# Financial report

# H1 2019

## Biocartis Group NV

BIOCARTIS

biocartis.com

# WE AIM TO PROVIDE DIRECT ACCESS TO PERSONALIZED MEDICINE FOR PATIENTS WORLDWIDE


**BIOCARTIS IS AN INNOVATIVE MOLECULAR DIAGNOSTICS COMPANY COMMITTED TO REVOLUTIONIZE MOLECULAR ONCOLOGY DIAGNOSTICS WITH ITS UNIQUE PROPRIETARY IDYLLA™ PLATFORM**

# CONTENT


1. Message from the CEO ..... 4
2. Responsibility statement ..... 4
3. Principal risks related to the business activities ..... 5
4. Business review of the first half of 2019 ..... 5
5. Condensed consolidated interim financial statements for the period ended 30 June 2019 ..... 12
6. Notes to the condensed consolidated interim financial statements ..... 17
7. Review report of the auditor ..... 29
8. Disclaimer and additional information ..... 30
9. Glossary ..... 32

# 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 2019.

During H1 2019, we realized continued commercial growth in Europe and our RoW[1] distributor markets and we maintain a good outlook for full year installed base growth. Despite the number of new high profile US customers that we attracted in the first half of this year, we encountered a delay in the actual US commercial cartridge volume ramp-up. While we take all actions to address this situation, our total cartridge volume growth for 2019 will be impacted.

Good progress was made on other fronts. We added another CE-marked IVD test to our menu, further progressed work on US FDA filings and ventured into the immuno-oncology space, one of our strategic focus areas, with BMS and Kite as partners. Furthermore, with the closing of our commercialization deal for Japan, our commercial footprint is now covering all major markets worldwide. Finally, we significantly strengthened our financial position for the upcoming years thanks to a successful equity raise and a convertible bonds issuance.

Overall, despite the delay incurred in US commercialization, we significantly strengthened our business in H1 2019 and feel confident about continuing our efforts for the remainder of the year, further supporting our ambitions towards building a leading global oncology business around the Idylla™ platform.

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-months' period ended 30 June 2019, 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 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' 2018 Annual Report, p. 58-64, 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 2018 Annual Report.

# 4. BUSINESS REVIEW OF THE FIRST HALF OF 2019

## H1 2019 IN A NUTSHELL

156 Idylla™ instruments added to the installed base, bringing the total to 1,129 as per 30 June 2019.

Commercial cartridge volume of 72k Idylla™ cartridges, representing a year-over-year increase of 24%. Commercial cartridge volume growth in H1 2019 was below expectations driven by a slower than foreseen pick-up in US cartridge volumes.

Successful CE marking of the Idylla™ MSI Test on 28 February 2019, further strengthening Biocartis' colorectal cancer (CRC) Idylla™ test menu.

Establishment immuno-oncology menu through new partnerships with BMS and Kite.

Total operating income increased year-over-year with 36% to EUR 17.3m driven by higher collaboration and product revenues.

Commercialization partnership announced for Japanese market with Nichirei Biosciences Inc.: the Biocartis commercial footprint is now covering all major markets worldwide. Post the reporting period, Biocartis and Fisher Healthcare announced the termination of their distribution collaboration for the US market.

## COMMERCIAL HIGHLIGHTS

- *Installed base* – The Idylla™ installed base increased with 156 instruments in H1 2019 driven by a continued growth across markets. The number of realized new placements in Europe and RoW[2] geographies exceeded expectations. On 26 February 2019, Biocartis announced to have added its 1,000th Idylla™ instrument to its installed base, placed in the US with the Diagnostic Medicine Institute at Geisinger[2]. End of June 2019, the total installed base amounted to 1,129 Idylla™ instruments. End of June 2019, the total installed base amounted to 1,129 Idylla™ instruments.

- *Commercial cartridge volume* – H1 2019 commercial cartridge volume amounted to 72k cartridges, representing a 24% year-over-year growth. Realized cartridge volume growth in H1 2019 was below expectations driven by a slower pick-up of US RUO[3] cartridge volumes.

- *European commercialization* – European direct markets performed well in H1 2019 with a continued growth in cartridge volumes and an installed base growth that exceeded expectations. This was mainly driven by an increased usage of Idylla™ in first line testing in amongst others the UK, France and Italy, as well as a strong overall contribution from pharma collaborations.

- *US commercialization* – During H1 2019, the US customer base was further expanded with new high profile customers. While efforts were made to accelerate the Idylla™ implementation timeline of instruments at these new customers, cartridge volume pick-up was below expectations due to a more gradual increase of cartridge orders after the Idylla™ instrument implementation. The latter is related to a variety of reasons including education on amended standard operational procedures and a gradual switch from current testing methodologies to Idylla™. A number of US customers is currently completing Idylla™ implementation which is expected to drive cartridge volume ramp-up over the course of H2 2019. We expect to accelerate further growth of the US customer base once the operational transition from Fisher Healthcare (see paragraph post-period events below) is completed and the expansion of the Biocartis US direct sales team is further progressed.

- *Distribution markets RoW*– Biocartis' RoW distribution markets realized a solid performance in H1 2019 with new instrument placements exceeding expectations and significant continued cartridge volume growth. This was driven by a strong customer base expansion in Canada, Asia, Eastern Europe and North Africa and new market authorizations for products in amongst others Colombia and Thailand.

- *China commercialization:* Completion of the closing of the joint venture with Wondfo ('China JV') in Q1 2019 resulted in the first capital contribution by both partners and subsequently the payment by the China JV of a license fee to Biocartis.

- *Japan commercialization*: On 7 January 2019, Biocartis announced the signing of an agreement with Nichirei Biosciences Inc., a leading supplier of biological and diagnostics products in Japan, for the product registrations and distribution of the Idylla™ platform in Japan. Upon successful registration, Nichirei Biosciences' sales force is expected to commercialize the Idylla™ platform across its network of approximately 2,000 pathology laboratories. During H1 2019, Biocartis and Nichirei Biosciences further progressed registration preparations for the Idylla™ instrumentation and assays for the Japanese market.

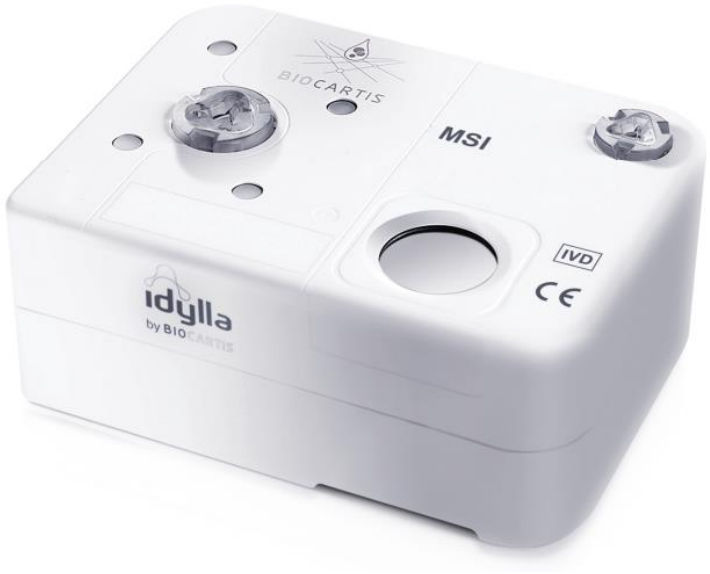
## MENU AND PARTNERSHIP HIGHLIGHTS

- *Colorectal cancer menu:*
  - CE-marking Idylla™ MSI Test – On 28 February 2019, Biocartis announced the CE-marking of its fully automated Idylla™ MSI Test. MSI testing is currently recommended for all colorectal and endometrial cancers[4] but is still underused since current methods are highly complex. The Idylla™ MSI Test has been developed to overcome these drawbacks. The test provides information on the MSI status[5] (i.e. Microsatellite Instability-High (MSI-H) or

[2] Source: www.geisinger.org, last consulted on 26 August 2019
[3] All Idylla™ assays sold in the US are for Research Use Only (RUO), not for use in diagnostic procedures
[4] Source: ASCO guidelines, www.asco.org/endorsements/HereditaryCRC
[5] Clinical Performance Study showed 99.7% concordance for MSI testing vs Promega (unpublished data); De Craene et al. (2018) Journal of Clinical Oncology 36:15 suppl, e15639; De Craene et al. (2017) Annals of Oncology 28 (suppl_5): v209-v268; Maertens et al. (2017) Annals of Oncology 28 (suppl_5): v22-v42

Microsatellite Stable (MSS)) of colorectal cancer (CRC) tumors within approximately 150 minutes from just one slice of FFPE[6] tumor tissue, without the need for a reference sample. The Idylla™ MSI Test[7] shows high concordance (>97%) and lower failure rates compared to standard methods. The unique aspects of the Idylla™ MSI Test could enable a broader penetration of MSI testing, and make this test a key addition to Biocartis' Idylla™ CRC test menu.

- US FDA submission of MSI assay – During H1 2019, further progress was made in the preparation of the regulatory US FDA submission documentation of the Idylla™ MSI Assay, which is expected in 2020, subject to further feedback from the US FDA.
- US FDA submission of RAS tests – During H1 2019, further progress was made in the preparation of Idylla™ RAS PMA[8] submission documentation with the US FDA which is expected in 2020, subject to further feedback from US FDA.




- *Lung cancer menu:*
  - ctEGFR – During H1 2019, further progress was made in the development of the liquid biopsy version of the Idylla™ EGFR Mutation Test. This test is planned for RUO[9] launch in Q4 2019 and is an important addition to Biocartis' lung cancer menu for liquid biopsy EGFR testing. Liquid biopsy EGFR testing is included in the guidelines[10] for situations where no tumor tissue is available for EGFR testing.
  - GeneFusion – During H1 2019, further progress was made in the development of the Idylla™ GeneFusion Panel. This assay is expected to be launched in 2020 and covers, together with the Idylla™ EGFR Mutation Test (CE-IVD), the majority of actionable lung cancer mutations.

- *Immuno-oncology menu*:
  - Partnership BMS – On 12 March 2019, Biocartis announced the signing of a collaboration agreement with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company, focused on MSI testing in connection with immuno-oncology therapies. Bristol-Myers Squibb's Opdivo® (nivolumab) plus low-dose Yervoy®[11] (ipilimumab) is the first immuno-oncology combination treatment approved by the US FDA for MSI-High or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with certain chemotherapies[12]. The collaboration agreement allows for joint developments and registrations of the Idylla™ MSI test for use in a variety of indications, commercial settings and geographies. The first focus under

[6] FFPE = formalin fixed, paraffin embedded
[7] The Idylla™ MSI Test uses a new set of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A & SULF2 genes, which were exclusively licensed to Biocartis in 2013 from VIB, the life sciences research institute in Flanders (Belgium), and originated from the research of the group of Prof. Diether Lambrechts (VIB-KU Leuven, Belgium). These MSI biomarkers are tumor-specific, show a high frequency in colorectal and endometrial cancers and are stable across different ethnicities ensuring excellent specificity of the assay
[8] PMA = Pre-Market Approval
[9] RUO = Research Use Only, not for use in diagnostic procedures
[10] Source: D. Planchard et al., 'Metastatic non-small cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up', published online 3 October 2018; updated 26 January 2019
[11] 3 mg/kg Opdivo® plus 1 mg/kg Yervoy®
[12] Treatment with fluoropyrimidine, oxaliplatin and irinotecan

the agreement is expected to be the registration in the US of the Idylla™ MSI assay as a companion diagnostic[13] (CDx) device in mCRC.
    - Partnership Kite – On 1 June 2019, Biocartis announced a master development and commercialization agreement with Kite Pharma, Inc., a Gilead Company (NASDAQ: GILD), a pharmaceutical company engaged in the development of innovative cancer cell therapies. The collaboration aims at the development of molecular-based assays on the Idylla™ platform that are supportive to Kite's therapies.

- *Breast cancer menu:*
    - Partnership Genomic Health Inc. – During H1 2019, the development of an Idylla™ version of the Oncotype DXi IVD Breast Recurrence Score® Test was further progressed. Moreover, preparations were initiated for Idylla™ instrument placements at early access sites for the validation studies in Europe, beginning in France and Germany. Importantly, on 20 June 2019, Genomic Health announced that the German Federal Joint Committee (G-BA) issued a positive reimbursement decision for the Oncotype DX Breast Recurrence Score® Test. This decision makes the Oncotype DX® the only multigene test reimbursed by statutory sick funds with wide national coverage in Germany, for use in all patients with primary node-negative, hormone receptor-positive, HER2-negative early-stage breast cancer when a decision for or against chemotherapy cannot be made based on clinical and pathological parameters alone[14].

- *Covance partnership:* On 23 April 2019, Biocartis announced the global strategic commercialization agreement with Covance, LabCorp's Drug Development business, aimed at offering the Idylla™ platform and its existing Idylla™ oncology assay menu to Covance's customer base globally to support customer needs for clinical trials and, when appropriate, to validate and implement companion diagnostic applications.

- *Idylla™ publications:* During H1 2019, approx. 30 abstracts, posters and publications were published on the Idylla™ platform and its assays, of which 12 in the US. Several were selected for publication at large scientific conferences, including:
    - Idylla™ MSI performance study at ASCO – On 16 May 2019, a multi-centered study[15] on the performance of the Idylla™ MSI Test (CE IVD) in comparison with the Promega MSI test ('Promega MSI Test') was selected for publication at the renowned ASCO (American Society of Clinical Oncology) Annual Meeting. This study showed high performance and a low invalid rate of the Idylla™ MSI Test, as such demonstrating the possibility of rapid, fully automated MSI testing with Idylla™.
    - USCAP Idylla™ studies – A total of six Idylla™ studies were presented by four different US customers at the United States and Canadian Academy of Pathology ('USCAP') Annual Meeting in Maryland, US: (1) Dartmouth Hitchcock Medical Center (a CRC focused prospective study and a melanoma focused study with comparison to NGS), (2) Medical College of Wisconsin (a CRC focused study with comparison to PCR[16] and IHC[17] for Microsatellite Instability Status and a multiple cancers focused study using challenging FFPE samples not suitable for conventional sanger and NGS testing), (3) Memorial Sloan Kettering Cancer Center (a hairy cell leukemia focused study using different sample types including stained smear slides, blood and bone marrow without pre-extraction) and (4) Wake Forest Baptist Health (a melanoma focused study using pigmented melanomas). The posters of the referenced studies can be found here.

## ORGANIZATIONAL AND OPERATIONAL HIGHLIGHTS

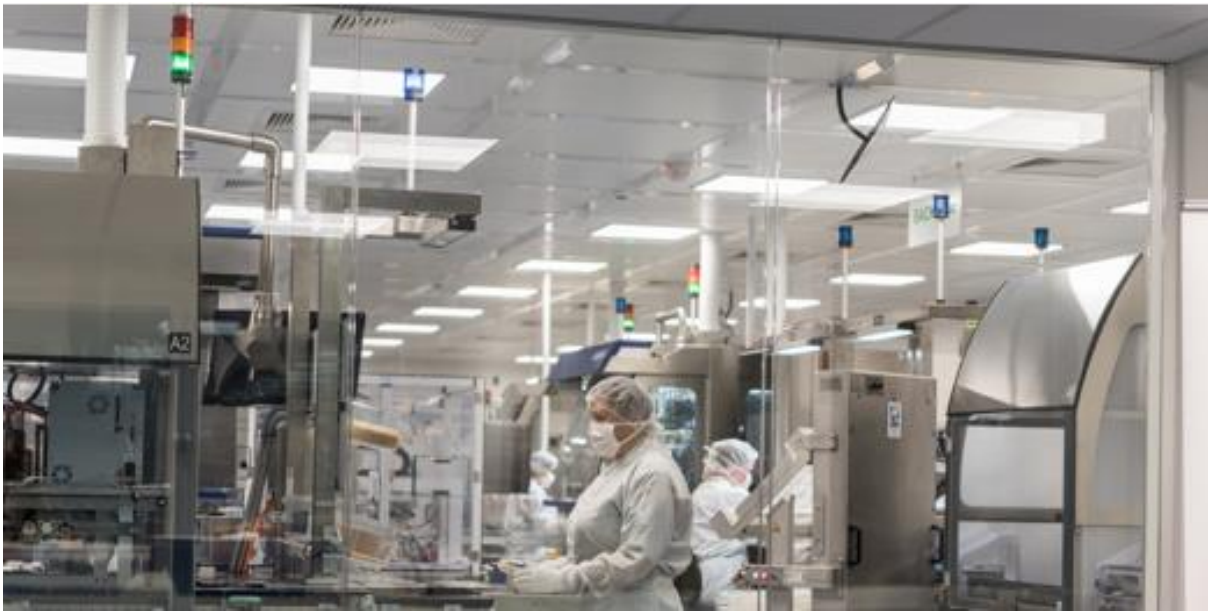
- *Management team* – In light of the Company's further international growth, expansion of its partner network and associated scaling of the organization, several changes to the Company's management team were effectuated:
    - Appointment Chief Operating Officer – Piet Houwen joined Biocartis as its Chief Operating Officer in April 2019.
    - Appointment Global Head Pharma Collaborations and Partnering – Dirk Zimmermann joined Biocartis in May 2019 as Global Head of Pharma Collaborations and Partnering.
    - Changes in the Chief Commercial Officer role – Biocartis and Hilde Eylenbosch, the Company's Chief Commercial Officer, have agreed to terminate their collaboration as per the end of April 2019. The tasks of the CCO have been

[13] An IVD companion diagnostic device is an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. Source: US FDA, last consulted on 16 August 2019
[14] The G-BA decision will become effective following its publication by the Ministry of Health in the Federal Gazette (Bundesanzeiger). Source: Genomic Health website, https://newsroom.genomichealth.com/news-releases/news-release-details/german-federal-joint-committee-g-ba-issues-exclusive-nationwide, last consulted on 26 August 2019
[15] Pauwels P. et al, 'The Idylla™ MSI Test multi-center concordance study: microsatellite instability detection in colorectal cancer samples', first published at ASCO Annual Meeting of the American Society of Clinical Oncology, 30 May – 4 June 2019, Chicago (IL), US
[16] Polymerase Chain Reaction
[17] Immunohistochemistry

temporarily reallocated to the Company's CEO and senior commercial management.

- *Board of directors* - The board mandates of Hilde Windels BVBA (represented by Hilde Windels) and Peter Piot expired at the closing of the annual general shareholders' meeting held on 10 May 2019. As from 10 May 2019, the board was composed of the following members: 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 Steenbergen), Luc Gijsens BVBA (represented by Luc Gijsens), Roald Borré and Herman Verrelst (CEO of Biocartis).

- *Cartridge manufacturing* – During H1 2019, progress was made in the production transfer to the new cartridge manufacturing line and commercial manufacturing of the Idylla™ KRAS Mutation Test was started on this line.



## FINANCIAL HIGHLIGHTS

- *Total operating income* – Total operating income increased year-over-year with 36% to EUR 17.3m driven by increased collaboration and product revenues. Collaboration revenues increased from EUR 3.6m in H1 2018 to EUR 6.8m in H1 2019, a growth of 93%. Product revenues amounted to EUR 10.0m in H1 2019, a year-over-year increase of 17%.

- *OPEX* – Total operating expenses (including cost of sales) increased from EUR 33.9m in H1 2018 to EUR 44.0m in H1 2019, an increase of 30%. This was amongst others driven by increased costs of sales due to higher commercial product volumes, increased R&D expenses due to the addition of menu partnerships, increased marketing & sales expenses due to the expansion of the US sales force and increased general & administrative expenses due to overall organizational growth as well as a general cost allocation that is shifting more towards a commercial stage organizational structure.

- *Equity raise* – On 23 January 2019, Biocartis announced that it successfully raised an amount of EUR 55.5m in gross proceeds by means of an over-subscribed private placement via an accelerated bookbuild offering.

- *Convertible bonds issue* – On 2 May 2019, Biocartis announced the issue of EUR 150 million senior unsecured convertible bonds due 9 May 2024. An application will be made for the convertible bonds to be listed and admitted to trading on the regulated market of Euronext Brussels by no later than 1 December 2019.

- *Repayment subordinated loan* – In June 2019, Biocartis exercised an early repayment option under its subordinated loan to optimize interest payment obligations. That loan had a nominal amount of EUR 15m, carried a 7% interest rate,

had an initial duration of 5 years and was due July 2021. The cash out related to the early repayment amounted to EUR 18.5m based on the nominal amount of the loan and capitalized interest.

- *Net cash flow and cash position* - Total net cash flow in H1 2019 amounted to EUR 145.8m versus EUR -21.4m in H1 2018. Biocartis' cash position as per end June 2019 amounted to EUR 209m.

- *Additional details* – See 'key figures for H1 2019' below for more details on the H1 2019 financials.

## H1 2019 FINANCIAL RESULTS

### Income statement

Collaboration revenues in H1 2019 increased year-over-year to EUR 6.8m driven by a strong growth in R&D services and license revenues, partially offset by the absence of milestone payments. R&D services, consisting of invoiced services to pharma and content partners, increased from EUR 2.6m in H1 2018 to EUR 4.4m in H1 2019 as a consequence of new partnerships closed in H2 2018 and H1 2019. License revenues increased from EUR 75k in H1 2018 to EUR 2.4m in H1 2019 and included a EUR 2m revenue recognition of a EUR 4m license payment from the China joint venture that was received in H1 2019 following the formal closing of that joint venture. No milestones revenues were recorded in H1 2019 versus EUR 0.8m of milestones in H1 2018.

Product sales revenues increased year-over-year with 17% to EUR 10.0m driven by an increase in cartridge sales and instrument revenues. Cartridge sales increased from EUR 6.6m in H1 2018 to EUR 7.5m in H1 2019, a year-over-year increase of 13%. Instrument revenues amounted to EUR 2.5m in H1 2019, a year-over-year increase of 28% as the consequence of the increase in installed base in H1 2019 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. 20% whereas R&D product revenues decreased with 29%.

Service revenues increased year-over-year with 40% to EUR 0.4m. Grants and other income amounted to EUR 0.2m in H1 2019. Consequently, total operating income amounted to EUR 17.3m versus EUR 12.7m in H1 2018, a year-over-year increase of 36%.

Total operating expenses (including cost of sales) amounted to EUR 44.0m in H1 2019 versus EUR 33.9m in H1 2018, an increase of 30%. Cost of sales increased year-over-year with 27% to EUR 8.7m in H1 2019 driven by higher cartridge as well as instrument volumes. Expenses for R&D amounted to EUR 20.0m in H1 2019, a year-over-year increase of 25% that was predominantly driven by higher staffing costs and allocated depreciation expenses (see comment below on adoption IFRS 16). Expenses for sales and marketing increased year-over-year with 23% and amounted to EUR 8.8m. This increase was mainly driven by higher staffing costs, as a consequence of an expansion of Biocartis' US sales team and higher expenses for consultancy and subcontracting. G&A expenses increased year-over-year with 68% to EUR 6.4m due to overall organizational growth as well as a general cost allocation that is shifting more towards a commercial stage organizational structure.

The above resulted in an operational result for H1 2019 equal to EUR –26.7m compared to EUR -21.1m in H1 2018. Following a net financial result for the period of EUR –2.8m, of which EUR 1.1 m is related to accrued interest of the outstanding convertible bond and EUR 1.0m related to interest and repayment of the Company's subordinated loan, the net result for H1 2019 equaled to EUR –29.7m compared to EUR -21.8m in H1 2018.

### Balance sheet

As required, Biocartis has adopted the new IFRS 16 standard for lease accounting with date of initial application on 1 January 2019. This standard introduces a single lessee accounting model and requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, eliminating the distinction between operating and finance leases. The first time adoption of IFRS 16 has an impact on the Group's balance sheet as well as results in a reclassification of operational expenses in the Group's income statement. Concretely, as of 1 January 2019, Biocartis also recognizes its operational leasing contracts (i.e. for buildings, company cars and office furniture) on its balance sheet in addition to the Group's financial leasing contracts (i.e. for manufacturing equipment). This resulted in a one-off increase in property, plant and equipment and lease liabilities of EUR 14.3m on 1 January 2019. Furthermore, as property, plant and equipment

is depreciated over time, the income statement recognizes deprecation charges and financing expenses for all the recognized leases versus previously the recognition of lease payments as e.g. building rent or facility & office expenses.

Property, plant and equipment increased in H1 2019 to EUR 43.7m as per end of June 2019 from EUR 30.4m at the end of 2018, an increase of EUR 13.3m. This increase was driven by a EUR 15.3m impact of IFRS 16 (as per 30 June 2019), EUR 2.8m of actual capital expenditures (mainly related to capitalization of instrumentation placed at clients under leasing or rental contracts) and a depreciation charge of around EUR 4.9m. Investments in associates and joint ventures was added to the balance sheet in H1 2019 in relation to the closing of the China joint venture and amounts to EUR 2.6m as per end of June 2019.

Inventory increased in H1 2019 to EUR 15.4m (versus EUR 11.9m per end 2018), predominantly driven by an increase in finished products of both cartridges and Idylla™ instrumentation. Trade and other receivables decreased in H1 2019 with EUR 1.14m due to lower trade receivables. On the other side of the balance sheet, trade payables decreased with EUR 2.8m to EUR 5.2m. Deferred income decreased with EUR 0.6m and accrued charges decreased with EUR 1.5m, the latter mainly driven by the first time adoption of IFRS 16.

The Group's cash and cash equivalents end of H1 2019 amounted to EUR 209.2m compared to EUR 63.5m end of 2018. Total financial debt end of H1 2019 amounted to EUR 166.7m, representing an increase of EUR 131.4m compared to end of 2018. This was the result of the issuance of a convertible bond, an increase in lease liabilities in the context of the first time adoption of IFRS 16 and the repayment of the Company's subordinated loan. Please note that the IFRS accounting treatment of the Company's convertible bond has resulted in an allocation of the EUR 150m nominal amount to financial debt (EUR 134m) and equity (EUR 12m, adjusted for related transaction costs) as per the end of H1 2019.

## Cash flow statement


The cash flow from operating activities in H1 2019 amounted to EUR –28.4m compared to EUR –20.3m in H1 2018. This increase is the result of a higher operating loss for the period, an increase in investments in working capital as well as higher interest and other financial expenses for H1 2019. The cash flow from investing activities in H1 2019 amounted to EUR –5.3m (compared to EUR -2.3m in H1 2018) and consisted of the initial capital contribution made to the China joint venture and capitalized Idylla™ systems. The cash flow from financing activities in H1 2019 amounted to EUR 179.5m (compared to EUR 1.3m in H1 2018) which was driven by the issuance of the convertible bonds (net proceeds of EUR 145.5m) and by the capital raise (net proceeds of EUR 53.4m), partially offset by the repayments of borrowings (predominantly the Company's subordinated loan) of EUR 19.4m.

Because of the aforementioned, the net cash flow of H1 2019 amounted to EUR 145.8m compared to EUR –21.4m in H1 2018.

# 5. CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS FOR THE PERIOD ENDED 30 JUNE 2019

## CONDENSED CONSOLIDATED INCOME STATEMENT

| In EUR 000 | Notes | For the 6 months ended 30 June 2019 | 30 June 2018 |
|---|---|---|---|
| **Revenue** | | | |
| Collaboration revenue | 6.4 | 6,816 | 3,535 |
| Product sales revenue | 6.4 | 9,980 | 8,555 |
| Service revenue | 6.4 | 351 | 251 |
| | | **17,147** | **12,341** |
| **Other operating income** | | | |
| Grants and other income | 6.5 | 151 | 400 |
| **Total operating income** | | **17,298** | **12,741** |
| **Operating expenses** | | | |
| Cost of sales | 6.6 | -8,742 | -6,890 |
| Research and development expenses | 6.7 | -20,031 | -16,029 |
| Sales and marketing expenses | 6.8 | -8,811 | -7,152 |
| General and administrative expenses | 6.9 | -6,399 | -3,809 |
| | | **-43,983** | **-33,880** |
| **Operating loss for the period** | | **-26,685** | **-21,139** |
| Financial expense | | -2,868 | -650 |
| Other financial results | | 46 | -41 |
| **Financial result, net** | | **-2,822** | **-691** |
| Share in the results of associates | | -181 | 0 |
| **Loss for the year before taxes** | | **-29,688** | **-21,830** |
| Income taxes | | 18 | 70 |
| **Loss for the year after taxes** | | **-29,670** | **-21,760** |
| Attributable to owners of the Group | | -29,670 | -21,760 |
| Attributable to non-controlling interest | | | |
| **Earnings per share** | | | |
| Basic and diluted loss per share | 6.11 | **-0.53** | **-0.42** |

## CONDENSED CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE INCOME

| In EUR 000 | Notes | For the 6 months ended 30 June 2019 | 30 June 2018 |
|---|---|---|---|
| **Loss for the year** | | **-29,670** | **-21,760** |
| **Other comprehensive income (loss), not to be reclassified to profit or loss:** | | | |
| Re-measurement gains and losses on defined benefit plan | | -27 | -80 |
| Income taxes on items of other comprehensive income | | 9 | 27 |
| **Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss:** | | | |
| Exchange differences on translation of foreign operations | | -188 | |
| **Total comprehensive loss for the year** | | **-29,876** | **-21,813** |
| Attributable to owners of the Group | | -29,876 | -21,813 |
| Attributable to non-controlling interest | | 0 | 0 |

## CONDENSED CONSOLIDATED BALANCE SHEET

| In EUR 000 | Notes | As of 30 June 2019 | 31 Dec 2018 |
|---|---|---|---|
| **Assets** | | | |
| **Non-current assets** | | | |
| Intangible assets | | 6,405 | 6,579 |
| Property plant and equipment | | 43,694 | 30,391 |
| Financial assets | | 5,052 | 5,052 |
| Investment in associates and joint ventures | 6.12 | 2,593 | 0 |
| Other non-current receivables | | 11 | 11 |
| Deferred tax assets | | 6,776 | 6,569 |
| | | **64,531** | **48,602** |
| **Current assets** | | | |
| Inventories | | 15,415 | 11,919 |
| Trade receivables | | 8,059 | 9,744 |
| Other receivables | | 4,327 | 3,751 |
| Other current assets | | 1,592 | 1,830 |
| Cash and cash equivalents* | | 209,200 | 63,539 |
| | | 238,593 | 90,783 |
| **Total assets** | | **303,124** | **139,385** |
| **Equity and liabilities** | | | |
| **Capital and reserves** | | | |
| Share capital | | -220,668 | -220,718 |
| Share premium | | 698,037 | 632,769 |
| Share based payment reserve | | 4,270 | 3,445 |
| Accumulated deficit | | -358,030 | -328,145 |
| **Total equity attributable to owners of the Group** | | **123,609** | **87,351** |
| **Non-current liabilities** | | | |
| Provisions | | 7 | 28 |
| Financial liabilities | 6.13 | 160,652 | 30,221 |
| Deferred income | 6.14 | 869 | 6 |
| Accrued charges | | 0 | 1,501 |
| | | **161,528** | **31,756** |
| **Current liabilities** | | | |
| Financial liabilities | 6.13 | 6,079 | 5,114 |
| Trade payables | | 5,210 | 7,973 |
| Deferred income | 6.14 | 1,547 | 3,010 |
| Other current liabilities | | 5,151 | 4,181 |
| | | **17,987** | **20,278** |
| **Total equity and liabilities** | | **303,124** | **139,385** |

*Cash and cash equivalents for 30 June 2019 include EUR 1.2 million restricted cash related to KBC lease financing

## CONDENSED CONSOLIDATED CASH FLOW STATEMENT

| In EUR 000 | Notes | For the 6 months ended 30 June 2019 | 30 June 2018 |
|---|---|---|---|
| **Operating activities** | | | |
| Loss for the period | | -29,670 | -21,760 |
| **Adjustments for** | | | |
| Depreciation and amortization | | 3,713 | 2,144 |
| Impairment losses | | 202 | |
| Income taxes in profit and loss | | -18 | -71 |
| Financial result, net | | 2,821 | 691 |
| Net movement in defined benefit obligation | | -48 | 51 |
| Share of net profit of associate and a joint venture | | 181 | 0 |
| Share based payment expense | | 825 | 496 |
| Other | | 47 | -110 |
| **Changes in working capital** | | | |
| Net movement in inventories | | -3,496 | -1,528 |
| Net movement in trade and other receivables and other current assets | | 1,695 | -1,109 |
| Net movement in trade payables & other current liabilities | | -2,167 | 1,705 |
| Net movement in deferred income | 6.14 | -600 | -733 |
| | | -26,515 | -20,224 |
| Interests paid | | -1,664 | -60 |
| Taxes paid | | -178 | -50 |
| **Cash flow used in operating activities** | | **-28,357** | **-20,335** |
| **Investing activities** | | | |
| Interest received | | 1 | 0 |
| Acquisition of property, plant & equipment | | -2,332 | -2,273 |
| Acquisition of intangible assets | | -162 | -28 |
| Acquisition of investment in a joint venture | | -2,774 | 0 |
| **Cash flow used in investing activities** | | **-5,267** | **-2,301** |
| **Financing activities** | | | |
| Proceeds from the issue of a convertible bond | | 145,542 | 0 |
| Net proceeds from the issue of ordinary shares, net of transaction costs | | 53,362 | 1,809 |
| Repayment of borrowings | 6.13 | -19,421 | -543 |
| Bank charges | | -18 | -15 |
| **Cash flow from financing activities** | | **179,465** | **1,251** |
| **Net increase / (decrease) in cash and cash equivalents** | | **145,841** | **-21,385** |
| Cash and cash equivalents at the beginning of the period | | 63,539 | 112,765 |
| Effects of exchange rate changes on the balance of cash held in foreign currencies | | -180 | -110 |
| **Cash and cash equivalents at the end of the period*** | | **209,200** | **91,269** |

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

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| In EUR 000 | Notes | Attributable to owners of the Group | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Share capital | Share premium | Share based payment reserve | Gains and losses on defined benefit plans | Accumulated deficit | Total equity attributable to the owners of the Group | Total equity |
| **Balance as at 1 January 2018** | | **-220,722** | **630,670** | **2,381** | **-45** | **-280,046** | **132,240** | **132,240** |
| Loss for the period | | | | | | -21,760 | -21,760 | -21,760 |
| Other comprehensive income | | | | | | 0 | 0 | 0 |
| *Total comprehensive income* | | | | | | *-21,760* | *-21,760* | *-21,760* |
| 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 2018** | | **-220,720** | **632,477** | **2,877** | **-125** | **-301,851** | **112,660** | **112,660** |
| **Balance as at 1 January 2019** | | **-220,718** | **632,769** | **3,445** | **-67** | **-328,078** | **87,351** | **87,351** |
| Loss for the period | | | | | | -29,670 | -29,670 | -29,670 |
| Re-measurement gains and losses on defined benefit plan | | | | | -27 | | -27 | -27 |
| Consolidation translation difference | | | | | | -188 | -188 | -188 |
| *Total comprehensive income* | | | | | *-27* | *-29,858* | *-29,885* | *-29,885* |
| Share-based payment expense | | | | 825 | | | 825 | 825 |
| Share issue – private placement on 23 January 2019 | | 50 | 55,450 | | | | 55,500 | 55,500 |
| Costs related to private placement on 23 January 2019 | | | -2,309 | | | | -2,309 | -2,309 |
| Share issue - exercise of stock options on 4 April 2019 | | 0 | 171 | | | | 171 | 171 |
| Issuance of convertible bond on 9 May 2019 | | | 11,956 | | | | 11,956 | 11,956 |
| Other | | | | | | | 0 | 0 |
| **Balance as at 30 June 2019** | | **-220,668** | **698,037** | **4,270** | **-94** | **-357,936** | **123,609** | **123,609** |

# 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 Group's mission is to become a global, fully integrated provider of novel molecular diagnostics solutions with industry-leading, high clinical value tests within the field of oncology. The Group has established subsidiaries in Mechelen (Belgium), Lausanne (Switzerland), New Jersey (US), and a joint venture in Hong Kong (China).

The consolidated financial statements have been authorized for issue on 26 August 2019 by the board of directors of the Group (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 2019 have been prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and as adopted by the European Union. The statements should be read in conjunction with the annual financial statements for the year ended 31 December 2018, 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 2018, except for the adoption of new and amended standards as set out below.

The consolidated financial statements are presented in Euro (EUR) and all values are rounded to the nearest thousand (EUR000), except when otherwise indicated.

These condensed interim financial statements have been subject to a review by the Group'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 2019:

- IFRS 16 Leases
- IFRIC 23 Uncertainty over Income Tax Treatments

- Amendments to IAS 19 Plan Amendment, Curtailment or Settlement
- Amendments to IAS 28 Long term interests in Associates and Joint Ventures
- Amendments to IFRS 9 Prepayment Features with Negative Compensation
- Annual improvements to IFRS Standards 2015-2017 Cycle

**IFRS 16 Leases**

IFRS 16 supersedes IAS 17 Leases and related interpretations. The standards sets out the principles for the recognition, measurement, presentation and disclosure of leases for lessees and lessors.

Lessees are required to account for all leases under a single on-balance sheet model, eliminating the distinction between operating and finance leases. Therefore, IFRS 16 will have an impact on the Group's balance sheet as the Group's operating leases are to be recognized under property, plant and equipment. Lessor accounting under IFRS 16 is not substantially changed under IAS 17. Lessors will continue to classify leases as either operating or finance leases using similar principles as in IAS 17. Therefore, the accounting treatment of the i.e. Group's reagent rental agreements is not impacted.

The Group adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of 1 January 2019. Under this method, the standard is applied retrospectively, which means that comparatives will not be restated. Furthermore, The Group decided to use the modified B retrospective method, which means that the assets will be measured at an amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments. All lease liabilities were recognized on the balance sheet based on the present value of the remaining lease payments, discounted using the incremental borrowing rate at the date of initial application. The Group applied the following available practical expedients:

- No reassessment whether a contract is, or contains, a lease at the date of initial application;
- Leases for which the lease term ends within 12 months of the date of initial application will be considered as short-term leases. As such, the short-term lease exemption will be used;
- Lease contracts for which the underlying asset has a value in new of below EUR 5,000 are considered as low value leases and hence exempt from recognition;
- A single discount rate is applied to a portfolio of lease contracts with reasonable similar characteristics;
- Reliance on previous assessments on whether leases are onerous instead of performing an impairment review;
- Use hindsight in determining the lease term for contracts that contain options to extend or terminate the lease.

The balance sheet impact of adopting IFRS 16 as at 1 January 2019 is as follows:

| In EUR 000 | As at 1 January 2019 |
|---|---|
| **Assets** | |
| Right-of-use assets | 35,133 |
| Property, plant and equipment | -20,796 |
| **Total assets** | **14,336** |
| **Liabilities** | |
| Non-current financial debt | 13,583 |
| Current financial debt | 2,228 |
| Accrued charges | -1,475 |
| **Total liabilities** | **14,336** |

Based on the foregoing, as at 1 January 2019:

- Right-of-use assets of EUR 35.1m were recognized under property, plant & equipment; this includes the lease assets recognized previously under finance leases of EUR 20.8m that were reclassified from assets held under lease.
- Additional lease liabilities of EUR 15.8m (included in financial debt) were recognized.
- Accrued lease payments of EUR 1.5m related to previous operating leases were derecognized.

The lease liabilities as at 1 January 2019 can be reconciled to the operating and finance lease commitments as of 31 December 2018 as follows:

In EUR 000

| | |
|---|---|
| **Operating lease commitments as at 31 December 2018** | **14,070** |
| Weighted average incremental borrowing rate as at 1 January 2019 | 4.18% |
| **Discounted operating lease commitments as 1 January 2019** | **13,054** |
| Commitments relating to short-term & low-value assets | -201 |
| Finance lease liabilities recognized as at 31 December 2018 | 20,796 |
| Payments in optional extension periods not recognized as at 31 December 2018 | 0 |
| Other | -283 |
| **Lease liabilities as at 1 January 2019** | **33,367** |
| Of which are: | |
| Current lease liabilities | 6,018 |
| Non-current lease liabilities | 27,349 |
| | **33,367** |

## 6.3. CRITICAL ACCOUNTING JUDGEMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

In the application of the Group's accounting policies, which are described above, the Group 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 2019 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 Group 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.

Revenue recognition relating to collaboration arrangements

Assessing the indicators for revenue recognition under collaboration arrangements requires judgement to determine (i) the nature of the contractual performance obligations and whether they are distinct or should be combined with other performance obligations, and (ii) the pattern of transfer of each promised component identified in the contract, using methods based on key assumptions such as forecasted costs and development timelines of the collaboration arrangements for the assessment of satisfaction of the performance obligation.

For all performance obligations linked to licensing agreements, the Group makes an assessment about whether or not the license is to be considered as a distinct performance obligation or not. The Group determines whether a promise to grant a license of intellectual property is distinct from other promised goods or services in the contract. As such, the Group assesses whether the customer can benefit from a license of intellectual property on its own or together with readily available resources (i.e., whether it is capable of being distinct) and whether the Group's promise to transfer a license of intellectual property is separately identifiable from other promises in the contract (i.e., whether it is distinct in the context of the contract). The assessment of whether a license of intellectual property is distinct is based on the facts and circumstances of each contract, e.g. interdependencies between the license and other services in the contract, the continuing involvement of the Group after the license has been granted.

If the transfer of the license is considered to be a separate performance obligation, revenue relating to the transfer of the license is recognized at a point in time or over time depending on the nature of the license, i.e. granting a right to use the intellectual property or the right to access the IP. Basically, the Group assesses whether the customer has the right to use the intellectual property as it exists at a certain period in time or whether it has access to the intellectual property as it exists at any time during the license period, where the latter requires more on-going activities from the Group.

## 6.4. REVENUE

The Group's revenue can be aggregated as follows:

| In EUR 000 | For the 6 months ended, | | | |
|---|---|---|---|---|
| | 30 June 2019 | | 30 June 2019 | 30 June 2018 |
| | At a point in time | Over time | | |
| **Collaboration revenue** | | | | |
| R&D services | 0 | 4,350 | 4,350 | 2,626 |
| License fees | 2,000 | 467 | 2,467 | 75 |
| Milestones | 0 | 0 | 0 | 833 |
| | **2,000** | **4,816** | **6,816** | **3,535** |
| **Product related revenue** | | | | |
| Idylla™ System Sales revenue | 1,515 | 0 | 1,515 | 1,130 |
| Idylla™ System Rental revenue | 984 | 0 | 984 | 822 |
| Cartridge revenue | 7,481 | 0 | 7,481 | 6,603 |
| | **9,980** | **0** | **9,980** | **8,555** |
| **Service revenue** | | | | |
| Idylla™ System Service revenue | 327 | 24 | 351 | 251 |
| | **327** | **24** | **351** | **251** |
| **Total** | **12,307** | **4,841** | **17,147** | **12,340** |

The Group has recognized the following revenue-related accrued and deferred income:

| In EUR 000 | As of | |
|---|---|---|
| | **30 June 2019** | **31 Dec 2018** |
| **Accrued income** | | |
| Collaboration arrangements | 33 | 30 |
| Product sales | 0 | 0 |
| Service arrangements | 0 | 0 |
| | **33** | **0** |
| **Deferred income** | | |
| Collaboration arrangements | -1,487 | -2.029 |
| Product sales | 0 | 0 |
| Service arrangements | 0 | 0 |
| | **-1,487** | **-2,029** |
| **Net accrued/deferred income** | **-1,454** | **-1,999** |

The above table corresponds to the revenue expected to be recognized in the future relating to (partially) unsatisfied performance obligations:

| In EUR 000 | **Deferred income** |
|---|---|
| 2019 | 1,011 |
| 2020 | 215 |
| 2021 | 0 |
| 2022 | 0 |
| 2023 | 0 |
| After 2023 | 0 |

For more information regarding the revenue statement above, we refer to chapter 4, 'Commercial highlights' and 'H1 2019 financial results'.

### 6.4.1. Revenues by region and major customers

| In EUR 000 | For the 6 months ended 30 June 2019 | 30 June 2018 |
|---|---|---|
| **Country of domicile** | **546** | **338** |
| Belgium | 546 | 338 |
| **Total all foreign countries, of which** | **16,600** | **12,003** |
| United states of America | 5,762 | 4,999 |
| China | 2,377 | 22 |
| Spain | 1,382 | 1,338 |
| Rest of the world | 7,080 | 5,644 |
| **Total** | **17,147** | **12,341** |

Revenues in the above table are assigned according to the location of the Group or parent company of the customer. The Group has not 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 2019 | 30 June 2018 |
|---|---|---|
| R&D project support (IWT grants) | 151 | 400 |
| Other project grants (EU) | 0 | 0 |
| Other income | 0 | 0 |
| **Total** | **151** | **400** |

## 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 2019 | 30 June 2018 |
|---|---|---|
| Employee benefit expenses | -2,582 | -2,257 |
| Material, lab consumables & small equipment | -4,395 | -3,056 |
| Depreciation and amortization | -805 | -635 |
| Royalty expense | -493 | -491 |
| Other | -466 | -452 |
| **Total** | **-8,742** | **-6,890** |

## 6.7.RESEARCH AND DEVELOPMENT EXPENSES

| In EUR 000 | For the 6 months ended 30 June 2019 | 30 June 2018 |
|---|---|---|
| Employee benefit expenses | -11,470 | -9,216 |
| R&D consultancy & subcontracting | -2,325 | -1,983 |
| Laboratory and cartridge costs | -586 | -778 |
| Quality, regulatory and intellectual property | -188 | -315 |
| Facilities, office & other | -875 | -1,685 |
| ICT | -680 | -459 |
| Travel, training & conferences | -344 | -251 |
| Depreciation and amortization | -3,563 | -1,342 |
| **Total** | **-20,031** | **-16,029** |

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.

Laboratory and cartridge costs include consumables and prototype costs related to the development of diagnostic platform prototypes and assays.

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

## 6.8.SALES AND MARKETING EXPENSES

| In EUR 000 | For the 6 months ended 30 June 2019 | 30 June 2018 |
|---|---|---|
| Employee benefit expenses | -5,459 | -4,438 |
| S&M consultancy & subcontracting | -777 | -78 |
| Sales and promotional expenses | -246 | -158 |
| Business development | -281 | -317 |
| Facilities, office & other | -353 | -554 |
| Travel, training & conferences | -1,272 | 1,080 |
| Depreciation and amortization | -368 | -401 |
| Impairment of receivables | -55 | -124 |
| **Total** | **-8,811** | **-7,152** |

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 2019 | 30 June 2018 |
|---|---|---|
| Employee benefit expenses | -4,352 | -2,150 |
| External advice | -498 | -515 |
| Facilities, office & other | -696 | -545 |
| Human resources | -455 | -393 |
| Travel, training & conferences | -242 | -211 |
| Depreciation and amortization expenses | -157 | 6 |
| **Total** | **-6,399** | **-3,808** |

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. EMPLOYEE BENEFIT EXPENSES

| In EUR 000 | For the 6 months ended 30 June 2019 | 30 June 2018 |
|---|---|---|
| Employee benefit expenses | -23,864 | -18,061 |
| Average number of full time equivalents | 448 | 366 |

## 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 2019 | 30 June 2018 |
|---|---|---|
| Profit/loss for the period attributable to the owners of the Group (in EUR 000) | -29,670 | -21,760 |
| Weighted average number of ordinary shares for basic loss per share (in number of shares) | 55,760,127 | 51,208,729 |
| **Basic loss per share (EUR)** | **-0.53** | **-0.42** |

## 6.12. INVESTMENT IN ASSOCIATES AND JOINT VENTURES

The closing of the joint venture for commercialization of the Idylla™ platform in China took place in January 2019. Per 30 June 2019, the financial participation in the joint venture WondfoCartis amounted to EUR 2.6m.

The Group has a 50% interest in the China JV. The Group does not control the China JV, as the Group does not have the power to direct the relevant activities and as such to direct the variable returns generated through those relevant activities.

The Group's investment in its joint venture is accounted for using the equity method. Under the equity method, the investment in a joint venture is initially recognized at cost. The carrying amount of the investment is adjusted to recognize changes in the Group's share of net assets of the joint venture since the acquisition date.

## 6.13. FINANCIAL LIABILITIES

The financial debt can be analyzed as follows:

| | As of | |
|---|---|---|
| In EUR 000 | **30 June 2019** | **31 Dec 2018** |
| PMV & FPIM loans | 0 | 16,272 |
| Lease liabilities | 25,803 | 13,767 |
| Bank borrowings | 120 | 182 |
| Convertible bond | 134,729 | 0 |
| **Total non-current** | **160,652** | **30,221** |
| PMV & FPIM loans | 0 | 1,202 |
| Lease liabilities | 5,955 | 3,790 |
| Bank borrowings | 123 | 122 |
| **Total current** | **6,079** | **5,114** |
| **Total financial liabilities** | **166,731** | **35,335** |

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. This lease has a current lease term is till 1 June 2021 , carries a 3.35% interest rate and includes a purchase option of EUR 0.1m. As per the end of H1 2019 EUR 0.1m is outstanding under this facility.

In 2015, Biocartis NV obtained two new financing facilities for the modifications to the current cartridge production line. The first new facility entails an investment credit for an amount of EUR 0.6mwith a payment term of 5 years and an interest rate of 1.93%. The second one entails a leasing facility for EUR 4.4m that carries a 1.77% interest, includes a purchase option of 1% of the financed amount and has a duration of 54 months. As per the end of H1 2019 EUR 2.5m is outstanding under these two facilities.

In 2016, Biocartis NV obtained a lease financing facility for the development of its second cartridge production line in Mechelen for EUR 15m. This facility was increased in 2018 with EUR 2.3m. The interest applicable for this facility equals 1.865% and includes a purchase option of 1% of the financed amount. As per the end of H1 2019. As per the end of H1 2019 EUR 13.3m is outstanding under this facility. As a security, a debt service reserve account is to be maintained for the above financing facilities of 2013, 2015 and 2016, the current debt service reserve account amounts to EUR 1.2m

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). This loan carried a 7% interest (which is capitalized in the first three years) and had an initial 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). In June 2019, this loan was fully redeemed based on the exercise of an early repayment option by Biocartis.

In 2017, Biocartis reached agreement with KBC and BNP Paribas Fortis for a committed multiple purpose credit facility of EUR 27.5m (not covered by a government guarantee). This facility consists of a EUR 18.5m rollover credit line and a EUR 9m working capital credit line. No amount has been withdrawn on this credit facility per 30 June 2019.

In 2018, Biocartis NV obtained an investment credit of EUR 1m from a bank to finance mold investments related to its first cartridge manufacturing facility. The investment credit has a payment term of 5 years and an interest rate of 2.53%. As per 30 June 2019, EUR 0.5m has been withdrawn on this credit facility.

On 9 May 2019, the Group issued a convertible bond of EUR 150m, with a maturity date of 9 May 2024 (i.e. 5-year duration) and a coupon of 4%. The bond can be converted into new/existing ordinary shares of the Group upon the discretion of the bondholder. Under IAS 32 – Financial instruments: Presentation the convertible bond is a compound financial instrument and contains, from the issuer's perspective, bot a liability (i.e. host debt instrument) and an equity component (i.e. an embedded share conversion option). The liability component amounts to EUR 134.7m as per 30 June 2019.

In H1 2019, Biocartis and the European Investment Bank agreed to extend the availability date to draw down the first tranche under the financing facility to 28 February 2020, and to reduce the duration of the facility to up to four years as of the disbursement of the first tranche. To date, no drawdowns have been made under 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 2019, and an credit line with a bank of EUR 0.6m for currency hedging, of which EUR 0.0m has been taken up as per 30 June 2019.

## 6.14. DEFERRED INCOME

| | As at | |
|---|---|---|
| In EUR 000 | **30 June 2019** | **31 Dec 2018** |
| Grants | 929 | 987 |
| Collaboration income | 1,487 | 2,029 |
| **Total** | **2,416** | **3,016** |
| Current | 1,547 | 1,010 |
| Non-current | 869 | 6 |

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 2017** | **1,574** |
| Invoiced | 2,454 |
| Recognized in profit or loss | -1,999 |
| **As per 31 December 2018** | **2,029** |
| Invoiced | 2,756 |
| Recognized in profit or loss | -3,298 |
| **As per 30 June 2019** | **1,487** |

## 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 2019 and 31 December 2018.
- The fair value of the participation in MyCartis is not significantly different than its carrying value on 31 December 2018 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 2019 and 31 December 2018.

Except for the borrowings (financial liabilities, see note 6.14), the carrying amount of the financial assets and liabilities approximate their fair values. The borrowings with a carrying amount of EUR 166.7m (31 December 2018: EUR 35.3m) have a fair value of EUR 166.9m (31 December 2018: EUR 35.1m).

### 6.15.2. Contingencies

The Group has no new contingencies compared to 31 December 2018.

### 6.15.3. Commitments

#### 6.15.3.1. Capital commitments

As per 30 June 2019, the Group has EUR 2.1m capital commitments mainly related to the upgrade of the current cartridge production lines located in Mechelen (Belgium) for which the Group is engaged in several contractual arrangements with specified suppliers. The Group had no other material commitments to capital expenditures on 30 June 2019.

#### 6.15.3.2. Operating commitments

As per 30 June 2019, the Group has operating commitments towards different suppliers for Idylla™ systems and cartridge parts for a total amount of EUR 7.6m. It is expected that the majority of the commitments will be fulfilled in 2019.

### 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. Apart from the remuneration of key management, there were no other transactions with related parties.

## 6.16. EVENTS AFTER THE BALANCE SHEET DATE

- *AACC* – On 5 August 2019, Biocartis announced that a study[18] poster on the performance of the Idylla™ NRAS-BRAF Mutation Assay (RUO) was presented by Dr. Gregory Tsongalis, PhD. (Director, Laboratory for Clinical Genomics and Advanced Technology of the Dartmouth-Hitchcock Medical Center) at the 71st AACC (American Association for Clinical Chemistry) Annual Scientific Meeting that took place between 4-8 August in Anaheim, CA (US). The study concluded that the Idylla™ system offers rapid and accurate testing of NRAS and BRAF mutations in melanoma directly from FFPE tissue, and that its simplicity and ease of use compared to other available molecular techniques make it suitable for small centers that lack specifically trained staff and infrastructure.

- *Termination distribution agreement Fisher Healthcare* – On 5 September 2019, Biocartis and Fisher Healthcare announced that they jointly agreed to terminate, with immediate effect, their distribution collaboration for the US market. Going forward, Biocartis' US direct sales team will drive US commercialization and will be further expanded according to market needs.

[18] M. Rabie Al-Turkmani et al., 'Evaluation of a Cartridge-Based System for Rapid Detection of BRAF and NRAS Mutations in Melanoma', Dartmouth-Hitchcock Medical Center and Geisel School of Medicine at Dartmouth, first published at the 71st AACC Annual scientific meeting & clinical lab expo, 4-8 August 2019, Anaheim (CA), US, available on https://www.abstractsonline.com/pp8/#!/6831/presentation/566

# 7. REVIEW REPORT OF THE AUDITOR

## Biocartis Group NV

### Report on the review of the consolidated interim financial information of Biocartis Group NV for the six-month period ended 30 June 2019

*The original text of this report is in Dutch*

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 2019, 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 flows 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 303 124 (000) EUR and the condensed consolidated income statement shows a consolidated loss (group share) for the period then ended of 29 670 (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, 4 September 2019

The statutory auditor

Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises CVBA/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. The Biocartis and Idylla™ trademark and logo are used trademarks owned by Biocartis. This report 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 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 2019 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 B
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

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| • Special Shareholders' Meeting | 27 September 2019 |
| • Q3 2019 business update | 14 November 2019 |
| • 2019 full year results | 27 February 2020 |
| • Publication 2019 annual report | 2 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. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. 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

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| **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-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. |
| **CAR-T (chimeric antigen receptor) T-cell therapy** | A type of treatment in which a patient's T cells (a type of immune system cell) are genetically modified so they will attack cancer cells. T cells are taken from a patient's blood. Then the gene for a special receptor that binds to a certain protein on the patient's cancer cells is added in the laboratory. The special receptor is called a chimeric antigen receptor (CAR). Large numbers of the CAR T cells are grown in the laboratory and given to the patient by infusion. CAR T-cell therapy is being studied in the treatment of some types of 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'). |
| **Cell therapy** | Cell therapy (or cellular therapy or cytotherapy) is therapy in which cellular material is injected, grafted or implanted into a patient. This generally means intact, living cells. For example, T cells capable of fighting cancer cells via cell-mediated immunity may be injected in the course of immunotherapy. |
| **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. |
| **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. |

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| **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. |
| **Immuno-oncology** | Immuno-oncology is the study and development of treatments that make use of the body's immune system to fight cancer. |
| **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 1.36 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. |
| **MRD (Minimal Residual Disease)** | MRD is used to refer to small numbers of leukaemic cells (cancer cells from the bone marrow) that remain in the person during treatment, or after treatment when the patient is in remission (no symptoms or signs of disease). It is the major cause of relapse in cancer and leukemia. In cancer treatment, particularly leukaemia, MRD testing has several important roles: determining whether treatment has eradicated the cancer or whether traces remain, comparing the efficacy of different treatments, monitoring patient remission status as well as detecting recurrence of the leukaemia or cancer, and choosing the treatment that will best meet those needs . |
| **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 Sequencin (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. |

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| | 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. |
| **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 spicing), have catalytic function (ribozymes), act as messengers for protein synthesis (mRNAs), regulate gene expression (miRNAs) or make up the genome of certain viruses. |
| **Targeted therapy** | Targeted therapy works by targeting the cancer's specific genes, proteins, or the tissue environment that contributes to cancer growth and survival. These genes and proteins are found in cancer cells or in cells related to cancer growth, like blood vessel cells. Molecular diagnostic tests are needed to identify the specific gene mutations that drive cancer, so the physician can use this information to define the best possible treatment for the patient. |

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