough test. Because of the launch timing of the Idylla™ EGFR Mutation Assay, a significant number of the new installations were placed with customers towards the end of Q2 2016.
- *Cartridge consumption:* Following installed base growth and the continued menu expansion, H1 2016 showed a significant pick-up in commercial cartridge consumption and associated product



revenues. This demonstrates an initial validation of the 'razor-razorblade' approach that Biocartis follows. The total commercial cartridge volume in H1 2016 was equal to more than twice the volume for the full year 2015. The top selling product in H1 2016 was the Idylla™ KRAS Mutation Test (colorectal cancer), followed by the Idylla™ BRAF Mutation Test (melanoma cancer).

## 4.2. Idylla™ test menu highlights

During H1 2016, Biocartis further advanced the development of new tests for its Idylla™ platform with a focus on completing its core menu for oncology (i.e. tests for melanoma, colon and lung cancer) and launching its second infectious disease test.

### *Oncology menu*

Biocartis currently markets five oncology tests, consisting of four solid biopsy tests and one liquid biopsy test. To date, these tests generate most of the commercial cartridge revenues.

- *Solid biopsy menu.* On 21 June 2016, Biocartis realised another important milestone in completing its core menu for oncology with the launch of a test for lung cancer, the Idylla™ EGFR Mutation Assay (RUO<sup>2</sup>).



This advanced, fully automated molecular test is designed to detect over 50 EGFR mutations which commonly occur in lung cancer and demonstrate, amongst others, the high multiplex capabilities of the Idylla™ platform. A CE-IVD version of the Idylla™

<sup>2</sup> Epidermal Growth Factor Receptor. The Idylla™ EGFR Mutation Assay is intended for Research Use Only (RUO), not for diagnostic procedures. Not for sale in the USA and Canada.

EGFR Mutation Assay is planned for 2017. A liquid biopsy version is also under development. Furthermore, in H1 2016 Biocartis continued the additional validation work needed to obtain CE-marking for its Idylla™ NRAS and NRAS/BRAF solid biopsy tests in H2 2016. Once obtained, Biocartis will be able to offer a complete RAS-BRAF analysis for clinical use on a same-day basis. The importance of offering this joint RAS-BRAF analysis was recently underlined with the new ESMO<sup>3</sup> guidelines as described below, which further opens up the route towards faster treatment selection ('same day results').

- *Liquid biopsy menu:* The promising results from liquid biopsies - which enable the identification of tumour mutations in the blood of patients - and concordance studies<sup>4</sup> currently being conducted are expected to further validate the clinical utility of these products. This underlines once more the importance of the various liquid biopsy tests Biocartis has under development. The development of liquid biopsy versions (RUO) of the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, as part of the collaboration signed with Merck KGaA in January 2016, is on track for launch in H2 2016. Upon launch, Idylla™ is expected to be the only platform that can offer sample-to-result extended RAS testing, for both solid and liquid biopsies, on the same system.
- *Performance of Idylla™ tests:* In H1 2016, Biocartis' research partners published three papers and a study at ASCO<sup>5</sup> demonstrating the high quality of the Idylla™ tests on the market.
  - *Idylla™ ctBRAF Mutation Assay<sup>6</sup>:* A publication by Dr. Filip Janku, PhD, assistant professor of Investigational Cancer

<sup>3</sup> European Society for Medical Oncology. Source: E. Van Cutsem et al, 'ESMO consensus guidelines for the management of patients with metastatic colorectal cancer', *Annals of Oncology*, published July 5, 2016.

<sup>4</sup> Diaz LA, Jr., Bardelli A. Liquid biopsies: genotyping circulating tumor DNA. *J Clin Oncol* 2014; 32: 579-586; Siravegna G, Bardelli A. Genotyping cell-free tumor DNA in the blood to detect residual disease and drug resistance. *Genome Biol* 2014; 15: 449; and Montagut C, Dalmases A, Bellosillo B et al. Identification of a mutation in the extracellular domain of the Epidermal Growth Factor Receptor conferring cetuximab resistance in colorectal cancer. *Nat Med* 2012; 18: 221-223.

<sup>5</sup> American Society of Clinical Oncology.

<sup>6</sup> Intended for Research Use Only, not for diagnostic procedures. Not for sale in the USA and Canada.

Therapeutics at MD Anderson Cancer Center (Houston, US) and his team<sup>7</sup> confirmed that the Idylla™ ctBRAF Mutation Assay can act as a faster and minimally invasive substitute for invasive tissue biopsy testing in advanced cancers such as melanoma or colorectal, which underlines that the test is perfectly suited for treatment monitoring. Similar findings were reported by Prof. Bart Neyns (Head of Medical Oncology, University Hospital Brussels, Belgium) and his team<sup>8</sup>.

- *Idylla™ KRAS Mutation Test*: A publication<sup>9</sup> by Prof. Troncone (University Federico II, Naples, Italy) researched the Idylla™ KRAS Mutation Test beyond the intended use of the test, in the setting of pancreatic cancer. The authors concluded<sup>9</sup> that the Idylla™ platform could easily be implemented in routine assessment of pancreatic DNA samples to quickly provide information on KRAS mutational status.
- *Idylla™ EGFR Mutation Assay<sup>6</sup>*: The new EGFR Mutation Assay was launched based on promising data from an alpha trial study which was accepted for publication at the upcoming ESMO meeting<sup>10</sup>. The study showed that the Idylla™ EGFR Mutation Assay demonstrated excellent specificity, sensitivity and ease of use combined with a fast turnaround time. Another study<sup>11</sup> by Prof. Troncone and colleagues (University Federico II, Naples, Italy) showed that >97% of lung cancer samples with insufficient DNA for Next Generation Sequencing (NGS) are still sufficient for testing with Idylla™. The study has been presented at the ASCO conference in June 2016.

- *Market potential*: Continued research shows that tumour mutation status (e.g. BRAF or KRAS) can drive several cancer types. Driven by such

<sup>7</sup> Janku et al. BRAF Mutation Testing in Cell-Free DNA from the Plasma of Patients with Advanced Cancers Using a Rapid, Automated Molecular Diagnostics System. *Mol Cancer Ther* (2016) 15(6): 1-8.

<sup>8</sup> Schreuer et al. Quantitative assessment of BRAF V600 mutant cell-free tumor DNA from plasma as a diagnostic and therapeutic biomarker in patients with BRAF V600 mutant melanoma. ASCO 2015.

<sup>9</sup> De Biase et al. 'Fully Automated PCR detection of KRAS Mutations on Pancreatic Endoscopic Ultrasound Fine Needle Aspirates'. *J Clin Pathol* 2016.

<sup>10</sup> Reijans et al. ESMO 2016, to be published on 6 October 2016.

<sup>11</sup> De Luca et al., *J Clin Pathol* 2016. .

research, recently adopted ESMO guidelines<sup>12</sup> recommend that tumour BRAF mutation status should also be assessed alongside the tumour RAS mutational status in metastatic colorectal cancer (mCRC). Biocartis is uniquely positioned to respond to this new recommendation through its combined KRAS and NRAS-BRAF test offering in mCRC.

### *Infectious disease menu*

Biocartis' focus within infectious diseases is on offering highly sensitive syndromic panel tests (initial focus on respiratory diseases), tests that support Biocartis' disease surveillance strategy and tests for fast monitoring of bloodstream infections ('BSI', including sepsis).

- *Respiratory tests*: Biocartis' partner Janssen Diagnostics successfully concluded US clinical studies for the Idylla™ Respiratory (IFV-RSV) Panel in H1 2016 to pursue US FDA 510k<sup>13</sup> clearance. The FDA submission file is currently being finalised, with expected submission in H2 2016.



- *Disease surveillance*: On 1 June 2016, Biocartis received Emergency Use Authorisation (EUA) by the U.S FDA for the Idylla™ Ebola Virus Triage Test that may be used to detect Ebola Zaire virus in patients with signs and symptoms of Ebola virus

<sup>12</sup> E. Van Cutsem et al, ESMO consensus guidelines for the management of patients with metastatic colorectal cancer, *Annals of Oncology Advance Access published July 5, 2016.*

<sup>13</sup> 510k clearance is a requirement by the FDA before a product is allowed on the US market. It requires a number of technical or clinical studies.

disease. Apart from being the first FDA achievement, this was a milestone for Biocartis as the Idylla™ Ebola Virus Triage Test is also a first cornerstone in its disease surveillance test offer. A collaborative study on the Idylla™ Ebola Virus Triage Test by the Institute of Tropical Medicine, Janssen Pharmaceutica, NIH (Bethesda, US) and Biocartis was published in the Journal of Infectious Diseases<sup>14</sup>, demonstrating that the Idylla™ test is fast, safe, easy to use and meets all performance criteria.

### 4.3. Financial highlights

- *Product revenues:* Total product revenues in H1 2016 grew 63% compared to H1 2015 from EUR 1.7m to EUR 2.7m. The increase in product revenues was driven by a strong growth in cartridge sales, which equalled EUR 1.7m in H1 2016 compared to EUR 0.4m in H1 2015 (increase of 314%).

+63% product revenues  
106 Idylla™ instruments  
added to installed base

This was due to significantly higher commercial cartridge consumption and cartridges sold to Janssen Diagnostics for the US clinical studies of the Idylla™ Respiratory (IFV-RSV) Panel.

- *System revenues:* (i.e. Idylla™ Instrument and Idylla™ Console revenues) in H1 2016 amounted to EUR 1m compared to EUR 1.2m in H1 2015, representing a decrease of 21%. The cause of a decrease in system revenues is driven by an increased amount of commercial instruments that are placed with clients under different types of so-called operational lease contracts. These include a successful early adopter program which stimulates cartridge consumption at new customers, with the aim of securing long term commitments. Instrument revenues of operational lease contracts are recorded over the duration of the contract through lease payments made by customers.
- *Total operating income:* Total operating income in H1 2016 amounted to EUR 6.8m compared to EUR 7.2m in H1 2015, representing a decrease of 7% due to increased product revenues that were offset by lower collaboration revenues. Collaboration revenues in H1 2016 included higher recognised upfront payments from strategic partners compared to H1 2015 (increase of 30%) but lower milestone payments (decrease of 100%) since one-off milestone payments of EUR 2m were received in H1 2015 whereas no milestone payments were collected in H1 2016.
- *Financial debt:* Post reporting date, on 20 July 2016 Biocartis announced that it has attracted EUR 55m of non-dilutive financing consisting of a EUR 40m bank and lease financing facility as well as a new subordinated loan of EUR 15m. The bank and lease financing facility consists of EUR 15m lease financing and EUR 25m multiple purpose credit lines (credit lines partially guaranteed by the Flemish Government through Gigarant). The lease financing will be used to finance the equipment of Biocartis' second cartridge manufacturing line and was signed before 30 June 2016. The other elements of the announced financing were signed in July 2016. As such, equipment investments for the second cartridge manufacturing facility made since initiation of the project in Q4 2015, were refinanced end of Q2 2016 with available lease

<sup>14</sup> Cnops et al. Development, Evaluation, and Integration of a Quantitative Reverse-Transcription Polymerase Chain Reaction Diagnostic Test for Ebola Virus on a Molecular Diagnostics Platform. J Inf Dis 2016. doi: 10.1093/infdis/jiw150.



financing. Following the above and including existing loans and lease facilities, total financial debt amounted to EUR 16.5m on 30 June 2016 compared to EUR 10.8m end of 2015.

- *Net cash flow:* Driven by increased operational expenses and higher investments for cartridge manufacturing expansion, of which most was refinanced with lease financing, the total net cash flow for H1 2016 amounted to EUR -28.3m.
- *Cash position:* Biocartis' cash position on 30 June 2016 amounted to EUR 75.8m compared to EUR 104.1m end of 2015 and approx. EUR 84m end of Q1 2016 (unaudited). The cash position on 30 June 2016 includes EUR 1.2m restricted cash related to KBC Lease financing.

#### 4.4. H1 2016 financial results

##### Income statement

Collaboration revenues in H1 2016 showed an increase of recognised upfront payments that were received from strategic partners compared to H1 2015 (increase of 30%). No milestone payments were collected in H1 2016 compared to the EUR 2m of one-off milestone payments that were collected in H1 2015. This caused total collaboration revenues to decrease in H1 2016 to EUR 3.4m (EUR 4.9m in H1 2015). Product sales in H1 2016 increased with 63% compared to H1 2015 to EUR 2.7m. Grants and other income in H1 2016 consisted of various R&D project grants. Total operating income in H1 2016 amounted consequently to EUR 6.8m versus EUR 7.2m in H1 2015.

Total operating expenses in H1 2016 equalled EUR 30.8m compared to EUR 24.0m in H1 2015, an increase of 28% driven by higher expenses in R&D as well as in Marketing and Distribution. R&D expenses increased from EUR 16.1m in H1 2015 to EUR 20.7m in H1 2016 (increase of EUR 4.6m) as a consequence of a growth of the R&D team to support continued

menu and platform expansion as well as to support life cycle management for the increased number of on-market products. Marketing and distribution expenses increased from EUR 3.2m in H1 2015 to EUR 5.3m in H1 2016 (increase of EUR 2.0m) as consequence of an expansion of the sales team and higher sales and promotional expenses. G&A expenses decreased in H1 2016 to EUR 2.9m compared to EUR 3.6m in H1 2015, driven by one-off expenses for external advice in H1 2015 related to the Company's initial public offer (IPO) on Euronext Brussels.

The above resulted in an operational result for H1 2016 equal to EUR -24.0m compared to EUR 16.8m in H1 2015 (increase of EUR -7.2m). Following a net financial result for H1 2016 of EUR -0.3m and positive income taxes of EUR 0.5m, the net result for H1 2016 equalled to EUR -23.8m compared to EUR -16.9m for the same period in 2015.

##### Balance sheet

Property, plant and equipment increased in H1 2016 to EUR 17.0m from EUR 14.2m at the end of 2015 (increase of EUR 2.8m) driven by capital expenditure additions in H1 2016 of EUR 4.8m and a depreciation charge of around EUR 2.0m.

Inventory increased from EUR 5.8m per 31 December 2015 to EUR 9.0m per 30 June 2016 (increase of EUR 3.2m), driven by an overall higher instrumentation and cartridge inventory in light of expected increased commercialisation in H2 2016 and due to Idylla™ systems that are placed at customers under the Company's early adopter program. Trade receivables in H1 2016 decreased from EUR 5.9m end of 2015 to EUR 2.1m due to the collection of upfront and milestone payments from strategic partners recorded end of 2015. Trade payables end of H1 2016 amounted to EUR 6.7m which is a decrease of EUR 7.3m compared to the EUR 13.9m as per 31 December 2015, mainly driven by the payment of advance invoices in relation to the second cartridge manufacturing line that were recorded end of 2015. Deferred income has decreased to EUR 3.6m per 30 June 2016, from EUR 5.2m per 31 December 2015,



mainly because of recognised upfront payments from Janssen Pharmaceutica in relation to the strategic licensing, development and commercialisation collaborations.

Total financial debt increased from EUR 10.8m as of 31 December 2015, to EUR 16.5m per 30 June 2016 (an increase of EUR 5.7m) driven by the new lease and bank financings for the manufacturing expansion.

The cash position of the Group on 30 June 2016 amounted to EUR 75.8m compared to EUR 104.1m per 31 December 2015. The cash position on 30 June 2016 includes EUR 1.2m restricted cash related to KBC Lease financing.

#### Cash flow statement

The cash flow from operating activities in H1 2016 amounted to EUR -25.3m compared to EUR -8.7m H1 2015. This increase is the result of higher operating expenses and investments in working capital for H1 2016 compared to significant positive movements in working capital for H1 2015. The cash flow from investing activities in H1 2016 amounted to EUR -6.9m compared to EUR -1.7m in H1 2015 principally driven by the increased capital expenditure for the cartridge manufacturing expansion. The cash flow from financing activities in H1 2016 amounted to EUR 3.9m mainly driven by proceeds of the lease and bank financing for the cartridge manufacturing equipment. In H1 2015 the cash flow from financing activities amounted to EUR 128.0m thanks to the cash inflow from the IPO (EUR 107.0m) in April 2015 and the capital increase of the second tranche of the series F round (EUR 21.5m) in January 2015. The Group's net cash flow in H1 2016 amounted to EUR -28.3m.



## 5. Condensed consolidated interim financial statements for the period ended 30 June 2016

### 5.1. Condensed consolidated balance sheet

In EUR000	Notes	As of	
		30 June 2016	31 Dec 2015
<b>Assets</b>			
<b>Non-current assets</b>			
Intangible assets		8,592	8,987
Property plant and equipment	6.13	17,043	14,245
Participating interests	6.14	5,052	5,052
Other long term receivables		11	11
Deferred tax assets	6.11	2,538	1,986
		<u>33,236</u>	<u>30,281</u>
<b>Current assets</b>			
Inventory	6.15	9,029	5,837
Trade receivables	6.16	2,110	5,852
Other receivables	6.16	1,316	1,063
Other current assets	6.17	1,543	1,258
Cash and cash equivalents*		75,757	104,087
		<u>89,755</u>	<u>118,097</u>
<b>Total assets</b>		<b><u>122,991</u></b>	<b><u>148,378</u></b>
<b>Equity and liabilities</b>			
<b>Capital and reserves</b>			
Legal share capital	6.18	405,892	405
Historical share capital adjustment	6.18	-221,232	-221,232
Share premium	6.18	523,073	522,708
Share based payment reserve	6.19	1,561	1,345
Accumulated deficit	6.18	-212,094	-188,310
<b>Total equity attributable to owners of the Company</b>		<b>91,714</b>	<b>114,916</b>
<b>Non-current liabilities</b>			
Provisions		194	0
Financial debt	6.21	6,860	2,662
Deferred income	6.23	791	1,342
Accrued charges		1,577	1,580
		<u>9,422</u>	<u>5,585</u>
<b>Current liabilities</b>			
Financial debt	6.21	9,684	8,152
Trade payables	6.22	6,656	13,927
Deferred income	6.23	2,807	3,812
Other current liabilities	6.22	2,707	1,986
		<u>21,855</u>	<u>27,877</u>
<b>Total equity and liabilities</b>		<b><u>122,991</u></b>	<b><u>148,378</u></b>

\* Cash and cash equivalents for 30 June 2016 include EUR 1.2 million restricted cash related to KBC Lease financing

## 5.2. Condensed consolidated income statement

In EUR000	Notes	As of	
		30 June 2016	30 June 2015
<b>Revenue</b>			
Collaboration revenue	6.4	3,377	4,866
Product sales revenue	6.4	2,711	1,663
Service revenue	6.4	20	48
		<u>6,109</u>	<u>6,578</u>
<b>Other operating income</b>			
Grants and other income	6.5	641	646
		<u>6,750</u>	<u>7,224</u>
<b>Total operating income</b>			
<b>Operating expenses</b>			
Cost of sales	6.6	-1,921	-1,158
Research and development expenses	6.7	-20,699	-16,092
Marketing and distribution expenses	6.8	-5,259	-3,219
General and administrative expenses	6.9	-2,874	-3,578
		<u>-30,754</u>	<u>-24,047</u>
		<u>-24,003</u>	<u>-16,823</u>
<b>Operating loss for the period</b>			
Financial income		58	31
Financial expense		-348	-440
Foreign exchange gains/(losses), net		8	-20
<b>Financial result, net</b>		<u>-282</u>	<u>-429</u>
<b>Loss for the period before taxes from continuing operations</b>			
Income taxes	6.11	501	337
<b>Loss for the period after taxes from continuing operations</b>		<u>-23,784</u>	<u>-16,915</u>
Gain (loss) for the year after taxes from discontinued operations		0	0
<b>Loss for the period</b>		<u><u>-23,784</u></u>	<u><u>-16,915</u></u>
attributable to owners of the Company		-23,784	-16,915
attributable to non-controlling interest			
<b>Earnings per share</b>			
basic and diluted loss per share from continuing and discontinued operations	6.12	-0.59	-0.50
basic and diluted loss per share from continuing operations	6.12	-0.59	-0.50

### 5.3. Condensed consolidated statement of other comprehensive income

<u>In EUR000</u>	<u>Notes</u>	<u>As of</u>	
		<u>30 June 2016</u>	<u>30 June 2015</u>
Loss for the period		-23,784	-16,915
Other comprehensive income (loss), not to be reclassified to profit or loss		0	0
Other comprehensive gain (loss) for the period, that may be reclassified to profit and loss		0	0
<b>Total comprehensive loss for the period</b>		<b>-23,784</b>	<b>-16,915</b>
Attributable to owners of the Company		-23,784	-16,915
Attributable to non-controlling interest		0	0

## 5.4. Condensed consolidated statement of changes in equity

in EUR000	Notes	Attributable to owners of the Company					Total equity attributable to the owners of the Company	Non-controlling interest	Total equity
		Legal share capital	Historical share capital adjustment	Share premium	Share based payment reserve	Accumulated deficit			
<b>Balance as at 31 December 2014</b>		<b>222,268</b>	<b>-221,232</b>	<b>166,592</b>	<b>1,166</b>	<b>148,513</b>	<b>20,280</b>	<b>20,280</b>	
Loss for the period						-	-		
						39,797	39,797	-39,797	
Share issue - tranche 2 of round F on 15 January 2015	6.18	20,488		1,025			21,513	21,513	
Share issue - contribution in kind of the participation in MyCartis on 15 January 2015	6.18	4,812		241			5,052	5,052	
Capital increase by incorporation of share premium on 15 January 2015	6.18	8		-8			-	-	
Capital decrease by conversion into share premium on 13 April 2015	6.18	-247,272		247,272			-	-	
Share issue -Initial Public Offering on 28 April 2015	6.18	87		99,913			100,000	100,000	
Share issue - exercise of over-allotment warrant on 19 May 2015	6.18	13		14,987			15,000	15,000	
Cost related to Initial Public Offering	6.18			-8,124			8,124	-8,124	
Share issue - exercise of stock options on 3 June 2015	6.18	0		171			171	171	
Share issue - exercise of stock options on 6 October 2015	6.18	0		313			313	313	
Share issue - exercise of stock options on 23 December 2015	6.18	0		295			295	295	
Costs related to capital increase	6.18			33			33	33	

Share-based payment expense	6.19				179		179		179
<b>Balance as at 31 December 2015</b>		<u>405</u>	<u>-221,232</u>	<u>522,707</u>	<u>1,345</u>	<u>188,310</u>	<u>114,916</u>		<u>114,916</u>
Loss for the period	6.18					-	-		
						23,784	23,784		-23,784
Share issue - exercise of stock options on 7 April 2016	6.18	0		366			366		366
Share-based payment expense	6.19				216		216		216
<b>Balance as at 30 June 2016</b>		<u>406</u>	<u>-221,232</u>	<u>523,073</u>	<u>1,561</u>	<u>212,094</u>	<u>91,714</u>	<u>-</u>	<u>91,714</u>

## 5.5. Condensed consolidated cash flow statement

In EUR000	Notes	As of	
		30 June 2016	30 June 2015
<b>operating activities</b>			
Loss for the period		-23,784	-16,915
<b>Adjustments for</b>			
Depreciation and amortisation	6.13	2,393	2,417
Impairments		113	0
Tax income in profit and loss	6.11	-552	-338
Financial result, net		264	419
Net movement in retirement benefit obligation	6.20	194	0
Share based payment expense	6.19	216	45
<b>Changes in working capital</b>			
Net movement in inventories	6.15	-3,192	-2,832
Net movement in trade and other receivables and other current assets	6.16	3,203	12,160
Net movement in trade payables & other current liabilities	6.22	-2,575	-1,021
Net movement in deferred income	6.23	-1,556	-2,587
Interests paid		-69	-67
<b>Cash flow from operating activities</b>		<b>-25,345</b>	<b>-8,719</b>
<b>Investing activities</b>			
Interest received		57	30
Purchases of property, plant & equipment	6.13	-6,866	-1,620
Purchases of intangible assets	6.13	-103	-89
<b>Cash flow from investing activities</b>		<b>-6,912</b>	<b>-1,679</b>
<b>Financing activities</b>			
Proceeds from the lease financing of property, plant and equipment	6.21	3,978	0
Proceeds from issue of preference shares F	6.18	0	21,513
Proceeds from the issue of common shares, net of transaction costs	6.18	366	107,047
Repayment of borrowings	6.21	-416	-576
Bank charges		-9	-7
<b>Cash flow from financing activities</b>		<b>3,919</b>	<b>127,977</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>		<b>-28,338</b>	<b>117,579</b>
Cash and cash equivalents at the beginning of the period		104,087	10,919
Effects of exchange rate changes on the balance of cash held in foreign currencies		7	-20
<b>Cash and cash equivalents at the end of the period*</b>		<b>75,757</b>	<b>128,477</b>

\* Including EUR 1.2 million restricted cash related to KBC Lease financing



## 6. Notes to the condensed consolidated interim financial statements

### 6.1. General information



Biocartis Group NV, a company incorporated in Belgium with registered address at Generaal De Wittelaan 11 B, 2800 Mechelen, Belgium (the 'Company') 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™ 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 Company 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 approved by the board of directors of the Company (the 'Board of Directors') on 1 September 2016.

### 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 2016 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 2015, which have been prepared in accordance with IFRS as adopted by the EU.

The accounting policies adapted in the preparation of the condensed interim financial statements are consistent with those applied in the preparation of the financial statements for the year ended 31 December 2015. New standards or interpretations applicable from 1 January 2016 do not have an 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 interim financial statements have been subject to a limited review by the Company's external auditor Deloitte Bedrijfsrevisoren BV CVBA.

The following new standards and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2016:

- Improvements to IFRS (2010-2012) (applicable for annual periods beginning on or after 1 February 2015)
- Improvements to IFRS (2012-2014) (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IFRS 11 Joint Arrangements - Accounting for Acquisitions of Interests in Joint Operations (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IAS 1 Presentation of Financial Statements – Disclosure Initiative (applicable

#### 6.2.2. Employee benefits

##### Post-employment benefits

Due to the fact that the Belgian law prescribes that the employer would guarantee a minimum rate of return on the contributions, such plans are classified as defined benefit plans under IFRS.

The cost of providing benefits is determined using the Projected Unit Credit (PUC) method, with actuarial valuations being carried out at the end of each annual reporting period.

Remeasurement, comprising actuarial gains and losses, the effect of changes to the asset ceiling (if applicable) and the return on plan assets (including interest), is reflected immediately in the statement of financial position with a charge or credit recognised in other comprehensive income in the period in

for annual periods beginning on or after 1 January 2016)

- Amendments to IAS 16 and IAS 38 Property, Plant and Equipment and Intangible Assets – Clarification of Acceptable Methods of Depreciation and Amortisation (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IAS 19 Employee Benefits – Employee Contributions (applicable for annual periods beginning on or after 1 February 2015)

which they occur. Remeasurement recognised in OCI (Other Comprehensive Income) is reflected immediately in retained earnings and will not be reclassified to P&L. Past service costs are recognised in profit or loss in the period of a plan amendment. Net interest is calculated by applying the discount rate at the beginning of the period to the net defined benefit liability or asset.

Defined benefit costs are categorised as follows:

- Service costs (including current service cost, past service cost, as well as gains and losses on curtailments and settlements);
- Net interest expense or income; and
- Remeasurement.

The Group presents the first two components of defined benefit costs in P&L. Curtailment gains and losses are accounted for as past service costs.



The retirement benefit obligation recognised in the consolidated balance sheet represents the actual deficit in the Group's defined benefit plans. Any surplus resulting from this calculation is limited to the present value of any economic benefits available in the form of returns from the plans or reductions in future contributions to the plans.

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 2016 show a negative result, and the balance sheet includes a loss carried forward. The Board of Directors has examined the statements and accounting standards. Taking into account the solid cash position and the securing of various non-dilutive financing facilities, the Board of Directors is of the opinion that it can submit the interim financial statements on a going concern basis.

### 6.3. Critical accounting judgements 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 judgements, 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.

## 6.4. Revenue

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

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
<b>Collaboration revenue</b>		
R&D services	115	354
Upfront license revenues	3,262	2,512
Milestone revenues	0	2,000
	<u>3,377</u>	<u>4,866</u>
<b>Product sales revenue</b>		
Idylla™ System Sales	988	1,246
Cartridge Sales	1,723	416
	<u>2,711</u>	<u>1,663</u>
<b>Service revenue</b>		
Service revenue	20	48
	<u>20</u>	<u>48</u>
<b>Total</b>	<u>6,109</u>	<u>6,577</u>

### 6.4.1. Collaboration revenue

Upfront license fees and milestone payments are earned under the Group's collaboration and development agreements as outlined below.

#### Janssen Pharmaceutica

The Group's main collaboration agreement is a license and development agreement with Janssen Pharmaceutica NV (JPNV), an entity linked to a shareholder of the Group. Under this agreement, the Group commits to further develop its Idylla™ platform and parties agree upon various test development collaborations. In return, the Group is entitled to non-refundable upfront payments, performance milestones and royalties on certain future test sales.

Certain upfront payments under this collaboration were recognised in collaboration revenues in the first half of 2016.

#### Abbott Molecular

Biocartis NV, a subsidiary of the Company, and Abbott Molecular signed a collaboration to develop and commercialise companion diagnostics tests. Under the agreement, the parties will leverage Biocartis' molecular diagnostics system, Idylla™, and Abbott's regulatory, scientific and commercialisation expertise. The agreement is a framework agreement which can be supplemented with specific project agreements in the future including the determination of the collaboration fees.

No revenue was recognised under this agreement in the first half of 2016.

#### Amgen Inc.

Biocartis NV, a subsidiary of the Company, and Amgen Inc. have entered into a collaboration agreement to evaluate Idylla™ RAS testing as a tool for rapid decentralised testing in Brasil, Canada, Colombia, Mexico, Saudi Arabia, Spain, and Turkey. Certain revenue recognised under this agreement in the first half of 2016 is shown under product sales as it relates to the placement of Idylla™ systems and cartridges.

## Merck KGaA (Merck)

Biocartis NV, a subsidiary of the Company, signed a collaboration agreement with Merck KGaA (Merck) for the development and commercialisation of a new liquid biopsy RAS biomarker test for patients with metastatic colorectal cancer (mCRC). The test will be developed on Idylla™. The new test aims to support clinical practice in performing integrated liquid biopsy RAS biomarker tests, independently of the laboratories' volume of testing or level of expertise.

Certain upfront payments under this collaboration were recognised in collaboration revenues in the first half of 2016.

### 6.4.2. Product sales revenue

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

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
Commercial revenue	1,705	1,272
Research & Development revenue	1,006	391
<b>Total</b>	<b>2,711</b>	<b>1,663</b>

### 6.4.3. Revenues by region and major customers

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
<b>Country of domicile</b>	<b>923</b>	<b>57</b>
Belgium	923	57
<b>Total all foreign countries, of which</b>	<b>5,186</b>	<b>6,520</b>
United states of America	2,979	5,082
Rest of the world	2,206	1,438
<b>Total</b>	<b>6,109</b>	<b>6,577</b>

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

The Group has recognised revenues from one customer representing at least 10% of the total revenues. This customer accounts for EUR 3.5 million of the revenues in the first half of 2016 (first half of 2015: EUR 5.0 million).

## 6.5. Other operating income

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
R&D project support (IWT grants)	641	639
Other project grants	0	0
Other income	0	8
<b>Total</b>	<b>641</b>	<b>646</b>

## 6.6. Cost of sales

The cost of sales in relation to the product sales is as follows:

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
Staff costs	-604	-413
Material, lab consumables & small equipment	-898	-536
Depreciation and amortisation	-271	-204
Royalty expense	-122	0
Other	-26	-4
<b>Total</b>	<b>-1,921</b>	<b>-1,158</b>

## 6.7. Research and development expenses

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
Staff costs	-10,645	-7,984
Subcontracting	-2,859	-2,696
Laboratory expenses	-1,195	-734
Platform and cartridge prototype costs	-1,046	-5
Consultancy	-538	-761
Quality and regulatory	-3	-6
Intellectual property	-369	-447
Facilities, office & other	-1,422	-1,374
ICT	-675	-329
Travel, training & conferences	-381	-349
Depreciation and amortization	-2,062	-2,176
Capitalized systems for internal use	497	770
<b>Total</b>	<b>-20,699</b>	<b>-16,092</b>

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

Platform and cartridge prototype costs relate to the development of diagnostic platform prototypes not taken into inventory for sale or into fixed assets for internal use. These include both the raw materials and (sub) assembly costs.

Capitalised systems for internal use are Idylla™ Consoles and Idylla™ Instruments used for amongst other assay development and quality purposes. Capitalised systems for rent are Idylla™ Consoles and Idylla™ Instruments that are leased by clients.

The remaining expenses relate to quality, regulatory, patenting, building facilities, ICT, office, maintenance of equipment, logistics, travel, training and conferences.

## 6.8. Marketing and distribution expenses

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
Staff costs	-2,708	-1,706
Subcontracting	-585	-413
Sales and promotional expenses	-594	-340
Business development	-144	-110
Consultancy	-123	-67
Facilities, office & other	-192	-29
Travel, training & conferences	-841	-520
Depreciation and amortisation	-72	-34
<b>Total</b>	<b><u>-5,259</u></b>	<b><u>-3,219</u></b>

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

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
Staff costs	-1,708	-1,400
External advice	-291	-1,018
Facilities, office & other	-416	-577
Human resources	-335	-437
Travel, training & conferences	-138	-143
Depreciation and amortisation expenses	14	-4
<b>Total</b>	<b><u>-2,874</u></b>	<b><u>-3,578</u></b>

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

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
Staff costs	-15,666	-11,503
Average number of full time equivalents	291	204

## 6.11. Taxes

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
Current income taxes	-51	-190
Deferred income taxes	552	527
<b>Total</b>	<b>501</b>	<b>337</b>



The deferred income taxes of EUR 0.6 million relate to the R&D tax credit carry-forwards in Belgium for the first half of 2016.

The Group has tax losses available to carry forward of EUR 163.4 million per 30 June 2016 (31 December 2015: EUR 133.8 million). Due to uncertainty surrounding the Group's ability to realise taxable profits in the near future, the Group has not recognised any deferred tax assets on tax loss carry forwards nor on deductible temporary differences.

## 6.12. Earnings per share

The Company has stock option 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 2016	30 June 2015
Profit/loss for the period attributable to the owners of the Company (in EUR000)	-23,784	-16,915
Weighted average number of ordinary shares for basic loss per share (in number of shares)	40,565,072	33,557,321
<b>basic loss per share (EUR)</b>	<b>-0.59</b>	<b>-0.50</b>

## 6.13. Property, plant and equipment

The table below provides an overview of the investments per subcategory. Total additions amount to EUR 4.8 million in the first half of 2016 of which EUR 3.2 million relate to investments for Idylla™ cartridge production expansion. The above mentioned investments are largely financed with banking and lease financing facilities.

<u>In EUR000</u>	<u>As of</u> <u>30 June 2016</u>
<b>Investments</b>	
ICT equipment	278
Laboratory equipment	230
Manufacturing equipment	443
Internally produced systems	497
Furniture and fixtures	105
Leasehold improvements	199
Other property and equipment	83
Equipment under construction	2,781
Systems for rent	189
<b>Total</b>	<b>4,804</b>

The investments done in the subcategory 'Equipment under construction' of EUR 2.8 million relate to the investments in the Idylla™ cartridge production expansion facilities.

## 6.14. Financial participation

In 2015, the Group acquired a financial participation of 13.5% in MyCartis NV through a contribution in kind for an amount of EUR 5.1 million by Debiopharm Diagnostics SA. The participation is not accounted for under the equity method as the Group has no significant influence over MyCartis NV. The stake in MyCartis NV has decreased to 8.40% per 30 June 2016 because Biocartis Group did not participate in the additional capital increase of March 2016 in MyCartis NV. No impairment has been made per 30 June 2016.

<u>In EUR000</u>	As of	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
Initial recognition amount	5,052	5,052
<b>Total</b>	<b>5,052</b>	<b>5,052</b>

## 6.15. Inventory

The inventory can be analysed as follows:

<u>In EUR000</u>	As of	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
<b>Inventory</b>		
Raw materials	3,460	2,379
Semi-finished products	646	190
Finished products	4,923	3,268
<b>Total</b>	<b>9,029</b>	<b>5,837</b>
Amount recognised as an expense	<b>-1,921</b>	<b>-2,642</b>

The inventory increase with EUR 3.2 million is mainly due to an increase of the strategic inventory of Idylla™ systems, also used for short demo purposes and Idylla™ systems placed at clients under an early adopter program. Also the raw materials inventory for the cartridges is increasing due to the increasing business needs, both for sale as for internal consumption.

## 6.16. Trade and other receivables

Trade receivables have decreased from EUR 5.9 million per 31 December 2015 to EUR 2.1 million per 30 June 2016. The decrease of EUR 3.7 million results from large payments in the first half of 2016 from strategic collaboration partners such as JPNV and Amgen, and from the contract manufacturer organisation related to the remaining Idylla™ systems inventory transfer in 2015.

<u>In EUR000</u>	As of	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
Trade receivables	2,110	5,852
Allowance for doubtful receivables	0	0
<b>Total</b>	<b>2,110</b>	<b>5,852</b>

The other receivables show an increase by EUR 0.3 million compared to 31 December 2015, which is explained by higher VAT receivables.

<u>In EUR000</u>	As of	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
VAT receivables	1,316	1,050
Other receivables	0	13
<b>Total</b>	<b>1,316</b>	<b>1,063</b>

#### 6.17. Other current assets

<u>In EUR000</u>	As of	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
Accrued grant income	644	570
Other accrued income	24	80
Deferred charges	876	609
<b>Total</b>	<b>1,544</b>	<b>1,258</b>

Other current assets include accrued grant income for EUR 0.6 million mainly related to Flemish government grants for IWT R&D projects and deferred charges of EUR 0.9 million.

#### 6.18. Equity

##### Issued share capital

The table below summarises the share capital and the outstanding shares of the Company.

	Biocartis Group NV	
	<u>Number of common shares issued and outstanding</u>	<u>Share capital in EUR000</u>
At 31 December 2015	<u>40,544,188</u>	<u>405</u>
Share issue - exercise of stock options on 7 april 2016	45,000	0
<b>At 30 June 2016</b>	<b><u>40,589,188</u></b>	<b><u>405</u></b>

The following capital transactions took place at the Company from 1 January 2016 until 30 June 2016:

On 7 April 2016, the Company raised EUR 0.4 million following the exercise of 45,000 stock options (taking the form of warrants). The amount is fully paid by an increase in share capital by EUR 0.00045 million and an increase in share premium by EUR 0.4 million.

## 6.19. Share based compensation

	<u>SOP 2008</u>	<u>SOP 2013</u>	<u>SOP 2015</u>	<u>SOP WHC</u>	<u>Total</u>
<b>Total outstanding at 31 December 2015</b>	<b>67,702</b>	<b>654,512</b>	<b>72,500</b>	<b>67,000</b>	<b>861,714</b>
Options granted	+		87,500		87,500
Options exercised	-	24,601	45,000		69,601
Options forfeited	-		20,267	33,000	53,267
Options cancelled	-				
<b>Total outstanding at 30 June 2016</b>	<b>43,101</b>	<b>589,245</b>	<b>160,000</b>	<b>34,000</b>	<b>826,346</b>

### 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 24,601 options were exercised in the first half of 2016 at CHF 4.14 exercise price and EUR 12.00 share price at the moment of the exercise of the options. A total of 43,101 options is still outstanding per 30 June 2016.

### ESOP 2013

The 2013 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options (which take the form of warrants). In total 45,000 options were exercised in the first half of 2016 at an exercise price of EUR 8.1309. The share price at the moment of the exercise was EUR 10.90. A total of 589,245 options are outstanding per 30 June 2016. A total number of 249,660 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 (which take the form of warrants). In total 87,500 options were granted in the first half of 2016 at weighted average exercise price of EUR 11.35. All new warrants granted in the first half of 2016 were to related parties. A total of 160,000 options are outstanding per 30 June 2016. As at 30 June 2016, a total number of 102,934 stock options could still be granted under the 2015 Plan.

### SOP WHC

In execution of a decision of the board of directors of Biocartis SA of 24 April 2014, options on shares of Biocartis SA were granted 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. On 25 November 2014, the option grant was rolled up in order to relate to the Company and the Company's shares instead of shares in Biocartis SA (total number of warrants equals 100,000). The options, called 'WHC Warrants', were formally granted by an award letter on 14 April 2015. In the first half of 2015, 33,000 options were forfeited. Additionally, 33,000 options were forfeited in the first half of 2016. None of the remaining 34,000 options 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 2016.

### Accounting for share based compensation

The shared-based compensation expense recognised in the income statement as such is given below:

<u>In EUR000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2016</u>	<u>30 June 2015</u>
share based compensation	216	45
<b>Total</b>	<b>216</b>	<b>45</b>

### 6.20. Defined benefit plans

Before the law changed on 18 December 2015, under the previous legal framework, the application of the Projected Unit Credit (PUC) method was considered problematic, and there was uncertainty with respect to the future evolution of the minimum guaranteed rates of return. Therefore, the Company did not apply the PUC method for the Belgian Defined Contribution Plans.

With the change in the law in December 2015, there was no longer a reason not to apply the PUC method. However, because of the late law change in and impact of applying the PUC method was estimated to be immaterial, the Company decided to only apply the PUC method in 2016.

<u>In EUR000</u>	<u>As of</u>	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
Provision for pensions and similar obligations	194	0
<b>Total</b>	<b>194</b>	<b>0</b>

### 6.21. Financial debt

The financial debt can be analysed as follows:

<u>In EUR000</u>	<u>As of</u>	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
PMV	0	0
Lease company	6,376	2,120
Bank	484	542
<b>Total non-current</b>	<b>6,860</b>	<b>2,662</b>
PMV	7,428	7,176
Lease company	2,140	918
Bank	116	58
<b>Total current</b>	<b>9,684</b>	<b>8,152</b>

In 2016, Biocartis NV obtained a new lease financing facility for the development of a second cartridge production line in Mechelen, for EUR 15 million, provided by a lease company, of which EUR 5.1 million was drawn per 30 June 2016. The interest applicable for this leasing facility equals approx. 2% and the leasing includes a purchase option of 1% of the financed amount.

In 2015, Biocartis NV obtained a lease financing facility for the modifications to the current cartridge production line in Mechelen, for a total amount of EUR 4.4 million, provided by a lease company of which EUR 2 million was drawn per 30 June 2016. The interest applicable for the leasing facility equals the 5 year Interest Rate Swap (IRS) plus a margin of 1.57% and will be fixed when the entire investment package is drawn. The leasing includes a purchase option of 1% of the financed amount.

In 2015, Biocartis NV also obtained a loan facility of EUR 0.6 million to partially finance additional mould investments related to the current cartridge production facility.

The strategic investment loan from PMV dates back from 2011 and will be fully reimbursed in December 2016.

Please also see the events after balance sheet date as this section includes important information on financial debt.

## 6.22. Trade payables and other current liabilities

Trade payables have decreased from EUR 13.9 million per 31 December 2015 to EUR 6.7 million per 30 June 2016. This is mainly explained by the payment of advance payment invoices related to the second cartridge production line.

<u>In EUR000</u>	As of	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
Trade payables	6,656	13,927
<b>Total trade payables</b>	<b>6,656</b>	<b>13,927</b>

The other current liabilities show an increase by EUR 0.7 million compared to 31 December 2015, which is explained by a higher provision for vacation pay, due to a higher number of average FTE's.

<u>In EUR000</u>	As of	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
Provision vacation pay and end-of-year premium	2,456	1,884
Other social debt	185	15
VAT payable	0	0
Other	66	88
<b>Total current liabilities</b>	<b>2,707</b>	<b>1,987</b>

## 6.23. Deferred income

<u>In EUR000</u>	As of	
	<u>30 June 2016</u>	<u>31 Dec 2015</u>
Grants	288	47
Partner income	3,310	5,107
<b>Total</b>	<b>3,598</b>	<b>5,154</b>
current	2,807	3,812
non-current	791	1,342

Deferred partner income includes upfront payments received from JPNV and Merck (since 2016) in relation to the strategic licensing, development and commercialisation collaborations. This amount will be recognised as collaboration revenue in the following 1.5 years with a majority in 2016.

	<u>Deferred partner income</u>
<b>As per 31 December 2014</b>	<b>9,559</b>
Invoiced	574
Recognised in profit or loss	-5,025
<b>As per 31 December 2015</b>	<b>5,108</b>
Invoiced	1,650
Recognised in profit or loss	-3,447
<b>As per 30 June 2016</b>	<b>3,310</b>

## 6.24. Other disclosures

### 6.24.1. 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 2016 and 31 December 2015.

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 consolidated balance sheet on 30 June 2016 and 31 December 2015.



In EUR000	Carrying value		Fair value	
	30 June 2016	31 Dec 2015	30 June 2016	31 Dec 2015
<b>Available for sale financial assets</b>				
Participating interest	5,052	5,052	5,052	5,052
<b>Total available for sale financial assets</b>	<b>5,052</b>	<b>5,052</b>	<b>5,052</b>	<b>5,052</b>
<b>Loans and receivables measured at amortised cost</b>				
Trade and other receivables (current)	3,426	6,914	3,426	6,914
Other long term receivables	11	11	11	11
Other current assets	1,543	1,258	1,543	1,258
<b>Total loans and other receivables</b>	<b>4,980</b>	<b>8,183</b>	<b>4,980</b>	<b>8,183</b>
<b>Cash &amp; cash equivalents</b>				
cash & cash equivalents*	75,757	104,087	75,757	104,087
<b>Total cash &amp; cash equivalents</b>	<b>75,757</b>	<b>104,087</b>	<b>75,757</b>	<b>104,087</b>
<b>Financial liabilities measured at amortised cost</b>				
Loans & Borrowings	16,544	10,815	16,534	11,171
Trade payables	6,656	13,927	6,656	13,927
Other liabilities and accrued charges	4,284	3,566	4,284	3,566
<b>Total financial liabilities measured at amortised cost</b>	<b>27,484</b>	<b>28,308</b>	<b>27,475</b>	<b>28,664</b>

\* For 30 June 2016: including EUR 1.2 million restricted cash related to KBC Lease financing.

## 6.24.2. Contingencies

### *Legal claims*

The Group is currently not facing any outstanding litigation that might have a significant adverse impact on the Group's financial position.

### *Potential claw back of government grants received*

The Group recognises grant income from Flemish, Dutch and European grant bodies when all contractual conditions are met. The government institutions may however perform an audit afterwards which may result in a (partial) claw back of the grant. The Group deems that the claw back risk is remote in view of the continuous monitoring of the contractual conditions. Currently the Group has fulfilled all the existing conditions relating to the recognition of its grant income. Contracts with these grant bodies also typically include clauses that define the need for future validation of the project results after completion of the initial grant term during which the subsidised expenses or investments have been incurred and for which the grant was earned. Should this validation not occur or be deemed inadequate, the grant bodies have the right to reclaim funds previously granted.

### *Royalties*

With respect to the Group's licensing agreements, the Group could in the future experience instances where royalty claims on sales of licensed products under these agreements exceed royalties reported by the Group.

### *Philips option*

Under contractual conditions, payments (milestone payment, royalties and other revenue sharing payments) may arise in the future to Philips, a shareholder of the Company. These payments may –at the sole discretion of the Group - be converted into common shares of the Company following the conversion option granted to Philips.

## 6.24.3. Commitments

### 6.24.3.1. Capital commitments

The Group has EUR 6.5 million capital commitments mainly related to investments in the cartridge manufacturing facilities in Mechelen.

### 6.24.3.2. Operating commitments

The Group has a contractual commitment to buy a certain number of Idylla™ systems from the CMO (Contract Manufacturing Organisation), to whom the production of Idylla™ systems was outsourced in 2015. The remaining commitment per 30 June 2016 amounts to EUR 1.6 million. It is expected that the commitment will be fulfilled per end of October 2016.

#### 6.24.4. Related-party transactions

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

<u>In EUR000</u>	<u>Sales of goods and services</u>	<u>Purchase of good and services</u>	<u>Interest cost</u>
30 June 2016	3,630	-339	-251
30 June 2015	5,285	-1,130	-235

<u>In EUR000</u>	<u>Trade receivables</u>	<u>Trade payables</u>	<u>Financial Debt</u>
30 June 2016	513	56	7,428
31 December 2015			7,176

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

- The interest cost and financial debt relate to the loan granted by PMV in 2011.
- Sales of goods and services and trade receivables mainly concern the collaboration and product sales towards Johnson & Johnson (or entities belonging to this group).

#### 6.25. Events after the balance sheet date

In July 2016, the Group announced that it has attracted a total of EUR 55 million of non-dilutive financing, consisting of a EUR 15 million new leasing facility (included in the accounts as per 30 June 2016), a EUR 25 million bank facility and a EUR 15 million subordinated loan. The funds will be used to finance the expansion of Biocartis' manufacturing capacity for its Idylla™ diagnostics tests, to refinance an existing loan of EUR 5 million and to strengthen the Company's financial position to continue the execution of the strategic plan.

## 7. Limited review report of the auditor

*The original text of this report is in Dutch.*

Biocartis Group NV

Report on review of the consolidated interim financial information for the six-month period ended 30 June 2016

### To the board of directors

In the context of our appointment as the company's statutory auditor, we report to you on the consolidated interim financial information. This consolidated interim financial information comprises the condensed consolidated balance sheet as at 30 June 2016, the condensed consolidated income statement, the condensed consolidated statement of 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 6.25.

### Report on the consolidated interim financial information

We have reviewed the consolidated interim financial information 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 122,991 (000) EUR and the condensed consolidated income statement shows a consolidated loss (group share) for the period then ended of 23,784 (000) EUR.

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

### Scope of review

We conducted our review of the consolidated interim financial information 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 consolidated interim financial information.

### Conclusion

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

Diegem, 2 September 2016

### 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

### 8.1. General information



Biocartis Group NV is a limited liability company organised 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 prevails.

An electronic version of the half year financial report 2016 is available on the [Biocartis website](#).

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

### 8.2. Contact IR

Biocartis Investor Relations  
Renate Degrave  
Generaal de Wittelaan 11 B3  
2800 Mechelen, Belgium  
+32 15 632 600  
[ir@biocartis.com](mailto:ir@biocartis.com)

### 8.3. Listing

Biocartis is listed on Euronext Brussels since 27 April 2015 under symbol BCART. Biocartis' ISIN code is BE0974281132.

### 8.4. Financial calendar

Q3 Business Update 2016: 17 November 2016  
Full year financial results 2016: 2 March 2017

### 8.5. Financial year

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

### 8.6. Auditor information

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

### 8.7. Forward-looking statement

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 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.

## 9. Glossary

<b>Assay</b>	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.
<b>Serine/threonine-protein kinase B-raf (BRAF)</b>	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.
<b>CE-mark</b>	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').
<b>Ct or cfDNA</b>	This is circulating tumor (ct) or cell free (cf) plasma DNA.
<b>Companion Diagnostics (CDx)</b>	CDx is a bio-analytical method designed to assess: (i) whether or not a patient will respond favourably to a specific medical treatment; (ii) what the optimal dose is for a patient; and (iii) whether the patient can expect certain side effects from a medical treatment. Any prescription of a drug with a CDx is based on the outcome of the CDx. CDx tests are also used in the drug development process.
<b>Deoxyribonucleic acid (DNA)</b>	DNA is a nucleic acid molecule that contains the genetic instructions used in the development and functioning of living organisms.

<a href="#">Epidermal growth factor receptor (EGFR)</a>	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.	<a href="#">Immunoassay</a>	Immunoassays are assays that measure biomarkers through antigen-antibody interaction technologies. In most cases such assays are used to measure biomarkers of the immune system itself, e.g. HCV or HIV antibodies produced by the bodies, which are detected by means of HCV or HIV antigens.
<a href="#">Emergency Use Authorisation (EUA)</a>	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.	<a href="#">Influenza</a>	Also known as 'the flu' is a highly contagious respiratory tract infection caused by the family of influenza viruses.
<a href="#">Formalin fixed, paraffin embedded (FFPE)</a>	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.	<a href="#">In vitro diagnostics or In vitro diagnosis (IVD)</a>	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).
<a href="#">US Food and Drug Administration (FDA)</a>	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.	<a href="#">Kirsten rat sarcoma-2 virus oncogene (KRAS)</a>	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.
		<a href="#">Metastatic Colorectal Cancer (mCRC)</a>	Colorectal Cancer (CRC) is the second most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually. According to the International Agency for Research on Cancer, an estimated 694,000 deaths from CRC occur worldwide every year, accounting for 8.5% of all cancer deaths and making it



the fourth most common cause of death from cancer.

**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 a 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 synthesised. 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.

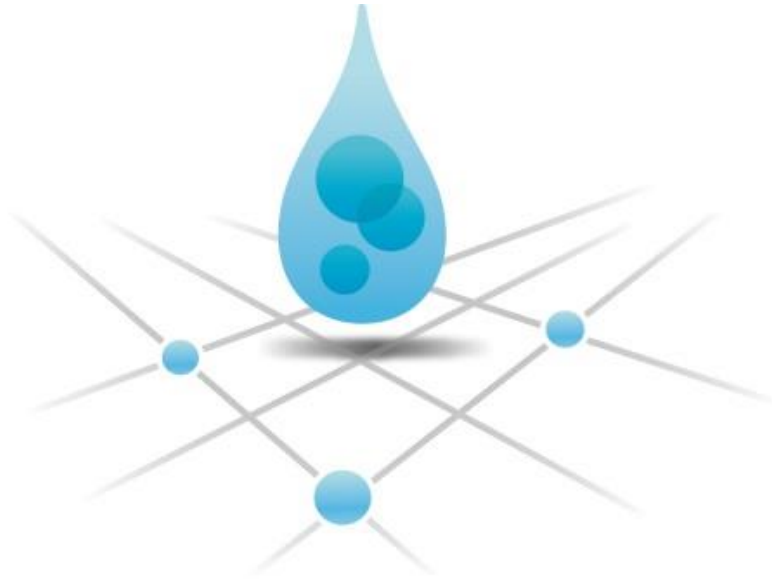
**Protein** Polypeptide chain built from the 20 natural amino acids. Proteins are synthesised from a messenger RNA copy of a gene and can have many functions in the cytoskeleton of the cell, enzymatic, messenger functions in cells and blood such as immune cytokines, DNA binding proteins that regulate 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.

**Ribonucleic acid (RNA)** RNA, like DNA, is a nucleic acid molecule. RNAs have a variety of different functions in living cells. They can have a scaffolding role in the build-up of complexes (ribosomes, SNRPs), provide sequence recognition (translation, RNA splicing), have catalytic function (ribozymes), act as messengers for protein synthesis (mRNAs), regulate gene expression (miRNAs) or make up the genome of certain viruses.

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



# BIOCARTIS

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