

Financial report

H1 2018

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 2018.

Our European direct and RoW¹ markets showed good momentum in H1 2018, Europe even exceeding our expectations. Furthermore, I am pleased that in H1 2018 we could significantly strengthen our commercial presence in the US by attracting amongst others top tier customers who fueled a strong US installed base growth. This demonstrates the attractiveness of the Idylla™ platform for the US market, paving the way for further market adoption.

All of this allowed us to grow our installed base to close to 800 instruments and to realize a doubling of cartridge volumes year-over-year. In addition to that, the expansion of existing and addition of new test menu collaborations in H1 2018 will allow us to further build on this momentum, as such collaborations have shown to be an accelerator in the market adoption of Idylla™. It is in this context that we have further redirected internal resources in H1 2018 to facilitate such partnerships.

Finally, driven by strong demand from customers, we accelerated the development of our unique MSI test and managed to successfully launch this product in July 2018, an important kick-starter for the second half of this year!

Herman Verrelst
CEO Biocartis

2. Responsibility statement

The undersigned hereby declare that to the best of their knowledge: a) the condensed consolidated financial statements for the six-month's period ended 30 June 2018, which have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union, give a true and fair view of the net equity, financial position and results of the Company and the companies included in the consolidation, and b) give a true and fair view of the main events and the impact thereof on the condensed consolidated financial statements c) as well as a description of the main risks and uncertainties with respect to the remaining months of the fiscal year, and the main transactions with related parties and the impact thereof on the condensed consolidated financial statements.

Herman Verrelst

Christian Reinaudo

CEO

Chairman

¹ RoW = Rest of the World. RoW is defined as the world excluding Europe, US, China and Japan.

3. Principal risks related to the business activities

The principal risks related to Biocartis' business activities are outlined in Biocartis' 2017 Annual Report, p. 18-23, 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 [2017 Annual Report](#).

4. Business review of the first half of 2018

4.1. Commercial highlights



- *Installed base* – The Idylla™ installed base increased with 149 instruments in H1 2018 driven by higher than expected growth in Europe and strong placements in the US, the latter contributing to approximately 1/3 of overall growth. End of June 2018, the total installed base amounted to 796 Idylla™ instruments.
- *Commercial cartridge volume*: H1 2018 commercial volume increased to approximately 58k cartridges, which is more than a doubling of the H1 2017 volume (approximately 27k cartridges). Europe followed by RoW contributed most to the growth in commercial cartridge volume.
- *European commercialization* – The H1 2018 performance of European direct markets exceeded expectations driven by amongst others an increased usage of Idylla™ in first line testing in amongst others the UK, France and Germany as well as a strong overall contribution from pharma collaborations.
- *US commercialization* - During H1 2018, Biocartis significantly expanded the US customer base with new high profile customers across small, medium and large volume laboratories and hospitals, including some of the [top 10 oncology hospitals in the US](#)². This has resulted in strong instrument placements with a promising volume potential and an initial ramp-up of cartridge volumes. Pending validation efforts at existing US customers, combined with an ongoing expansion of Biocartis' US sales team is expected to fuel further growth of both the US installed base and cartridge volume growth in H2 2018. In H2 2018, the market adoption of Idylla™ in the US will be further supported by [Biocartis' presence at the leading Association for Molecular Pathology \(AMP\) conference](#) in November 2018. Here, Biocartis will amongst others host a workshop with testimonials from Maria E. Arcila, MD (Director Diagnostic Molecular Pathology Laboratory) and Khedoudja Nafa, PharmD PhD (Molecular Geneticist) of Memorial Sloan Kettering Cancer Center, a leading cancer treatment and research hospital in the US, and during which several Idylla™ performance studies by US KOLs³ will be presented.
- *Distribution markets RoW* – Biocartis obtained additional market authorizations for its products in Argentina, Brazil, Canada, Malaysia, Mexico, Singapore and Uruguay in H1 2018. A promising growth in cartridge volumes was observed across key RoW markets driven by increased commercialization efforts of both distribution and pharma partners.

² Source: US NEWS Top 10 hospital ranking, <https://www.usnews.com/info/blogs/press-room/articles/2017-08-08/us-news-announces-2017-18-best-hospitals>, last consulted on 9 August 2018.

³ Key Opinion Leaders.

H1 2018 in a nutshell

Installed base + 149 instruments to a total of **796**
instruments and **+ 58,000** cartridges

New R&D center in the **US** and strong instrument
placements, including at some of the **top 10 US**
oncology hospitals

Idylla™ review study: out
of the nearly 2,500
Idylla™ tests,
98.1%
generated a valid result

Product revenues **y-o-y +68%** to **EUR 8.6m**,
predominantly driven by **cartridge revenues** that
more than doubled. Collaboration
revenues increased y-o-y close to **five times** to
EUR 3.7m

Milestone Genomic
Health partnership:
demonstration of full
feasibility of Idylla™ IVD
Oncotype DX Breast
Cancer test on Idylla™

EUR 24m debt financing facility
from the European Investment Bank which can be used to part-
finance up to 50% of further investments in infectious diseases
diagnostics solutions.

Second CDx
development
agreement with
Amgen

Strong progress in the
validation of the **2nd**
cartridge
manufacturing line

China
strategy: joint
venture
announcement
with
Wondfo

Additional market authorizations in **Argentina,**
Brazil, Canada, Malaysia,
Mexico, Singapore and
Uruguay

Partnership
Immunexpress for
development &
commercialization
SeptiCyte™
test on Idylla™

4.2. Partnership menu highlights



- *CDx business* - On 9 January 2018, Biocartis announced its second CDx development agreement with Amgen, a leading biotechnology company (NASDAQ: AMGN), aimed at the development of Idylla™ CDx biomarker tests for a novel oncology compound to be used in the treatment of certain solid tumors.
- *Undisclosed feasibility projects* - In H1 2018, Biocartis advanced promising undisclosed pharma-sponsored feasibility projects aimed at the development of new Idylla™ assays that are to be used for monitoring purposes, of which one focused on the field of immuno-oncology.
- *Partnership Genomic Health* - On 3 June 2018, Biocartis' partner Genomic Health, Inc. (NASDAQ: GHDX) announced the results of its long-awaited TAILORx⁴ study, the largest ever breast cancer treatment trial, which provided definitive evidence that the Oncotype DX Breast Recurrence Score test identified 70 percent of early-stage breast cancer patients who receive no benefit from chemotherapy, and can be effectively treated with endocrine therapy alone. Additionally, the trial established that chemotherapy may provide life-saving benefit to 30 percent of patients. These results are expected to be an important driver in the market adoption of the future Idylla™ Oncotype DX[®] test in Europe. During H1 2018, Genomic Health and Biocartis reached an important milestone in the development of the Idylla™ IVD Oncotype DX Breast Cancer test by demonstrating full feasibility of that test on the Idylla™ platform. Furthermore, early access sites to conduct validation studies for the test were selected with the aim to launch in the second half of 2019, beginning in France and Germany.
- *Infectious diseases partnership* - On 24 January 2018, Biocartis and Immunexpress Pty Ltd ('Immunexpress'), a host response molecular diagnostic company, announced a partnership agreement aimed at the development and commercialization of Immunexpress' SeptiCyte™ test for use on the Idylla™ platform. The SeptiCyte™ LAB test recently received 510(k) clearance from the US FDA for use on a manual PCR⁵ instrument, and aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS) systemic inflammation in critically ill patients on their first day of their admission in the ICU (intensive care unit). Under the partnership, parties will co-develop the SeptiCyte™ Idylla™ test, whereas Immunexpress will take the lead in the commercialization, with an initial focus on the US and the European markets.

4.3. Menu highlights

- *Review external performance studies* - On 27 June 2018, Biocartis announced the publication of a study in the Journal of Clinical Pathology⁶ that reviewed 18 Idylla™ performance studies⁷, showing a strong performance of Idylla™ compared to reference methods commonly used in clinical practice today to determine biomarker status (BRAF, NRAS, KRAS and EGFR mutations) that drive frequently occurring cancers (i.e. melanoma, colorectal, lung, thyroid and pancreatic cancer⁸). Results showed that out of the nearly 2,500 Idylla™ tests, 98.1% of the tests generated a valid result. The study also showed an excellent concordance rate of 94.8% between Idylla™ and the reference methods. The data generated by the studies demonstrated as such the high accuracy of the Idylla™ platform to test for actionable BRAF, NRAS, KRAS and EGFR mutations in different cancers, underlining the cost-effectiveness of Idylla™ testing compared to other molecular methods.

⁴ Trial Assigning Individualized Options for Treatment (Rx), or TAILORx. Source: Genomic Health website, last consulted on 3 August 2018, <http://newsroom.genomichealth.com/releasedetail.cfm?ReleaseID=1069104>.

⁵ Polymerase Chain Reaction.

⁶ The review study was performed by Dr. Arnaud Uguen (MD, PhD, Department of Pathology of the Brest University Hospital, Brest, France) and Dr. Giancarlo Troncone (MD, PhD, Professor of Anatomic Pathology, University of Naples Federico II, Naples, Italy).

⁷ The Medline and Google Scholar databases were searched to retrieve studies addressing the Idylla™ system performance in comparison to other diagnostic methods. Only original papers were taken into account, excluding congress abstracts. Data analyzed included the number and types of samples, the specific Idylla™ cartridges used and the non-Idylla™ reference method. Special care was also taken to record discordant cases, focusing on the underlying reasons of disagreements between Idylla™ and non-Idylla™ methods.

⁸ Overall, five studies were dedicated to colorectal cancer, four to lung cancer, four to melanoma, one to thyroid cancer, one to pancreatic cancer and three to different tumors including the aforementioned types as well as a few examples of other tumors. The studies included the following Idylla™ test cartridges used: Idylla™ BRAF Mutation Test (CE-IVD), Idylla™ NRAS-BRAF-EGFRS492R Mutation Assay (RUO or Research Use Only), Idylla™ NRAS-BRAF Mutation Test (CE-IVD), Idylla™ KRAS Mutation Test (CE-IVD), Idylla™ NRAS Mutation Test (CE-IVD), Idylla™ EGFR Mutation Assay (RUO).

- *Colorectal cancer menu* – A total of three performance studies of Idylla™ CRC tests were published in H1 2018:
 - *ctRAS testing at AACR* - On 15 March 2018, Biocartis announced that a study abstract⁹ on the analytical and clinical validation of its liquid biopsy Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests¹⁰ was selected for oral presentation at the renowned AACR (American Association for Cancer Research) Annual Meeting in Chicago, IL (US). Results demonstrated that the Idylla™ ctKRAS and ctNRAS-BRAF Mutation Tests¹¹ provide a sensitive, reliable and fast solution for liquid biopsy RAS-BRAF ctDNA (circulating tumor DNA) testing, and that RAS-BRAF mutation status can be adequately determined using blood plasma from metastatic colorectal cancer (mCRC) patients with liver metastases. RAS-BRAF mutation analysis is mandatory by all major international guidelines¹² for mCRC patients.
 - *MSI testing at ASCO* - On 17 May 2018, Biocartis announced that two studies conducted in cooperation with the Flemish Institute for Biotechnology (VIB) regarding the performance of its exclusively licensed novel set of biomarkers for microsatellite instability (MSI)¹³ that are included in the Idylla™ MSI Assay (the 'MSI Biomarkers'), were selected for publication at the ASCO (American Society of Clinical Oncology) Annual Meeting, which took place between 1-5 June 2018 in Chicago, IL (US). The [first study](#)¹⁴ used the prototype Idylla™ MSI Assay in finalized design and shows superior performance of the MSI assay compared to reference methods. The [second study](#)¹⁵ underlined the potential of Biocartis' MSI Biomarkers to be used as a companion diagnostic to predict immunotherapy outcome in MSI-High endometrial and colorectal tumors. Biocartis launched its Idylla™ MSI Assay (RUO) on 17 July 2018, early than initially planned.



- *Lung cancer menu* – On 28 May 2018, Biocartis announced the publication of a study¹⁶ in the Journal of Clinical Pathology demonstrating that the Idylla™ EGFR Mutation Test (CE-IVD) was able to rescue 80% of the EGFR samples whose assessment was unsuccessful with Next Generation Sequencing (NGS). The study concluded that the Idylla™ EGFR Mutation Test is a viable alternative to NGS for rapid treatment decisions¹⁷ in patients with acute deterioration, in particular when testing is performed on a less than optimal tumor tissue sample, which frequently yields insufficient amounts of DNA for proper NGS analysis. There was a 100% concordance with NGS for the valid results, where Idylla™ confirmed the EGFR mutational status. For a large portion (20/25 or 80%) of the cases whose NGS assessment was invalid, Idylla™ was able to process the sample and adequately produced a result.
- *Breast cancer menu* – See under 'Menu partnership highlights' – partnership Genomic Health.

⁹ B Jacobs, B Claes, P Laurent-Puig, JP Bachet, S Tejpar, G Maertens, E Sablon, "Analytical and clinical validation of the Idylla™ ctKRAS and ctNRAS-BRAF Liquid biopsy tests", first presented at the 2018 AACR Annual Meeting in Chicago, US, 14-18 April 2018.

¹⁰ These tests were developed under the collaboration with Merck KGaA, Darmstadt, Germany.

¹¹ The Idylla™ ctKRAS Mutation Test and the Idylla™ ctNRAS-BRAF Mutation Test are CE-marked IVD's in Europe and not for sale in the US. Please check availability with the local Biocartis sales representative.

¹² http://www.amp.org/committees/clinical_practice/CRCOpenComment.cfm; ESMO (ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1-37, 2016); NCCN (NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016); ASCO (Allegra CJ, et al. Extended RAS gene mutation testing in metastatic Colorectal Carcinoma to predict response to antiepidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. Journal of Clinical Oncology 2016; 34(2):179-85) and CAP/AMP/ASCO

¹³ Microsatellite instability or MSI is the result of inactivation of the body's so-called DNA mismatch repair (MMR) system. Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, contributing to tumor growth and evolution. Current MSI testing methods rely on manual, lengthy and complex procedures involving amongst others obtaining and testing of a second reference sample.

¹⁴ B. De Craene et al, "Detection of microsatellite instability (MSI) in colorectal cancer samples with a novel set of highly sensitive markers by means of the Idylla™ MSI Assay prototype", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, IL (US).

¹⁵ H. Zhao et al., "A novel set of 7 homopolymer indels for detection of MSI is associated with tumor mutation burden and total indel load in endometrial and colorectal cancers", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, US. The methodology used for detection of the seven biomarkers, TMB (tumor mutation burden), and indel load, was whole-exome sequencing.

¹⁶ De Luca et al, University of Naples Federico II, "The Idylla™ Assay and Next Generation Sequencing: an integrated EGFR mutational testing algorithm", Journal of Clinical Pathology, to consult online on <http://jcp.bmj.com/content/jclinpath/early/2018/05/24/jclinpath-2018-205197.full.pdf?ijkey=V8eBoaMDpKZ7t9N&keytype=ref>.

¹⁷ To be taken by a multidisciplinary team.

4.4. Organizational and operational highlights

- *New board composition* – Following the annual shareholders' meeting (AGM) held on Friday 11 May 2018, five new independent board members were appointed and three board members whose mandate expired at the closing of the AGM, were re-appointed. The new board composition allows for a transition towards a board of directors consisting predominantly of independent directors and consists of: CRBA Management BVBA (represented by Christian Reinaudo), chairman of the board, Ann-Christine Sundell, Scientia II LLC (represented by Harry Glorikian), CLSCO BVBA (represented by Leo Steenberg), Luc Gijsens BVBA (represented by Luc Gijsens), Peter Piot¹⁸, Hilde Windels BVBA (represented by Hilde Windels¹⁹), Roald Borré²⁰ and Herman Verrelst (CEO of Biocartis).



- *US R&D center* - On 1 March 2018, Biocartis announced to have established an R&D center in the US as the result of a transfer of R&D staff members and Idylla™ related assay development assets and tests of Janssen Diagnostics (a division of Janssen Pharmaceuticals, Inc.). With the establishment of this US R&D center, Biocartis supports the execution of its strategy to accelerate test menu expansion on the Idylla™ platform through predominantly CDx collaborations and assay content partnerships.

- *Cartridge manufacturing* – Strong progress was made during H1 2018 in the validation of Biocartis' second cartridge manufacturing line that should provide for an additional annual cartridge capacity of over 1 million Idylla™ cartridges. The aim is to start commercial cartridge production on this line by year-end.

4.5. Financial highlights

- *Total operating income* – Total operating income increased year-over-year with 83% to EUR 12.7m driven by increased product and collaboration revenues. Product revenues increased year-over-year from EUR 5.1m to EUR 8.6m, an increase of 68%, which was predominantly driven by cartridge revenues that more than doubled. Collaboration revenues increased from EUR 0.8m in H1 2017 to EUR 3.6m in H1 2018, a year-over-year increase of close to five times.
- *OPEX* – Total operating expenses (including cost of sales), amounted to EUR 33.9m in H1 2018 versus EUR 30.7m in H1 2017, an increase of around 10% that was mainly driven by higher costs of sales. Operating expenses excluding costs of sales in H1 2018 amounted to EUR 27.0m versus EUR 27.4m in H1 2017, a decrease of approx. 2% predominantly due to lower expenses for research & development that was partially offset by higher expenses for sales & marketing and general & administrative expenses.
- *Net cash flow* - Total net cash flow in H1 2018 amounted to EUR -21.4m versus EUR -24.2m in H1 2017, a year-over-year improvement of approximately 12%.
- *Cash position* - Biocartis' cash position as per end June 2018 amounted to EUR 91.3m compared to EUR 112.8m as per 31 December 2017. In addition, the Company has EUR 27.5m of multiple purpose credit lines at its disposal on which no drawdowns were made as per end of H1 2018.
- *EIB financing facility* – On 1 March 2018, Biocartis announced to have obtained a EUR 24m debt financing facility from the European Investment Bank. The financing facility is supported by InnovFin – EU Finance for Innovators' Infectious Diseases Finance Facility, with the financial backing of the European Union under its research and innovation program

¹⁸ Independent director.

¹⁹ Non-executive director.

²⁰ Non-executive director.

Horizon 2020. It can be used to part-finance up to 50% of further investments in infectious diseases diagnostics solutions.

- *Additional details* – See 'H1 2018 financial results' below for more details on the H1 2018 financials.

4.6. H1 2018 financial results

Income statement

Collaboration revenues
increased y-o-y close to five
times to EUR 3.7m

Collaboration revenues in H1 2018 increased year-over-year with close to five times to EUR 3.6m driven by a strong growth in R&D services and milestone revenues as the consequence of new partnerships closed in H2 2017 and H1 2018. R&D services, consisting of invoiced services to pharma and content partners, increased from EUR 45k in H1 2017 to EUR 2.6m in H1 2018. Milestone revenues amounted EUR 0.8m in H1 2018 (versus no milestone revenues in H1 2017) and consisted of realized assay development milestones.

Product revenues _{y-o-y}
+68% to EUR 8.6m,
predominantly driven by cartridge
revenues that more than
doubled.

Product sales revenues increased year-over-year with 68% to EUR 8.6m driven by a doubling of cartridge sales from EUR 3.3m in H1 2017 to EUR 6.6m in H1 2018. Instrument revenues amounted to EUR 2.0m in H1 2018, a year-over-year increase of 7% as the consequence of the increase in installed base in H1 2018 and of an increased revenue contribution from instruments placed at clients under leasing contracts in previous periods. Year-over-year, commercial product revenues increased with approx. 58% and R&D product revenues with about 8 times, the latter as the consequence of the increased number of content partnerships. Grants and other income amounted to EUR 0.4m in H1 2018 which resulted in a total operating income of EUR 12.7m versus EUR 7.0m in H1 2017, a year-over-year increase of 83%.

Total operating expenses (including cost of sales) amounted to EUR 33.9m in H1 2018 versus EUR 30.7m in H1 2017, an increase of 10% as the consequence of higher cost of sales. Cost of sales increased year-over-year with 110% to EUR 6.9m in H1 2018 driven by higher cartridge as well as instrument volumes. Operating expenses excluding cost of sales amounted 27.0m in H1 2018, a year-over-year decrease of 2% as higher expenses for marketing and distribution and G&A were offset by a decrease in R&D expenses. Expenses for R&D amounted to EUR 16.0m in H1 2018, a year-over-year decrease of 17% that was predominantly driven by lower platform and cartridge prototype costs, allocated depreciation expenses and staffing costs. Expenses for marketing and distribution increased year-over-year with 35% and amounted to EUR 7.2m. This increase was mainly driven by higher staffing costs as the consequence of an expansion of Biocartis' sales team, of which most for the US market. G&A expenses increased year-over-year with 37% to EUR 3.8m as the consequence of higher staffing costs (including non-cash share based payment expenses), external advice and facility costs.

The above resulted in an operational result for H1 2018 equal to EUR -21.1m compared to EUR -23.7m in H1 2017, an improvement of 11%. Following a net financial result for the period of EUR -0.7m, the net result for H1 2018 equaled to EUR -21.8m compared to EUR -24.0m in H1 2017.

Balance sheet

Property, plant and equipment increased in H1 2018 to EUR 29.5m as per end of June 2018 from 26.2m at the end of 2017 (increase of EUR 3.3m) driven by capital expenditures in H1 2018 of EUR 5.1m (predominantly related to investments for cartridge manufacturing expansion and capitalized Idylla™ systems) and a depreciation charge of around EUR 1.8m. Inventory increased in H1 2018 to EUR 10.6m (versus EUR 9.1m per end 2017), predominantly driven by an increase in finished products of both cartridges and Idylla™ instrumentation. Trade and other receivables increased in H1 2018 with EUR 0.9m due to predominantly higher VAT receivables. On the other side of the balance sheet, trade payables increased in H1 2018 with EUR 0.9m and deferred income decreased with EUR 0.7m.

The Company's cash and cash equivalents end of H1 2018 amounted to EUR 91.3m compared to EUR 112.8m end of 2017. Total financial debt end of H1 2018 amounted to EUR 38.1m, representing an increase of approx. EUR 2.8m compared to end of 2017. 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

Net cash flow

EUR -21.4m,

a year-over-year improvement of
12%

The cash flow from operating activities in H1 2018 amounted to EUR -20.3m compared to EUR -22.2m in H1 2017 (an improvement of 8%), primarily driven by an improved result for the period which was partially offset by higher investments in working capital. The cash flow from investing activities in H1 2018 amounted to EUR -2.3m (compared to EUR -1.5m in H1 2017) and is mainly related to capitalized Idylla™ systems placed with customers under (reagent) rental agreements and Idylla™ systems used for internal needs. The EUR 3.2m investments for cartridge manufacturing expansion in H1 2018 are excluded from the cash flow from investing activities since these invoices were directly financed through our leasing partner. The cash flow from financing activities in H1 2018 amounted to EUR 1.3m (compared to EUR -0.5m in H1 2017) and predominantly relates to proceeds from warrants exercises that are partially offset by repayments of borrowings. Because of the aforementioned, the net cash flow of H1 2018 amounted to EUR -21.4m compared to EUR -24.2m in H1 2017, representing an improvement of 12% year-over-year.



5. Condensed consolidated interim financial statements for the period ended 30 June 2018

5.1. Condensed consolidated income statement

In EUR 000	Notes	For the 6 months ended	
		30 June 2018	30 June 2017
Revenue			
Collaboration revenue	6.4	3,535	716
Product sales revenue	6.4	8,555	5,092
Service revenue	6.4	251	104
		<u>12,341</u>	<u>5,912</u>
Other operating income			
Grants and other income	6.5	400	1,066
		<u>12,741</u>	<u>6,978</u>
Operating expenses			
Cost of sales	6.6	-6,890	-3,278
Research and development expenses	6.7	-16,029	-19,320
Marketing and distribution expenses	6.8	-7,152	-5,308
General and administrative expenses	6.9	-3,809	-2,781
		<u>-33,880</u>	<u>-30,687</u>
		<u>-21,139</u>	<u>-23,709</u>
Operating loss for the period			
Financial income		0	-2
Financial expense		-650	-714
Foreign exchange gains/(losses), net		-41	-13
Financial result, net		<u>-691</u>	<u>-729</u>
Loss for the year before taxes from continuing operations			
		<u>-21,830</u>	<u>-24,438</u>
Income taxes		70	456
Loss for the year after taxes from continuing operations		<u>-21,760</u>	<u>-23,982</u>
Gain (loss) for the year after taxes from discontinued operations			
		0	0
Loss for the year		<u><u>-21,760</u></u>	<u><u>-23,982</u></u>
Attributable to owners of the Company			
		-21,760	-23,982
Attributable to non-controlling interest			
Earnings per share			
Basic and diluted loss per share from continuing operations	6.11	-0.42	-0.54

5.2. Condensed consolidated statement of other comprehensive income

In EUR 000	Notes	For the 6 months ended	
		30 June 2018	30 June 2017
Loss for the year		-21,760	-23,982
Other comprehensive income (loss), not to be reclassified to profit or loss			-2
Actuarial gain (loss) on defined benefit plan		-80	0
Tax impact actuarial gain (loss)		27	0
Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss		0	0
Total comprehensive loss for the year		-21,813 ⁰	-23,984
Attributable to owners of the Company		-21,813	-23,984
Attributable to non-controlling interest		0	0

5.3. Condensed consolidated balance sheet

In EUR 000	Notes	As of	
		30 June 2018	31 Dec 2017
Assets			
Non-current assets			
Intangible assets		9,842	10,267
Property plant and equipment		29,519	26,199
Participating interests	6.12	5,052	5,052
Other long term receivables		11	11
Deferred tax assets		6,736	6,572
		<u>51,160</u>	<u>48,102</u>
Current assets			
Inventory		10,588	9,060
Trade receivables		6,977	6,892
Other receivables		3,683	2,856
Other current assets		1,714	1,517
Cash and cash equivalents*		91,269	112,765
		<u>114,231</u>	<u>133,090</u>
Total assets		<u>165,391</u>	<u>181,191</u>
Equity and liabilities			
Capital and reserves			
Legal share capital		513	511
Historical share capital adjustment		-221,232	-221,232
Share premium		632,477	630,670
Share based payment reserve		2,877	2,381
Accumulated deficit		-301,851	-280,046
Other comprehensive income		-124	-45
Total equity attributable to owners of the Company		112,660	132,239
Non-current liabilities			
Provisions		67	16
Financial debt	6.13	31,842	31,359
Deferred income	6.14	6	10
Accrued charges		2,053	1,767
		<u>33,968</u>	<u>33,152</u>
Current liabilities			
Financial debt	6.13	6,302	4,029
Trade payables		6,454	5,555
Deferred income	6.14	2,048	2,777
Other current liabilities		3,958	3,439
		<u>18,763</u>	<u>15,800</u>
Total equity and liabilities		<u>165,391</u>	<u>181,191</u>

*Cash and cash equivalents for 30 June 2018 include EUR 1.2 million restricted cash related to KBC Lease financing

5.4. Condensed consolidated cash flow statement

In EUR 000	Notes	For the 6 months ended	
		30 June 2018	30 June 2017
Operating activities			
Loss for the period		-21,760	-23,982
Adjustments for			
Depreciation and amortization		2,144	2,428
Tax income in profit and loss		-71	-421
Financial result, net		691	635
Net movement in retirement benefit obligation		51	-21
Share based payment expense		496	151
Other		-110	0
Changes in working capital			
Net movement in inventories		-1,528	-94
Net movement in trade and other receivables and other current assets		-1,109	-542
Net movement in trade payables & other current liabilities		1,705	-27
Net movement in deferred income	6.14	-733	-133
Interest & other financial expenses paid		-60	-52
		-20,284	-22,058
Taxes paid		-51	-114
Cash flow used in operating activities		-20,335	-22,172
Investing activities			
Interest received		0	-2
Purchases of property, plant & equipment		-2,273	-1,461
Purchases of intangible assets		-28	-68
Cash flow from / (used in) investing activities		-2,301	-1,531
Financing activities			
Proceeds from borrowings		0	0
Proceeds from the lease financing of property, plant and equipment		0	0
Net proceeds from the issue of common shares, net of transaction costs		1,809	0
Repayment of borrowings	6.13	-543	-470
Bank charges		-15	-9
Cash flow from financing activities		1,251	-479
Net increase / (decrease) in cash and cash equivalents¹		-21,385	-24,182
Cash and cash equivalents at the beginning of the period		112,765	83,246
Effects of exchange rate changes on the balance of cash held in foreign currencies		-110	-22
Cash and cash equivalents at the end of the period²		91,269	59,042

¹ Excludes effects of exchange rate changes on the balance of cash held in foreign currencies

² Including EUR 1.2 million restricted cash related to KBC Lease financing

5.5. Condensed consolidated statement of changes in equity

In EUR 000	Notes	Attributable to owners of the Company						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	Accumulated deficit		
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
<i>Total comprehensive income</i>							<i>-23,984</i>	<i>-23,984</i>	<i>-23,983</i>
Share-based payment expense					151		-0	150	150
Actuarial gain/loss on defined benefit plan						-33	-0	-34	-34
Consolidation translation difference							-	-	-
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>
Balance as at 1 January 2018		<u>511</u>	<u>-221,232</u>	<u>630,670</u>	<u>2,381</u>	<u>-45</u>	<u>-280,046</u>	<u>132,240</u>	<u>132,240</u>
Loss for the period							-21,760	-21,760	-21,760
Other comprehensive income							-0	-0	-0
<i>Total comprehensive income</i>							<i>-21,760</i>	<i>-21,760</i>	<i>-21,760</i>
Share-based payment expense					496			496	496
Share issue - exercise of stock options on 5 April 2018		2		1,807				1,809	1,809
Actuarial gain/loss on defined benefit plan						-80		-80	-80
Consolidation translation difference							-45	-45	-45
Balance as at 30 June 2017		<u>513</u>	<u>-221,232</u>	<u>632,477</u>	<u>2,877</u>	<u>-125</u>	<u>-301,851</u>	<u>112,660</u>	<u>112,660</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') commercialize 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 with a focus on oncology.

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), 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 consolidated financial statements have been authorized for issue on 30 August 2018 by the board of directors of the Company (the 'board of directors').

6.2. Summary of significant accounting policies

The principal accounting policies for preparing these consolidated 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 2018 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 2017, 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 2017. New standards or interpretations applicable from 1 January 2018 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 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 2018:

- Amendments to IAS 40 Transfers of Investment Property
- Amendments to IFRS 2 Classification and Measurement of Share-based Payment Transactions
- Amendments to IFRS 4 Applying IFRS 9 Financial Instruments with IFRS 4 Insurance Contracts
- Annual improvements to IFRS Standards 2014-2016 Cycle: Amendments to IFRS 1 and IAS 28
- IFRIC 22 Foreign Currency Transactions and Advance Consideration
- IFRS 9 Financial Instruments and subsequent amendments
- IFRS 15 Revenue from Contracts with Customers

The above application of new standards did not have a significant impact on the financial position and the results of the Group.

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 2018 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 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 2018	30 June 2017
Collaboration revenue		
R&D services	2,626	45
License fees	75	671
Milestones	833	0
	3,535	716
Product related revenue		
Idylla™ System Sales revenue	1,130	1,272
Idylla™ System Rental revenue	822	549
Cartridge Sales	6,603	3,270
	8,555	5,091
Service revenue		
Service revenue	251	105
	251	105
Total	12,341	5,912

6.4.1. Collaboration revenue

Revenues from collaboration agreements may include license fees, milestone payments and/or income from R&D services.

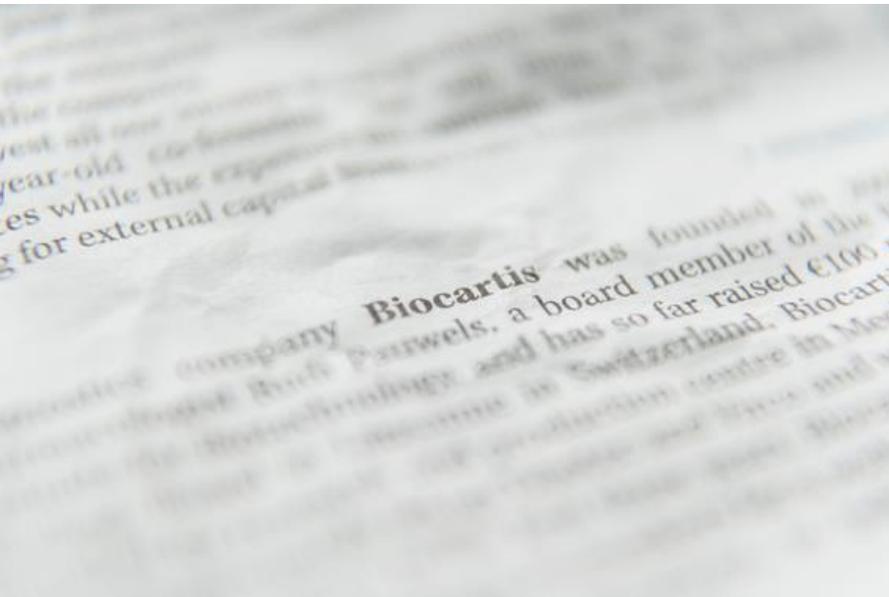
Unless up-front fees are paid in exchange for products delivered or services performed and, therefore, substantial risks and rewards have been transferred to the buyer in a separate transaction, such fees are not recognized as revenue up front but rather deferred as unearned revenue (even if they are non-refundable) and recognized pro rata over the expected performance period under each respective arrangement.

The Group makes its best estimate of the period over which it expects to fulfil its performance obligations, which may include technology transfer assistance, research and development activities, clinical, medical and regulatory activities, manufacturing and commercialization activities.

License fees

License fees include technology access fees to the Idylla platform technology. A distinction is made between right to use and right to access fees. Right to use fees are fees paid to use the IP as it exists when the license is granted, which means that the revenue recognition will happen at a point in time. Right to access fees are fees paid to access IP throughout a certain license period, which means that the revenue recognition will happen over time.

For the period, the group recognized EUR 0.1 m of license fees.



Milestones

A contingent consideration received by the Group upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part either on the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity.

A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with the Group's performance required to achieve the milestone or the increase in value to the collaboration

resulting from the Group's performance, related solely to the Group's past performance, and is reasonable relative to all of the other deliverables and payments within the overall collaboration arrangement.

In certain situations, the Group may receive contingent payments after the end of its period of continued involvement. In such circumstances, the Group would recognize 100% of the contingent revenues when the contingency is achieved and collection is reasonably assured.

For the period, the group recognized EUR 0.8m of milestone payments.

R&D Services

Cost reimbursements resulting from collaboration agreements, or a similar type of compensation received for costs incurred under R&D collaborations are recorded as R&D services as the related costs are incurred and upon agreement by the parties involved. The corresponding expenses are generally recorded under research and development expenses. Revenues from R&D Services are in general recognized over the duration of the collaboration agreement, if relevant subject to when the required services are provided or costs are incurred.

For the period, the group recognized EUR 2.6m of income from R&D services.

6.4.2. Product sales revenue

Product sales relate to Idylla™ system sales (Idylla™ Instruments and Idylla™ Consoles) and cartridge sales 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 2018	30 June 2017
Commercial revenue	7,950	5,024
Research & Development revenue	605	66
Total	8,555	5,091

6.4.3. Revenues by region and major customers

In EUR 000	For the 6 months ended	
	30 June 2018	30 June 2017
Country of domicile	338	262
Belgium	338	262
Total all foreign countries, of which	12,003	5,650
United states of America	4,999	1,298
Spain	1,338	857
Rest of the world	5,666	3,495
Total	12,341	5,912

Revenues in the above table are assigned according to the location of the Group or parent company of the customer. The Group hasn't recognized revenues from one customer representing at least 10% of the total revenues.

6.5. Other operating income

In EUR 000	For the 6 months ended	
	30 June 2018	30 June 2017
R&D project support (VLAIO)	376	966
Production Training support (VLAIO)	24	0
Other project grants (EU)	0	62
Other income	0	38
Total	400	1,066

6.6. Cost of sales

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

In EUR 000	For the 6 months ended	
	30 June 2018	30 June 2017
Staff costs	-2,257	-747
Material, lab consumables & small equipment	-3,056	-1,773
Depreciation and amortization	-634	-387
Royalty expense	-491	-336
Logistics	-185	0
Rent	-98	-35
Maintenance	-170	0
Total	-6,890	-3,278

6.7. Research and development expenses

In EUR 000	For the 6 months ended	
	30 June 2018	30 June 2017
Staff costs	-9,216	-9,895
Subcontracting	-704	-922
Laboratory expenses	-855	-1,005
Platform and cartridge prototype costs	-653	-2,578
Consultancy	-1,279	-1,020
Quality and regulatory	-9	-38
Intellectual property	-306	-294
Facilities, office & other	-1,685	-1,650
ICT	-459	-568
Travel, training & conferences	-251	-301
Depreciation and amortization	-1,342	-1,892
Capitalized systems for internal use	730	845
Total	-16,029	-19,320

Subcontracting includes expenses in relation to services provided by research and development providers such as services related to the development of assay cartridges, platform instrumentation design of manufacturing equipment and engineering services.

Platform and cartridge prototype costs relate to the development of 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 other assay development and quality purposes.

6.8. Marketing and distribution expenses

In EUR 000	For the 6 months ended	
	30 June 2018	30 June 2017
Staff costs	-4,438	-3,046
Subcontracting	-43	-44
Sales and promotional expenses	-158	-239
Business development	-317	-147
Consultancy	-35	-96
Facilities, office & other	-554	-438
Travel, training & conferences	-1,080	-1,124
Depreciation and amortization	-401	-174
Provision for doubtful debtors	-124	0
Total	-7,152	-5,308

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

In EUR 000	For the 6 months ended	
	30 June 2018	30 June 2017
Staff costs	-2,150	-1,545
External advice	-515	-311
Facilities, office & other	-545	-430
Human resources	-393	-392
Travel, training & conferences	-211	-109
Depreciation and amortization expenses	6	6
Total	-3,809	-2,781

External advice expenses include fees, service and consulting expenses related to legal, human resources, investor relations, accounting, audit and tax services.

6.10. Personnel expenses

In EUR 000	For the 6 months ended	
	30 June 2018	30 June 2017
Staff costs	-18,061	-15,233
Average number of full time equivalents	366	313

6.11. Loss 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. The basis for the basic and diluted earnings per share is the net loss for the year attributable to the owners of the Company.

	For the 6 months ended	
	30 June 2018	30 June 2017
Profit/loss for the period attributable to the owners of the Company (in EUR 000)	-21,760	-23,982
Weighted average number of ordinary shares for basic loss per share (in number of shares)	51,208,729	44,648,105
Basic loss per share (EUR)	-0,42	-0,54

6.12. 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 7.10% per 30 June 2018 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 2018.

<u>In EUR 000</u>	As of	
	<u>30 June 2018</u>	<u>31 Dec 2017</u>
Initial recognition amount	5,052	5,052
Total	5,052	5,052

6.13. Financial debt

The financial debt can be analyzed as follows:

<u>In EUR 000</u>	As of	
	<u>30 June 2018</u>	<u>31 Dec 2017</u>
PMV & FPIM	16,902	16,331
Lease company	14,696	14,723
Bank	244	305
Total non current	31,842	31,359
PMV & FPIM	0	0
Lease company	6,181	3,909
Bank	121	120
Total current	6,302	4,029

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. The interest applicable for this leasing facility equals 1.77% and the leasing includes a purchase option of 1% of the financed amount. The duration of the leasing agreement is 54 months.

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, the amount is fully withdrawn per 30 June 2018. 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.

End of Q3 2017, Biocartis reached agreement with KBC and BNP Paribas Fortis to replace the Company's EUR 25m committed multiple purpose credit facility (partially guaranteed by the Flemish Government) with a new committed

multiple purpose credit facility of EUR 27.5m (not covered by a government guarantee). The new committed multiple purpose credit facility consists of a EUR 18.5m rollover credit line and a EUR 9m working capital credit line, and has lower overall financing costs compared to the previous facility. No drawdowns were made under this facility as per 30 June 2018.

On 1 March 2018, Biocartis announced to have obtained a EUR 24m debt financing facility from the European Investment Bank. The financing facility is supported by InnovFin – EU Finance for Innovators’ Infectious Diseases Finance Facility, with the financial backing of the European Union under its research and innovation programme Horizon 2020. It can be used to part-finance up to 50% of further investments in infectious diseases diagnostics solutions. No drawdowns were made under this facility as per 30 June 2018.

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 2018, 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 2018.

6.14. Deferred income

In EUR 000	As of	
	30 June 2018	31 Dec 2017
Grants	1,141	1,213
Partner income	913	1,575
Total	2,054	2,787
current	2,048	2,777
non current	6	10

Deferred partner income includes upfront payments from collaboration partners in relation to the strategic licensing, development and commercialization collaborations.

	Deferred partner income
As per 31 December 2016	1,837
Invoiced	1,145
Recognized in profit or loss	-1,772
As per 31 December 2017	1,575
Invoiced	444
Recognized in profit or loss	-1,105
As per 30 June 2018	913

6.15. Other disclosures

6.15.1. 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 2018 and 31 December 2017.

- The fair value of the participation in MyCartis is not significantly different than its carrying value on 31 December 2017 and is based upon the valuation used in the latest capital increase in MyCartis in July 2017. The fair value measurement is classified as level 2.

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
- 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 2018 and 31 December 2017.

In EUR 000	Carrying value		Fair value	
	30 June 2018	31 Dec 2017	30 June 2018	31 Dec 2017
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)	10,660	9,748	10,660	9,748
Other long term receivables	11	11	11	11
Other current assets	1,714	1,517	1,714	1,517
Total loans and other receivables	12,385	11,276	12,385	11,276
Cash & cash equivalents				
Cash & cash equivalents*	91,269	112,765	91,269	112,765
Total cash & cash equivalents	91,269	112,765	91,269	112,765
Financial liabilities measured at amortized cost				
Loans & Borrowings	38,145	35,388	27,993	34,675
Trade payables	6,454	5,555	6,454	5,555
Other liabilities and accrued charges	6,012	5,206	6,012	5,206
Total financial liabilities measured at amortized cost	50,610	46,149	40,458	45,436

* For 30 June 2018: including EUR 1.2m restricted cash related to KBC Lease financing.

6.15.2. Contingencies

The Group has no new contingencies compared to 31 December 2017.

6.15.3. Commitments

6.15.3.1. Capital commitments

As per 30 June 2018, the Group has EUR 3.3m capital commitments mainly related to investments in the second cartridge production line. This production line is located in Mechelen (Belgium) for which the Group is engaged in several contractual arrangements with specified suppliers.

6.15.3.2. Operating commitments

As per 30 June 2018, the Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 5.2m. It is expected that the majority of the commitments will be fulfilled in 2018.

6.15.4. Related-party transactions

Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes. The remuneration of key management and a list of the subsidiaries are disclosed below. There were no other transactions with related parties.

A NEW ERA IN MSI TESTING

IDYLLA™

MSI ASSAY

- *Launch Idylla™ MSI Assay* – On 17 July 2018, Biocartis launched its innovative Idylla™ MSI Assay (RUO) that provides information on the MSI status²¹ (i.e. MSI-High or Microsatellite stable) of a tumor within approximately 150 minutes from just one slice of FFPE²² tumor tissue, without requiring a reference sample. This fully automated Idylla™ MSI Assay includes a novel set of seven exclusively licensed MSI biomarkers, consisting of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2 genes. Several multi-center studies²² comparing the standard methods²³ with the Idylla™ MSI Assay showed a >95% concordance between results. Furthermore, compared to standard methods, the Idylla™ MSI Assay has a significantly lower failure rate²² provides automated result reporting and includes MSI-specific pan-tumor biomarkers, independent of ethnicity²². Once validated for diagnostic use, the test is expected to significantly strengthen Biocartis' colorectal cancer test menu and since MSI is an independent factor that may predict a patient's response to certain immunotherapies²⁴, it provides Biocartis with further opportunities to enter into the field of immuno-oncology.
- *RAS performance study at AACC* – On 31 July 2018, Biocartis announced that a study abstract²⁵ on the performance of the Idylla™ KRAS and NRAS-BRAF-EGFR492 Mutation Assays compared with Next Generation Sequencing (NGS) using colorectal cancer (CRC) tissue samples was selected for oral presentation at the 70th AACC (American Association for Clinical Chemistry) Annual Scientific Meeting in Chicago, IL (US). In the study, 44 archived FFPE colorectal cancer (CRC) tissue samples previously analyzed by NGS²⁶ were tested on Idylla™. The Idylla™ platform successfully detected all of the target KRAS, NRAS and BRAF mutations previously identified by the NGS method, resulting in an Idylla™ sensitivity of 100%. Analysis of the control samples²⁷ demonstrated agreement for all sample results with 100% reproducibility. The study concluded that the Idylla™ platform offers reliable and sensitive testing of mutations in KRAS, NRAS and BRAF directly from FFPE tumor tissue sections, and that it may complement NGS and other molecular testing systems at larger diagnostic centers by providing significantly faster turnaround times through its simplicity and ease of use.

²¹ Maertens G. et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42; De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268; De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639) >.

²² Formalin fixed, paraffin embedded.

²³ Including IHC and Promega MSI analysis system 1.2.

²⁴ ESMO (ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. Annals of Oncology 0: 1–37, 2016); NCCN (NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016); ASCO (Allegra C.J. et al. Extended RAS gene mutation testing in metastatic Colorectal Carcinoma to predict response to antiepidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. Journal of Clinical Oncology 2016; 34(2):179-85) and CAP/AMP/ASCO.

²⁵ M. Rabie Al-Turkmani et al., "Rapid Somatic Mutation Testing in Colorectal Cancer Using a Fully Automated System and Single-Use Cartridge: A Comparison with Next-Generation Sequencing", first presented at 70th AACC Annual Scientific Meeting in Chicago, IL (US).

²⁶ Using the Ion AmpliSeq 50-gene Cancer Hotspot Panel v2 (Thermo Fisher Scientific).

²⁷ Horizon mutated samples.

- *Agreement with Hospital del Mar* – On 28 August 2018, Biocartis announced that it has obtained exclusive worldwide license rights for highly innovative EGFR ectodomain mutations that have shown to determine response to targeted therapy for patients with metastatic colorectal cancer (mCRC)²⁸. The new agreement is a conversion of two existing agreements with Hospital Del Mar (Barcelona, Spain) and inventors Dr. Bardelli and Dr. Arena from the University of Torino (Torino, Italy) in relation to two patent families of EGFR ectodomain mutations. Biocartis is now entitled to sublicense the licensed rights to third parties.
- *China strategy* – On 3 September 2018, Biocartis and Guangzhou Wondfo Biotech Co., Ltd. ('Wondfo', SHE: 300482), a fast growing diagnostics leader in China, announced entering into a joint venture aimed at the commercialization of the fully automated molecular diagnostics (MDx) Idylla™ platform in mainland China, within the field of oncology. The joint venture will be 50% owned by Biocartis and 50% owned by Wondfo. The initial activities of the joint venture are focused on the local manufacturing, commercialization and registration with the Chinese Regulatory Authorities (CFDA) of the existing products in the Idylla™ MDx oncology test menu for amongst others colorectal and lung cancer. This is a first important step in unlocking Idylla™'s commercial potential in China that will provide a broader cancer patient population with access to personalized medicines.

²⁸ ESMO (ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. *Annals of Oncology* 0: 1–37, 2016); NCCN (NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016); ASCO (Allegra C.J. et al. Extended RAS gene mutation testing in metastatic Colorectal Carcinoma to predict response to anti-epidermal growth factor receptor monoclonal antibody therapy. *American Society of Clinical Oncology Provisional Clinical Opinion Update* 2015. *Journal of Clinical Oncology* 2016; 34(2):179-85) and CAP/AMP/ASCO.

7. Review report of the auditor

Biocartis Group NV

Report on the review of the consolidated interim financial information for the six-month period ended 30 June 2018

The original text of this report is in Dutch

Report on the review of the consolidated interim financial information of Biocartis Group NV for the six-month period ended 30 June 2018

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 2018, the condensed consolidated income statement, the condensed consolidated statement of other comprehensive income, the condensed consolidated statement of changes in equity and the condensed consolidated cash flow statement for the period of six months then ended, as well as selective notes.

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 Accounting Standard (IAS) 34, "Interim Financial Reporting" as adopted by the European Union.

The condensed consolidated balance sheet shows total assets of 165 391 (000) EUR and the condensed consolidated income statement shows a consolidated loss (group share) for the period then ended of 21 760 (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, 5 September 2018

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

About Biocartis

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. Throughout this report, the term 'Biocartis NV' refers to the non-consolidated Belgian subsidiary company and references to 'the Group' or 'Biocartis' include Biocartis Group NV together with its subsidiaries.

Use of the Idylla™ trademark, logo and CE-marking

Biocartis and Idylla™ are registered trademarks in Europe, the United States and other countries. Biocartis trademark and logo and Idylla™ trademark and logo are used trademarks belonging to Biocartis. This report is not for distribution, directly or indirectly, in any jurisdiction where to do so would be unlawful. Any persons reading this report 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 report 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.

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 2018 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 Investor Relations

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

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

- | | |
|----------------------------------|------------------|
| • Q3 2018 business update | 15 November 2018 |
| • 2018 full year results | 28 February 2019 |
| • Publication 2018 annual report | 4 April 2019 |

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 report 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 report regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this report, those results or developments may not be indicative of results or developments in future periods. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this report as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this report or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this report.

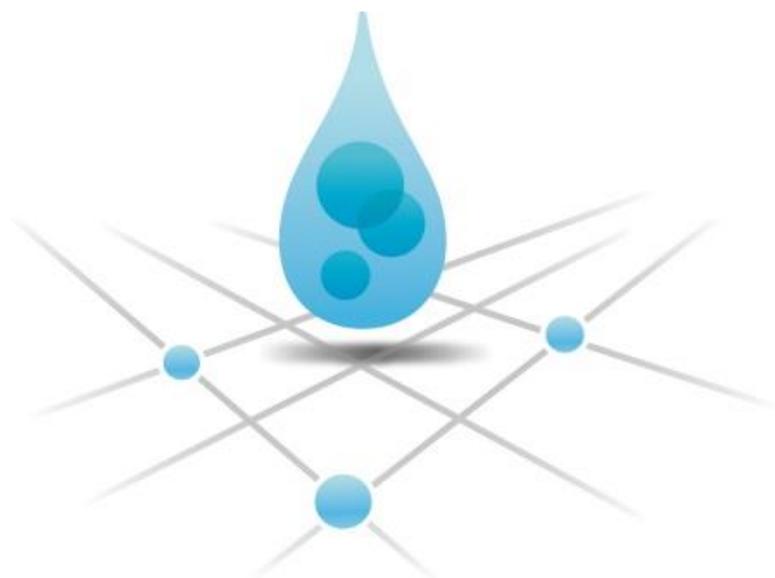
9. Glossary

Assay	In the field of diagnostics, an assay is a process or method aimed at determining the presence or amount (quantitative assay) of a certain substance in a sample.
Biopsy (solid/liquid)	The Idylla™ platform is capable of processing both solid biopsies (FFPE tissue which is the standard tissue type for solid tumor 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-BRAF 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 favorably 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.
CLIA	The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease (source: https://wwwn.cdc.gov/clia/).
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.
MDSAP (Medical Device Single Audit Program)	The MDSAP allows medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program’s main mission is to “...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers.”
Metastatic Colorectal Cancer (mCRC)	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.
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.



BIOCARTIS

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