

Financial report

H1 2017

Biocartis Group NV



Biocartis Group NV
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1. Message from the CEO

Dear Shareholder,

Dear Stakeholder,

I am pleased to present to you our financial report for the first six months of 2017.

Our performance in H1 2017 was best characterized by the 195% growth that we realized year-over-year in commercial product revenues. This shows that our investments in menu and geographical expansion successfully translated into higher commercial volumes, demonstrating the adoption of the Idylla™ platform in our current markets.

We are thrilled to start selling in the US market in the second half of this year and look forward to important tests launches in the coming months. This will put us in an excellent position to continue this impressive growth curve.

I am confident that under the leadership of Herman Verrelst, our new CEO as of 1 September, Biocartis will also continue to deliver on its promises, globally impacting the way molecular diagnostics is performed.

Hilde Windels

CEO ad interim Biocartis (until 31 August 2017¹)

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 2017, 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

Hilde Windels
CEO ad interim Biocartis (until 31 August 2017¹)

¹ Hilde Windels was CEO ad interim of Biocartis between 2 March 2017 and 31 August 2017. Herman Verrelst took up the role as CEO of Biocartis as from 1 September 2017.

3. Principal risks related to the business activities

The principal risks related to Biocartis' business activities are outlined in Biocartis' 2016 Annual Report, p. 25-32, 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 2016 Annual Report.

4. Business review of the first half of 2017

4.1. Commercial highlights

27.000
Idylla™ cartridges

+ 108 Idylla™
instruments

- *Cartridge consumption:* Strong continued ramp-up of commercial Idylla™ cartridge consumption in H1 2017 driven by menu expansion and installed base growth. H1 2017 commercial volume increased to approximately 27k cartridges, being 110% of the total volume for the full year 2016. Cartridges for colorectal cancer (CRC) testing represented the majority of the volume in H1 2017.
- *Installed base:* A total of 108 Idylla™ instruments were added to the installed base in H1 2017, resulting in a total installed base of 497 instruments as per end of June 2017. H1 2017 showed strong placements in both the European and RoW² markets.
- *Commercial footprint:* During H1 2017, Biocartis established its US subsidiary, recruited its core US team and initiated the training of the sales force of Fisher Healthcare (a division of Thermo Fisher Scientific Inc.) aimed at starting US commercialization of the Idylla™ platform in H2 2017. Furthermore, Biocartis signed additional distribution agreements in Asia and Latin America and added product registrations in Asia, the Middle East and Latin America.
- *CDx business:* In January 2017, Biocartis signed its first companion diagnostic ('CDx') partnership with an undisclosed pharmaceutical company (ranked amongst the global top 10 pharmaceutical companies in terms of sales) for the joint development of an Idylla™ CDx test for an undisclosed phase II oncology compound.

The CDx partnership between Abbott Molecular and Biocartis expired in H1 2017.

4.2. Idylla™ test menu highlights

As per end H1 2017, Biocartis' oncology menu consisted of 10 Idylla™ tests of which six for colorectal cancer, two for lung cancer and two for melanoma testing.

- *Colorectal cancer menu* – In H1 2017, Biocartis expanded its CRC menu with the launch of the Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (RUO) and the CE-marking of Idylla™ NRAS Mutation Test. The Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay is the third liquid biopsy test of Biocartis and marked an important milestone in the partnership with the leading science and technology company Merck³. The solid biopsy Idylla™ NRAS Mutation Test, alongside Biocartis' existing Idylla™ NRAS-BRAF Mutation Test, will allow for more flexibility in geographies where BRAF testing

² RoW = Rest of the World. RoW is defined as the world excluding Europe, US, China and Japan.

³ Merck KGaA, Darmstadt, Germany.



for metastatic CRC patients is not reimbursed.

- *Lung cancer* - In June 2017, Biocartis CE-marked its solid biopsy Idylla™ EGFR Mutation Test, which is an important addition to Biocartis' oncology menu. This test is the only on-market fully automated CE-IVD test detecting all relevant EGFR mutations according to international guidelines and is able to produce results faster and easier⁴, based on only one slice of tumor tissue. Furthermore, in H1 2017, Biocartis advanced the development of a liquid biopsy version of the Idylla™ EGFR Test aimed for launch later this year. This test, now able to operate directly from plasma, will further strengthen Biocartis' lung cancer menu as tumor tissue in lung cancer is often not available and it allows for patient monitoring.
- *Melanoma menu* - In March 2017, a study⁵ by Prof. Dr. Bart Neyns from the University Hospital in Brussels (Belgium) was published in the renowned clinical oncology journal *The Lancet Oncology*. This study showed that advanced metastatic melanoma cancer patients that had become resistant to their BRAF-targeted treatment⁶ were successfully given a retreatment with that same therapy, following a three months pause after resistance confirmation. This is an important finding that could lead to more routine use of retreatment, especially for patients where no effective alternative treatment is available. Biocartis' liquid biopsy test, the Idylla™ ctBRAF Mutation Assay (RUO), was used in this study for the monitoring of the mutational status.
- *Breast cancer menu* - In June 2017, Biocartis initiated the development of the first test for its breast cancer menu aimed at monitoring of metastatic breast cancer patients for resistance to hormone therapy. Breast cancer is the most common cancer among women worldwide: one in eight women is diagnosed with breast cancer in her lifetime⁷. This test will be jointly developed under a new partnership with LifeArc (formerly MRC Technology), focused on developing selected molecular diagnostic tests for use on the Idylla™ platform.
- *MSI testing* - In March 2017, Biocartis received a grant of approx. EUR 750k from VLAIO, the Flanders organization for Innovation & Entrepreneurship, for the further development of a fully automated microsatellite instability (MSI) test on the Idylla™ platform. The MSI test that Biocartis has under development and aims to launch in 2018, could be validated as a prognostic test for CRC and a predictive test for cancer immunotherapies, the latter being a fast growing market, expected to be worth over USD 100bn by 2021⁸.

4.3. Organizational highlights

- *Change in CEO position* - In March 2017, Biocartis announced a change in the CEO position as Rudi Pauwels took on the role of Chairman of a new Strategy Committee of the Board and Hilde Windels assumed the role of interim CEO. On 10 May 2017, Biocartis announced its new CEO Herman Verrelst, who started 1 September 2017. Herman is a seasoned

⁴ Based on a comparison between the Biocartis' Idylla™ platform for the detection of EGFR mutations in archived formalin-fixed paraffin-embedded (FFPE) tumor samples with the results obtained by the TherascreenEGFR Pyro assay (Qiagen)-ISO 15189 accredited laboratory method.

⁵ Schreuer et al., 'Combination of dabrafenib plus trametinib for BRAF and MEK inhibitor pretreated patients with advanced BRAFV600-mutant melanoma: an open-label, single arm, dual-centre, phase 2 clinical trial', *The Lancet Oncology* 2017, published online 3 March 2017.

⁶ It concerns treatments with dabrafenib and/or trametinib (Tafinlar™ and Mekinist™, both products marketed by Novartis)

⁷ Source: World Cancer Research Fund International, <http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/breast-cancer-statistics>, last consulted on 17 May 2017.

⁸ Source: Cancer Immunotherapy Market by Type (Monoclonal Antibodies, Cancer Vaccines, Check Point Inhibitors & Immunomodulators), Application (Lung, Breast, Colorectal, Melanoma, Prostate, Head & Neck), End User (Hospital and Clinics) - Global Forecast to 2021, published by MarketsandMarkets.

executive with a proven international commercial track-record in molecular diagnostics and held the position of Vice President and General Manager of the Genomics and Clinical Applications Division of Agilent Technologies Inc. (NYSE: A) prior to joining Biocartis. Hilde Windels will continue to support the company as Executive Director within the Biocartis Board of Directors.

- *US General Manager* – In April 2017, Biocartis announced the appointment of Vishal Sikri as its US General Manager. Before joining Biocartis, Vishal was Managing Director and VP Commercial Operations responsible for all global commercial operations of Sysmex Inostics, the molecular diagnostics' division of Sysmex Corporation (TYO: 6869).
- *Galenus Prize* – In May 2017, Biocartis won the prestigious 2016 Galenus Prize for the Most Innovative Medical Device, leading the way to better treatments, with its fully automated Idylla™ NRAS-BRAF Mutation Test for CRC patients.

4.4. Financial highlights

+ 195%
total commercial
product sales

- *Product sales revenues* – Product sales revenues showed a year-over-year growth of 88% and amounted to EUR 5.1m in H1 2017. During the same period, cartridge sales grew year-over-year with 90% to EUR 3.3m and Idylla™ system sales with 84% to EUR 1.8m. Total commercial product sales amounted in H1 2017 to EUR 5.0m, representing a year-over-year growth of 195% that was mainly driven by the increased commercial cartridge consumption.
 - *Operational expenses* – Total operating expenses (including cost of sales), amounted to EUR 30.7m in H1 2017 versus EUR 30.8m in H1 2016. Operating expenses excluding costs of goods in H1 2017 amounted to EUR 27.4m versus EUR 28.8m in H1 2016, a decrease of approx. 5% predominantly due to lower expenses for research and development.
- *Net cash flow* – Total net cash flow in H1 2017 amounted to EUR -24.2m versus EUR -28.3m in H1 2016, a year-over-year improvement of 15%.
 - *Cash position* – Biocartis' cash position as per end June 2017 amounted to EUR 59.0m compared to EUR 83.2m as per 31 December 2016. In addition, the Company has EUR 25m of multiple purpose credit lines at its disposal on which no drawdowns were made as per end of H1 2017.
 - *Additional details* – see 'key figures for H1 2017' below for more details on the H1 2017 financials.

4.5. H1 2017 financial results

Income statement

Collaboration revenues in H1 2017 decreased year-over-year with approx. 79% to EUR 0.7m primarily driven by significantly lower recognized upfront license revenues from strategic partners: EUR 3.3m in H1 2016 versus EUR 0.7m in H1 2017. Product sales revenue on the other hand increased year-over-year with approx. 88% in H1 2017 to EUR 5.1m driven by higher revenues from commercial activities. Furthermore, grant and other income increased year-over-year with approx. 66% to EUR 1.1m due to higher R&D project support grants and training subsidies related to the establishment of a second cartridge manufacturing line. Total operating income consequently amounted to EUR 7.0m in H1 2017 versus EUR 6.8m in H1 2016, representing an increase of 3%.

Total operating expenses in H1 2017 remained with EUR 30.7m more or less on the same level of H1 2016 (EUR 30.8m) due to an increase in costs of sales that was offset by lower expenses for R&D and G&A. Costs of sales increased in H1 2017 to EUR 3.2m (71% year-over-year growth) due to higher commercial cartridge and instrumentation volumes.

Expenses for R&D decreased year-over-year with approx. 7% to EUR 19.3m in H1 2017. This was predominantly driven by lower staff and subcontracting costs, partially offset by higher Idylla™ platform and cartridge prototype costs and increased consultancy expenses. Expenses for Marketing & Distribution remained year-over-year on the same level and amounted to EUR 5.3m in H1 2017 as higher costs for staff, facilities and TT&C (Travel, Training and Conferences) were offset by lower subcontracting and sales & promotional expenses. G&A expenses decreased year-over-year with 3% to EUR 2.8m as the consequence of lower staff and TT&C costs that were only partially offset by higher costs for human resources and external advice. Overall, operational expenses excluding costs of sales amounted to EUR 27.4m in H1 2017, representing a year-

over-year decrease of approximately 5%.

The above resulted in an operational result for H1 2017 equal to EUR -23.7m compared to EUR -24.0m in H1 2016. Following a net financial result for H1 2017 of EUR -0.7m and positive income taxes of EUR 0.5m, the net result for H1 2017 equaled to EUR -24.0m compared to EUR -23.8m for the same period in 2016.

Balance sheet

Property, plant and equipment increased in H1 2017 to EUR 24.3m from EUR 23.1m at the end of 2016 (increase of EUR 1.2m) driven by capital expenditures in H1 2017 of EUR 3.3m (predominantly related to investments for cartridge manufacturing expansion) and a depreciation charge of around EUR 2.0m. Inventory slightly increased to EUR 9.9m (year-over-year increase of 1%) as higher stock of finished products (predominantly Idylla™ cartridges) were nearly fully offset by lower levels of raw materials and semi-finished products driven by ongoing supply chain efficiency initiatives. An increase in trade and other receivables of approx. EUR 0.1m in H1 2017 was offset by an increase in trade payables with a comparable amount. Other current assets increased year-over-year with approx. 22% to EUR 2.4m in H1 2017 as the consequence of higher accrued grant income.

The Company's cash and cash equivalents end of H1 2017 amounted to EUR 59.0m compared to EUR 83.2m end of 2016. Total financial debt end of H1 2017 amounted to EUR 33.3m, representing an increase of approx. EUR 1.9m compared to end of 2016. This was the result of an increase in lease financing in the context of the ongoing cartridge manufacturing expansion, as well as the addition of capitalized interest to the Company's subordinated loan.

Cash flow statement

The cash flow from operating activities in H1 2017 amounted to EUR -22.2m compared to EUR -25.3m H1 2016 (an increase of approx. 13%), primarily because of modest working capital investments in H1 2017 (compared to material investments in working capital and significant movements in deferred income in H1 2016). The cash flow from investing activities in H1 2017 amounted to EUR -1.5m (compared to EUR -6.9m in H1 2016) and is mainly related to capitalized Idylla™ systems placed with customers under (reagent) rental agreements and Idylla™ systems used for internal needs. The EUR 1.8m investments for cartridge manufacturing expansion are excluded from the cash flow from investing activities since these were directly paid via lease financing. The cash flow from financing activities in H1 2017 amounted to EUR -0.5m (compared to EUR 3.9m in H1 2016) and relates to repayments of borrowings. Because of the aforementioned, the net cash flow of H1 2017 amounted to EUR -24.2m compared to EUR -28.3m in H1 2016, representing an increase of 15% year-over-year.



5. Condensed consolidated interim financial statements for the period ended 30 June 2017

5.1. Condensed consolidated income statement

In EUR 000	Notes	For the 6 months ended	
		30 June 2017	30 June 2016
Revenue			
Collaboration revenue	6.4	716	3.377
Product sales revenue	6.4	5.092	2.711
Service revenue	6.4	104	20
		<u>5.912</u>	<u>6.109</u>
Other operating income			
Grants and other income	6.5	1.066	641
		<u>6.978</u>	<u>6.750</u>
Operating expenses			
Cost of sales	6.6	-3.278	-1.921
Research and development expenses	6.7	-19.320	-20.699
Marketing and distribution expenses	6.8	-5.308	-5.259
General and administrative expenses	6.9	-2.781	-2.874
		<u>-30.687</u>	<u>-30.754</u>
		<u>-23.709</u>	<u>-24.003</u>
Operating loss for the period			
Financial income		-2	58
Financial expense		-714	-348
Foreign exchange gains/(losses), net		-13	8
Financial result, net		<u>-729</u>	<u>-282</u>
Loss for the year before taxes			
		<u>-24.438</u>	<u>-24.285</u>
Income taxes		456	501
Loss for the year		<u><u>-23.982</u></u>	<u><u>-23.784</u></u>
Attributable to owners of the Company			
		-23.982	-23.784
Attributable to non-controlling interest			
Earnings per share			
Basic and diluted loss per share	6.11	-0,54	-0,59

5.2. Condensed consolidated balance sheet

In EUR 000	Notes	As of	
		30 June 2017	31 Dec 2016
Assets			
Non-current assets			
Intangible assets		9,584	9,921
Property plant and equipment	6.12	24,317	23,088
Participating interests	6.13	5,052	5,052
Other long term receivables		11	11
Deferred tax assets		3,624	3,090
		<u>42,588</u>	<u>41,162</u>
Current assets			
Inventory	6.14	9,922	9,829
Trade receivables	6.15	3,012	2,935
Other receivables	6.15	2,233	2,201
Other current assets	6.16	2,364	1,932
Cash and cash equivalents*		59,042	83,246
		<u>76,574</u>	<u>100,143</u>
Total assets		<u>119,162</u>	<u>141,305</u>
Equity and liabilities			
Capital and reserves			
Legal share capital		446	446
Historical share capital adjustment		-221,232	-221,232
Share premium		554,065	554,065
Share based payment reserve		1,867	1,716
Accumulated deficit		-262,073	-238,088
Other comprehensive income		-51	-19
Total equity attributable to owners of the Company		<u>73,022</u>	<u>96,889</u>
Non-current liabilities			
Provisions		59	47
Financial debt	6.17	29,320	27,709
Deferred income	6.19	22	142
Accrued charges		1,414	1,610
		<u>30,815</u>	<u>29,508</u>
Current liabilities			
Financial debt	6.17	3,959	3,698
Trade payables	6.18	6,396	6,293
Deferred income	6.19	1,951	1,963
Other current liabilities	6.18	3,019	2,954
		<u>15,325</u>	<u>14,908</u>
Total equity and liabilities		<u>119,162</u>	<u>141,305</u>

*Cash and cash equivalents for 30 June 2017 include EUR 1.2m restricted cash related to KBC Lease financing

5.3. Condensed consolidated cash flow statement

In EUR,000	Notes	For the 6 months ended	
		30 June 2017	30 June 2016
Operating activities			
Loss for the period		-23,982	-23,784
Adjustments for			
Depreciation and amortization	6.12	2,428	2,393
Impairments		0	113
Tax income in profit and loss		-421	-552
Financial result, net		635	264
Net movement in retirement benefit obligation		-21	194
Share based payment expense		151	216
Changes in working capital			
Net movement in inventories	6.14	-94	-3,192
Net movement in trade and other receivables and other current assets	6.15	-542	3,203
Net movement in trade payables & other current liabilities	6.18	-27	-2,575
Net movement in deferred income	6.19	-133	-1,556
Interests paid		-52	-69
		-22,058	-25,345
Taxes paid		-114	0
Cash flow used in operating activities		-22,172	-25,345
Investing activities			
Interest received		-2	57
Purchases of property, plant & equipment	6.12	-1,461	-6,866
Purchases of intangible assets		-68	-103
Cash flow from / (used in) investing activities		-1,531	-6,912
Financing activities			
Proceeds from the lease financing of property, plant and equipment	6.17	0	3,978
Proceeds from the issue of common shares: Private Placement		0	366
Repayment of borrowings	6.17	-470	-416
Bank charges		-9	-9
Cash flow from financing activities		-479	3,919
Net increase / (decrease) in cash and cash equivalents		-24,182	-28,338
Cash and cash equivalents at the beginning of the period		83,246	104,087
Effects of exchange rate changes on the balance of cash held in foreign currencies		-22	7
Cash and cash equivalents at the end of the period*		59,042	75,757

* Including EUR 1.2m restricted cash related to KBC Lease financing

5.4. Condensed consolidated statement of other comprehensive income

In EUR 000	Notes	For the 6 months ended	
		30 June 2017	30 June 2016
Loss for the year		-23,982	-23,784
Other comprehensive income (loss), not to be reclassified to profit or loss		-2	0
Actuarial gain (loss) on defined benefit plan		0	0
Tax impact actuarial gain (loss)		0	0
Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss		0	0
Total comprehensive loss for the year		-23,984	-23,784
Attributable to owners of the Company		-23,984	-23,784
Attributable to non-controlling interest		0	0

5.5. Condensed consolidated statement of changes in equity

In EUR 000	Notes	Attributable to owners of the Company					Accumulated deficit	Total equity attributable to the owners of the Company	Total equity
		Legal share capital	Historical share capital adjustment	Share premium	Share based payment reserve	Gains and losses on defined benefit plans			
Balance as at 1 January 2016		<u>405</u>	<u>-221,232</u>	<u>522,707</u>	<u>1,345</u>	<u>0</u>	<u>-188,310</u>	<u>114,916</u>	<u>114,916</u>
Loss for the period							-23,784	-23,784	-23,784
Share issue - exercise of stock options on 7 April 2016		0		366				366	366
Share-based payment expense					216			216	216
Balance as at 30 June 2016		<u>406</u>	<u>-221,232</u>	<u>523,073</u>	<u>1,561</u>	<u>0</u>	<u>-212,094</u>	<u>91,714</u>	<u>91,714</u>
Balance as at 1 January 2017		<u>446</u>	<u>-221,232</u>	<u>554,065</u>	<u>1,716</u>	<u>-19</u>	<u>-238,088</u>	<u>96,889</u>	<u>96,889</u>
Loss for the period							-23,982	-23,982	-23,982
Other comprehensive income							-1	-1	-1
Total comprehensive income							-23,984	-23,984	-23,984
Consolidation translation difference							0	-0	-0
Share-based payment expense					151		-0	150	150
Recognition of net defined benefit liability						-33	-0	-34	-34
Balance as at 30 June 2017		<u>446</u>	<u>-221,232</u>	<u>554,065</u>	<u>1,867</u>	<u>-52</u>	<u>-262,073</u>	<u>73,021</u>	<u>73,021</u>

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 virtually 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), Lausanne (Switzerland) and New Jersey (US). 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. 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 31 August 2017.

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 2017 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 2016, 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 2016. New standards or interpretations applicable from 1 January 2017 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 2017:

- Annual improvements to IFRS Standards 2014-2016 Cycle: Amendments to IFRS 12 (applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed by the EU)
- Amendments to IAS 7 Statement of Cash Flows - Disclosure Initiative (applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed by the EU)
- Amendments to IAS 12 Income Taxes - Recognition of Deferred Tax Assets for Unrealized Losses (applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed by the EU)

As referenced in the annual report of 2016, the management of the Group has re-investigated per 30 June 2017 the impact of the initial application of IFRS 15 and concluded that the application will not have a significant impact on the timing or value of the Group's revenue.

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 recognized 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 2017 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 multipurpose credit facilities that the Company has at its disposal, the Board of Directors 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:

In EUR 000	For the 6 months ended	
	30 June 2017	30 June 2016
Collaboration revenue		
R&D services	45	115
Upfront license revenues	671	3,262
Milestone revenues	0	0
	716	3,377
Product sales revenue		
Idylla™ System Sales	1,821	988
Idylla™ Cartridge Sales	3,270	1,723
	5,091	2,711
Service revenue		
Service revenue	105	20
	105	20
Total	5,912	6,109

6.4.1. Collaboration revenue

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



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 recognized in collaboration revenues in the first half of 2017.



On 3 February 2016, Biocartis NV, a subsidiary of the Company, and Amgen entered into a collaboration agreement to evaluate Idylla™ RAS testing as a tool for rapid decentralized testing in Brasil, Canada, Colombia, Mexico, Saudi Arabia, Spain, and Turkey. This collaboration was expanded in December 2016 with a new agreement that includes up to 10 European countries and that will enable several dozen additional selected hospitals to accelerate access to RAS biomarker information using Biocartis' Idylla™ platform and RAS tests. Product revenue recognized under this agreement is shown under product sales as it relates to the placement of Idylla™ systems and cartridges.



Biocartis NV, a subsidiary of the Company, signed a collaboration agreement with Merck KGaA (Merck, Darmstadt, Germany) for the development and commercialization 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.

No upfront payments or milestone revenue under this collaboration were recognized in revenues in the first half of 2017. Product revenue recognized under this agreement is shown under product sales as it relates to the placement of Idylla™ systems and cartridges.

6.4.2. Product sales revenue

The product sales relate to Idylla™ system sales (Idylla™ Instruments and Idylla™ Consoles) and test sales (cartridges) to customers and collaboration partners. The total product sales can be categorized in commercial sales and research & development revenue.

In EUR.000	For the 6 months ended	
	30 June 2017	30 June 2016
Commercial revenue	5,024	1,705
Research & Development revenue	66	1,006
Total	5,091	2,711

6.4.3. Revenues by region and major customers

<u>In EUR 000</u>	For the 6 months ended	
	<u>30 June 2017</u>	<u>30 June 2016</u>
Country of domicile	262	923
Belgium	262	923
Total all foreign countries, of which	5,650	5,186
US	1,298	2,979
Spain	857	74
Rest of the world	3,495	2,132
Total	5,912	6,109

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 EUR 1.1m of the revenues in the first half of 2017 (first half of 2016: EUR 0.1m).

6.5. Other operating income

<u>In EUR 000</u>	For the 6 months ended	
	<u>30 June 2017</u>	<u>30 June 2016</u>
R&D project support (IWT grants)	966	641
Other project grants	62	0
Other income	38	0
Total	1,066	641

6.6. Cost of sales

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

<u>In EUR 000</u>	For the 6 months ended	
	<u>30 June 2017</u>	<u>30 June 2016</u>
Staff costs	-747	-604
Material, lab consumables & small equipment	-1,773	-898
Depreciation and amortization	-387	-271
Royalty expense	-336	-122
Other	-35	-26
Total	-3,278	-1,921

6.7. Research and development expenses

<u>In EUR 000</u>	For the 6 months ended	
	<u>30 June 2017</u>	<u>30 June 2016</u>
Staff costs	-9,895	-10,645
Subcontracting	-922	-2,859
Laboratory expenses	-1,005	-1,195
Platform and cartridge prototype costs	-2,578	-1,046
Consultancy	-1,020	-538

Quality and regulatory	-38	-3
Intellectual property	-294	-369
Facilities, office & other	-1,650	-1,422
ICT	-568	-675
Travel, training & conferences	-301	-381
Depreciation and amortization	-1,892	-2,062
Capitalized systems for internal use	845	497
Total	-19,320	-20,699

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.

Capitalized systems for internal use are Idylla™ Consoles and Idylla™ Instruments used for amongst others assay development and quality purposes.

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 EUR 000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2017</u>	<u>30 June 2016</u>
Staff costs	-3,046	-2,708
Subcontracting	-44	-585
Sales and promotional expenses	-239	-594
Business development	-147	-144
Consultancy	-96	-123
Facilities, office & other	-438	-192
Travel, training & conferences	-1,124	-841
Depreciation and amortization	-174	-72
Total	-5,308	-5,259

Sales and promotional 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 EUR 000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2017</u>	<u>30 June 2016</u>
Staff costs	-1,545	-1,708
External advice	-311	-291
Facilities, office & other	-430	-416
Human resources	-392	-335
Travel, training & conferences	-109	-138
Depreciation and amortization expenses	6	14
Total	-2,781	-2,874

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

6.10. Personnel expenses

<u>In EUR 000</u>	<u>For the 6 months ended</u>	
	<u>30 June 2017</u>	<u>30 June 2016</u>
Staff costs	-15,233	-15,666
Average number of full time equivalents	313	291

6.11. 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.

	<u>For the 6 months ended</u>	
	<u>30 June 2017</u>	<u>30 June 2016</u>
Profit/loss for the period attributable to the owners of the Company (in EUR 000)	-23,982	-23,784
Weighted average number of ordinary shares for basic loss per share (in number of shares)	44,648,105	40,565,072
Basic loss per share (EUR)	<u>-0.54</u>	<u>-0.59</u>

6.12. Property, plant and equipment

The table below provides an overview of the investments per subcategory. Total additions amount to EUR 3.3m in the first half of 2017 of which EUR 1.8m relate to investments for the Idylla™ cartridge production expansion. The below-mentioned investments are largely financed with banking and lease financing facilities.

<u>In EUR 000</u>	<u>As of</u>
	<u>30 June 2017</u>
Investments	
ICT equipment	18
Laboratory equipment	55
Manufacturing equipment	73
Internally produced systems	410
Furniture and fixtures	44
Leasehold improvements	154
Other property and equipment	0
Equipment under construction	1,687
Systems for rent	825
Total	<u>3,266</u>

The investments done in the subcategory 'Equipment under construction' of EUR 1.7m relate to the investments in the Idylla™ cartridge production expansion facilities.

6.13. 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 5.1m 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 8.26% per 30 June 2017 because the Company did not participate in any subsequent capital increases in MyCartis NV since acquisition of its financial participation. No impairment has been made per 30 June 2017.

<u>In EUR 000</u>	As of	
	<u>30 June 2017</u>	<u>31 Dec 2016</u>
Initial recognition amount	5,052	5,052
Total	<u>5,052</u>	<u>5,052</u>

6.14. Inventory

The inventory can be analyzed as follows:

<u>In EUR 000</u>	As of	
	<u>30 June 2017</u>	<u>31 Dec 2016</u>
Inventory		
Raw materials	4,194	4,881
Semi-finished products	896	1,151
Finished products	4,832	3,796
Total	<u>9,922</u>	<u>9,829</u>
Amount recognized as an expense	<u>-3,278</u>	<u>-5,319</u>

The inventory value as a whole remains stable but we see shifts in between the categories. Finished products increased due to the increasing business needs, both for sale as for internal consumption. Raw materials & semi-finished have decreased due to efficiency improvements in material supply.

6.15. Trade and other receivables

<u>In EUR 000</u>	As of	
	<u>30 June 2017</u>	<u>31 Dec 2016</u>
VAT receivables	1,234	1,304
Other receivables	999	897
Total	<u>2,233</u>	<u>2,201</u>

In EUR 000	As of	
	30 June 2017	31 Dec 2016
Trade receivables	3,395	3,318
Allowance for doubtful receivables	-383	-383
Total	3,012	2,935

6.16. Other current assets

In EUR 000	As of	
	30 June 2017	31 Dec 2016
Accrued grant income	1,233	769
Other accrued income	2	6
Deferred charges	1,129	1,157
Total	2,364	1,932

Other current assets include accrued grant income mainly related to Flemish government grants for EUR 1.2m. The Group evaluates continuously if it fulfils the specific conditions as per specific grant agreements to justify that none of the grants receivables are to be impaired.

6.17. Financial debt

The financial debt can be analyzed as follows:

In EUR 000	As of	
	30 June 2017	31 Dec 2016
PMV & FPIM	15,797	15,263
Lease company	13,159	12,022
Bank	365	425
Total non current	29,320	27,709
PMV & FPIM	0	0
Lease company	3,840	3,581
Bank	119	118
Total current	3,959	3,698

In 2013, Biocartis NV refinanced about 50% of its Idylla™ semi-automated cartridge manufacturing line in Mechelen (Belgium) via a sale and lease back operation. The lease had an initial term of 5 years at a 3.35% interest rate and included a purchase option of EUR 0.2m. In 2015, the term was extended until 1 June 2021 to align with the new 2015 lease as described below. The purchase option was also reduced to EUR 0.1m. As a security, a debt service reserve account is to be maintained, starting at EUR 2.5m, decreasing over time according to the following

milestones: fundraising 2013, CE approval, FDA approval. The current debt service reserve account amounts to EUR 1.2m.



In 2015, Biocartis NV obtained two new financing facilities for the modifications to the current cartridge production line in Mechelen. The first new facility entails an investment credit for an amount of EUR 0.6m, provided by a bank. This facility has a payment term of 5 years and an interest rate of 1.93%. The second one entails a leasing facility for EUR 4.4m, provided by a lease company, of which EUR 3.9m was drawn per 30 June 2017. The interest applicable for this leasing facility equals approx. 1.77% and the leasing includes a purchase option of 1% of the financed amount.

In 2016, Biocartis NV obtained a lease financing facility for the development of a second cartridge production line in Mechelen, for EUR 15m, provided by a lease company, of which EUR 12.5m was drawn per 30 June 2017. The interest applicable for this leasing facility equals approx. 1.87% and the leasing includes a purchase option of 1% of the financed amount.

In 2016, Biocartis NV and the Company also obtained a subordinated loan of EUR 15m provided by a consortium of PMV (Participatie Maatschappij Vlaanderen) and the Belgian 'Federal Holding and Investment Company' (FPIM). Both PMV and FPIM granted a loan of EUR 7.5m each, bearing an interest rate of 7% and with a maturity date at 30 September 2021 (except in case of extension of the loan upon the Company's request or voluntary or mandatory early repayment). The interest on the loans is capitalized during the first three years of the agreement and accrued in the consolidated balance sheet at the year-end. The agreement contains a set of business covenants, which require obtaining the lenders' approval for certain major transactions outside the ordinary course of business.

In July 2016, the Group also obtained a EUR 25m credit line facility from a bank to strengthen the Company's financial position and to continue the execution of the strategic plan. The credit line facility consists of a EUR 10m working capital credit line and of a EUR 15m roll-over credit line. These facilities are 50% guaranteed by the Flemish Guarantee Fund Gigarant. As per 30 June 2017, no withdrawals have been made by the Company on this facility.

In addition, the Group also has access to a bank guarantee line of EUR 0.5m of which EUR 0.5m has been taken up for rental guarantees as per 30 June 2017, and an credit line with a bank of EUR 0.6m for currency hedging, of which EUR 0m has been taken up as per 30 June 2017.

6.18. Trade payables and other current liabilities

In EUR 000	As of	
	30 June 2017	31 Dec 2016
Trade payables	6,396	6,293
Total trade payables	6,396	6,293
In EUR 000	30 June 2017	31 Dec 2016
Provision vacation pay and end-of-year premium	2,351	2,357
Other social debt	720	563
VAT payable	0	4
Other	-51	30
Total current liabilities	3,019	2,954

6.19. Deferred income

In EUR 000	As of	
	30 June 2017	31 Dec 2016
Grants	764	268
Partner income	1,209	1,837
Total	1,973	2,106
Current	1,951	1,963
Non current	22	142

Deferred partner income includes upfront payments received from Amgen Inc. and upfront payments received from JPNV in relation to the strategic licensing, development and commercialization collaborations.

In EUR 000	Deferred partner income
As per 31 December 2015	5,107
Invoiced	1,668
Recognized in profit or loss	-4,939
As per 31 December 2016	1,837
Invoiced	1,145
Recognized in profit or loss	-1,772
As per 30 June 2017	1,209

6.20. Other disclosures

6.20.1. Fair value

The fair value of the financial assets has been determined based on 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 based on their credit risk and interest rate. Their fair value is not significantly different from its carrying value on 30 June 2017 and 31 December 2016.

The fair value of the financial liabilities has been determined based on 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 2017 and 31 December 2016.



In EUR 000	Carrying value		Fair value	
	30 June 2017	31 Dec 2016	30 June 2017	31 Dec 2016
Available for sale financial assets				
Participating interest	5,052	5,052	5,052	5,052
Total available for sale financial assets	5,052	5,052	5,052	5,052
Loans and receivables measured at amortized cost				
Trade and other receivables (current)	5,246	5,136	5,246	5,136
Other long term receivables	11	11	11	11
Other current assets	2,364	1,932	2,364	1,932
Total loans and other receivables	7,621	7,079	7,621	7,079
Cash & cash equivalents				
Cash & cash equivalents*	59,042	83,246	59,042	83,246
Total cash & cash equivalents	59,042	83,246	59,042	83,246
Financial liabilities measured at amortized cost				
Loans & Borrowings	33,279	31,407	36,290	34,979
Trade payables	6,396	6,293	6,396	6,293
Other liabilities and accrued charges	4,433	4,563	4,433	4,563
Total financial liabilities measured at amortized cost	44,109	42,264	47,120	45,835

* For 30 June 2017: including EUR 1.2m restricted cash related to KBC Lease financing.

6.20.2. 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 recognizes 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 subsidized 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.

Phillips option

Under contractual conditions, payments (royalties and other revenue sharing payments) may arise in the future to Phillips, 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 Phillips.

6.20.3. Commitments

6.20.3.1. Capital commitments

As per 30 June 2017, the Group has EUR 6.5m capital commitments mainly related to investments in the cartridge manufacturing facilities in Mechelen.

6.20.3.2. Operating commitments

As per 30 June 2017, the Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 2.5m. It is expected that the majority of the commitments will be fulfilled in 2017.

6.20.4. Related-party transactions

Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes. Apart from the remuneration of key management, there were no other transactions with related parties.



6.21. Events after the balance sheet date

- *Breast cancer menu* – In July 2017, Biocartis and ETPL (the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research) initiated the development of second test for the Idylla™ breast cancer menu: a fully automated solid biopsy assay, aimed at supporting optimal therapy selection decisions for breast cancer patients. This development is part of a renewed five-year strategic partnership with ETPL⁹ focused on the development of molecular diagnostic assays for Biocartis' Idylla™ platform. The partnerships with ETPL and LifeArc fit well with Biocartis' strategy to accelerate the expansion of its menu of molecular diagnostic tests through third party partnerships.
- *510(k) exemption Idylla™ instrumentation* – In July 2017, the US FDA¹⁰ published a final list of devices that it has exempted from 510(k) premarket notification requirements. The product codes applicable to the Biocartis Idylla™ Instrument and Idylla™ Console are included on this list. The exemption of the Biocartis Idylla™ Instrument and Idylla™ Console is expected to accelerate the introduction of the Idylla™ platform in the US.
- *MSI performance data* – On 31 August 2017, Biocartis announced the publication of two study abstracts, selected for presentation at the ESMO congress in September 2017, regarding the performance of its exclusively licensed novel set of biomarkers for microsatellite instability (MSI) that are to be included in the Idylla™ MSI Test (the 'MSI Biomarkers'). Both studies (of which one conducted in collaboration with Merck KGaA, Darmstadt, Germany) showed superior performance of the MSI Biomarkers compared to the reference methods.
- *US FDA 510(k) clearance Idylla™ Respiratory (IFV-RSV) Panel* – On 5 September 2017, Biocartis announced that the US Food and Drug Administration (FDA) has granted 510(k) clearance¹¹ for the Idylla™ Respiratory (IFV-RSV) Panel.

⁹ On 17 July 2015, Biocartis signed a partnership agreement with ETPL, the commercialization 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 had access to novel biomarkers (including those discovered within A*STAR's research institutes) from the Diagnostics Development Hub under ETPL.

¹⁰ US Food and Drug Administration.

¹¹ Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k).

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 2017

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 2017, the condensed consolidated income statement, the condensed consolidated cash flow statement, the condensed consolidated statement of other comprehensive income and the condensed consolidated statement of changes in equity for the period of six months then ended, as well as selective notes.

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 consolidated condensed statement of financial position shows total assets of 1 19 162 (000) EUR and the consolidated condensed income statement shows a consolidated loss for the period then ended of 23 982 (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.

Zaventem, 1 September 2017

The statutory auditor

DELOITTE Bedrijfsrevisoren / Réviseurs 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 organized under the laws of Belgium and has its registered office at Generaal de Wittelaan 11 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 2017 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.

The Biocartis trademark and logo are trademarks of Biocartis and are used and registered in Europe. Idylla™ is a registered trademark in the United States and other countries. The Idylla™ trademark and logo are trademarks of and used by Biocartis. This press release is not for distribution, directly or indirectly, in any jurisdiction where to do so would be unlawful. Any persons reading this press release should inform themselves of and observe any such restrictions. Biocartis takes no responsibility for any violation of any such restrictions by any person. Please refer to the product labeling for applicable intended uses for each individual Biocartis product. This press release does not constitute an offer or invitation for the sale or purchase of securities in any jurisdiction. No securities of Biocartis may be offered or sold in the United States of America absent registration with the United States Securities and Exchange Commission or an exemption from registration under the U.S. Securities Act of 1933, as amended.

8.2. Contact Investor Relations

Biocartis Investor Relations
Renate Degrave
Generaal de Wittelaan 11 B3
2800 Mechelen, Belgium
+32 15 632 600
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8.3. Listing

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

8.4. Financial calendar

- | | | |
|---|--|-------------------|
| • | Extraordinary General Meeting Biocartis Group NV | 11 September 2017 |
| • | Q3 2017 business update | 16 November 2017 |
| • | 2017 full year results | 1 March 2018 |
| • | Publication 2017 annual report | 5 April 2018 |

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
Gateway Building
Luchthaven Nationaal 1J
1930 Zaventem
Belgium

8.7. Forward-looking statement

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, 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 updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. 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

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.
Biopsy (solid/liquid)	The Idylla™ platform is capable of processing both solid biopsies (FFPE tissue which is the standard tissue type for solid tumour diagnostics, and fresh (frozen) tissue samples) and liquid biopsies. These are easier to obtain sample types such as blood plasma or urine. Liquid biopsy based assays will facilitate monitoring of treatments and disease progression, and possible earlier disease detection.
Serine/threonine-protein 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.
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').
ctDNA	This is circulating tumor DNA.
Companion Diagnostics (CDx)	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.
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 Authorization (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 tumors, 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.

Immunoassay

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.

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.

Metastatic Colorectal Cancer (mCRC)

Colorectal Cancer (CRC) is the second most common cancer worldwide, with an estimated incidence of more than 1.36m 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.

Microsatellite 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.

Next-Generation Sequencing (NGS)

Sequencing is the process of determining the precise order of nucleotides within a DNA molecule. It includes any method or technology that is used to determine the order of the four bases—adenine, guanine, cytosine, and thymine—in a strand of DNA. The high demand for low-cost sequencing has driven the development of high-throughput sequencing technologies that parallelize the sequencing process, producing thousands or millions of sequences concurrently. High-throughput sequencing technologies are intended to lower the cost of DNA sequencing beyond what is possible with standard dye-terminator methods.

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)

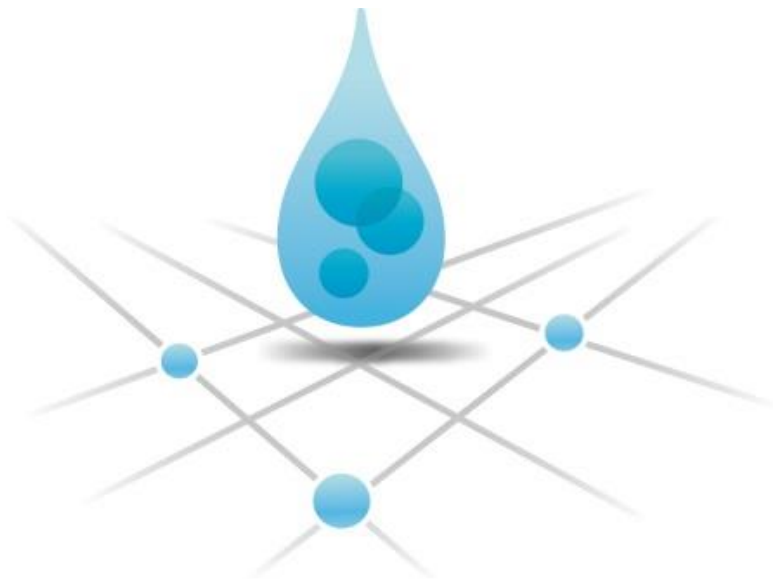
This is a category of non-approved (i.e. no CE-marking and FDA approval) medical device products that can solely be used for research purposes. Many producers introduce their products first as RUO and/or IUO products, prior to obtaining 510(k) clearance or PMA approval.

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.



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