



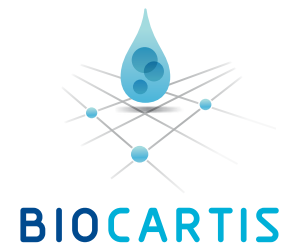
Biocartis  
Annual Report 2015

“Sooner  
or later,  
we are **all**  
patients.”

RUDI PAUWELS, FOUNDER  
AND CEO BIOCARTIS

|  |    |  |     |
|--|----|--|-----|
| 2015 Highlights  | 05 | 4. Remuneration report   | 76  |
| Interview Biocartis Chairman Rudi Mariën<br>and CEO & Founder Rudi Pauwels | 07 | 4.1. Remuneration policy   | 76  |
| Disclaimer and other information   | 09 | 4.2. Remuneration of Directors   | 76  |
| <hr/>  |    | 4.3. Remuneration of members of the<br>executive team  | 77  |
| 1. Business section  | 10 | 4.4. Relative weighting of each component of<br>the remuneration                                     | 80  |
| 1.1. About Biocartis Group   | 12 | 4.5. Characteristics of the stock options  | 80  |
| 1.2. Risks related to our business   | 18 | 4.6. Changes to the remuneration policy  | 82  |
| 1.3. Review 2015   | 25 | 4.7. Remuneration policy for the next two<br>financial years (2016-2017)                             | 83  |
| 1.4. Biocartis as an organisation  | 35 | 4.8. Main contractual conditions   | 83  |
| 1.5. Activities  | 39 | <hr/>  |     |
| <hr/>  |    | 5. Consolidated annual accounts  | 86  |
| 2. The Biocartis share   | 52 | 5.1. Consolidated financial statements as of<br>and for the years ended 31 December<br>2015 and 2014 | 86  |
| 2.1. Outstanding shares and share capital                                  | 52 | 5.2. Notes to the consolidated financial<br>statements   | 91  |
| 2.2. Share performance   | 53 | <hr/>  |     |
| 2.3. Trading volume  | 53 | 6. Statutory Annual Accounts   | 140 |
| 2.4. Shareholders  | 54 | 6.1. Abbreviated statutory annual accounts   | 140 |
| 2.5. Analyst coverage  | 56 | 6.2. Activity Biocartis Group NV   | 140 |
| 2.6. Financial calendar  | 56 | 6.3. Income statement and balance sheet<br>Biocartis Group NV  | 140 |
| 2.7. Investor relation details   | 56 | 6.4. Discussion of statutory accounts  | 141 |
| <hr/>  |    | 6.5. Appropriation of results  | 143 |
| 3. Corporate Governance  | 60 | 6.6. Going concern valuation rules   | 143 |
| 3.1. Introduction  | 60 | <hr/>  |     |
| 3.2. Internal & External control   | 61 | 7. Statutory Auditor's Report  | 144 |
| 3.3. Protection schemes  | 63 | 7.1. Statutory Auditor's Report  | 144 |
| 3.4. Board of Directors  | 66 | 7.2. Disclosure Audit fees   | 145 |
| 3.5. Committees of the board of directors                                  | 69 | <hr/>  |     |
| 3.6. Other information   | 70 | 8. Glossary  | 146 |
| 3.7. Executive management  | 72 |  |     |
| 3.8. Share ownership of the members of the<br>executive management team    | 73 |  |     |

# Innovative molecular diagnostics company



COMMITTED TO ESTABLISH A  
NEW GOLD STANDARD IN  
DIAGNOSTIC TESTING WITH  
ITS UNIQUE PROPRIETARY  
MOLECULAR DIAGNOSTICS  
PLATFORM IDYLLA™

Biocartis provides next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and the industry.

Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample, in virtually any setting, allowing fast and effective treatment selection and treatment progress monitoring.

Biocartis' solutions focus on addressing unmet needs in oncology and infectious diseases.



Listed on Euronext  
Brussels since April 2015,  
ticker BCART



Commercialising an  
unique proprietary MDx  
platform Idylla™

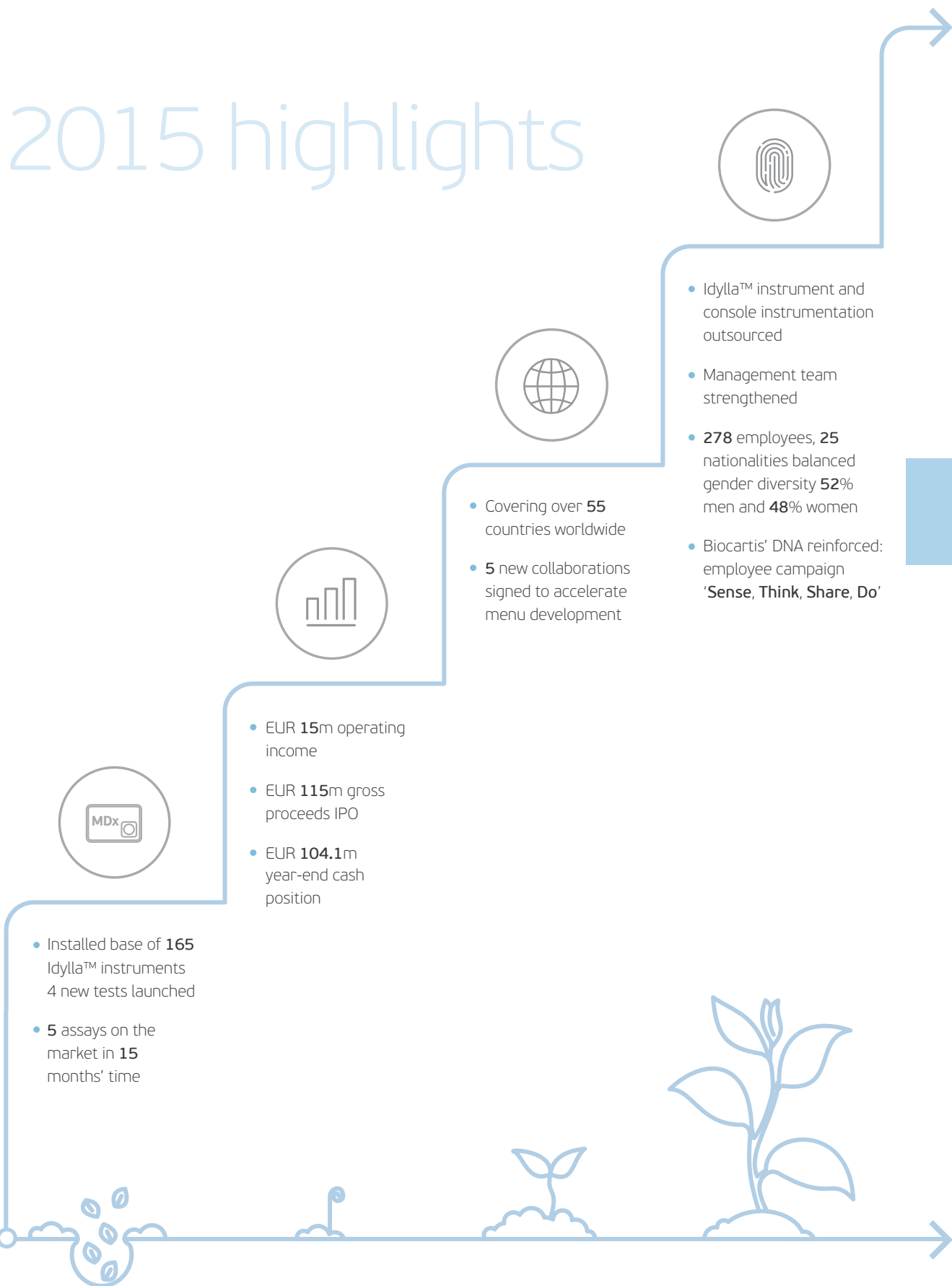


Headquartered in  
Belgium (Mechelen)



Focused on oncology and  
infectious diseases

# 2015 highlights



“

“WE PRESENT TO YOU OUR VERY FIRST ANNUAL REPORT AS A LISTED COMPANY. IN THIS REPORT, WE WANT TO TAKE YOU ON BOARD IN OUR JOURNEY TOWARDS FASTER, HIGHLY ACCURATE DIAGNOSTICS, CLOSER TO THE POINT OF IMPACT AND UPDATE YOU ON OUR ACHIEVEMENTS FOR 2015.”

RUDI PAUWELS, BIOCARTIS CEO & FOUNDER

# Chairman and CEO reflections and outlook

BIOCARTIS CHAIRMAN RUDI MARIËN AND CEO & FOUNDER RUDI PAUWELS LOOK BACK ON 2015 AND REFLECT ON THE CHALLENGES AND OPPORTUNITIES THAT LIE AHEAD

**B**ased on Biocartis' nature as an innovative commercial stage molecular diagnostics (MDx) company providing next generation diagnostic solutions, we have a specific role in developing universally accessible, sustainable healthcare on a global scale. As such, we aim to create value for our shareholders and for society, by growing our Idylla™ installed base and expanding our menu of tests. Therefore, in addition to the financial information, we decided to include some key sustainability/ ESG (environmental, social and governance) information in this report, based on some guiding principles of the international sustainability reporting guidelines, the Global Reporting Initiative (GRI) G4 Guidelines

2015 was a successful year for Biocartis during which we significantly executed upon our strategy to establish a new gold standard for diagnostic testing by launching four new tests and growing our installed base to over 160 Idylla™ instruments. Furthermore, we strengthened our financial position, following, amongst others, our Initial Public Offering (IPO) in April 2015."

## What did the IPO mean for Biocartis?

**Rudi Mariën:** "The first year-half of 2015 was marked by our 6.5x oversubscribed successful (IPO), in which Biocartis raised gross proceeds of EUR 115m. It was the largest Life Sciences capital markets transaction in 2015 on the European markets, and ranks amongst the 10 largest IPOs over the last 10 years on Euronext Brussels, underpinning the strong belief of institutional and retail investors in the potential of Biocartis. Our IPO attracted a wide interest from a mix of long-term, specialist investors across continental Europe, the UK and the US.

The IPO was a logical next step for Biocartis to further finance the commercialising of our Idylla™ molecular diagnostics platform. We are very pleased with the proceeds that we raised as it puts the company in a solid position to execute our business plan."

**Rudi Pauwels:** "We experience an increasing positive momentum around our Idylla™ platform,

driven by an increased need for accurate measurements via near-patient molecular testing. Budgetary pressure on healthcare systems worldwide, calls for tools that provide accurate diagnosis and enable improved treatments, resulting in optimal use of healthcare resources. These trends require fast and accurate sample-to-result testing solutions such as Idylla™."

## What were major achievements in 2015?

**Rudi Pauwels:** "I am pleased to state that we exceeded our growth target for 2015 by adding 83 Idylla™ instruments to our installed base, bringing it to 165. This is the result of, amongst others, great work from our sales and marketing team. They realised an impressive expansion of our commercial footprint. We are now covering more than 55 countries worldwide."

"Next to commercial success, our efforts to increase our menu of tests bore fruit as well: we successfully launched four new tests in 2015. In June 2015 we launched the world's first fully

automated CE-IVD KRAS test for routine use to match novel guidelines that is capable of detecting an extended panel of 21 KRAS mutations with high sensitivity, in an unprecedented timeframe of approximately two hours. In November 2015, we introduced our very first infectious disease test to the market, the Idylla™ Respiratory (IFV-RSV) Panel, developed by Janssen Diagnostics (Johnson & Johnson). This test is able to detect various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV)."

"In December 2015, the launch of the Idylla™ ctBRAF Mutation Assay (RUO<sup>1</sup>), the world's first and only fully automated liquid biopsy assay which allows for diagnostic testing based on circulating tumour (ct) DNA fragments in the blood, was a true milestone on its own. At the same time, we also launched the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay that together with the Idylla™ KRAS Mutation Test enables a complete RAS analysis on a same-day basis, reducing anxiety for the affected patients and their relatives and opening up the route towards faster treatment selection."

**Rudi Mariën:** "The state-of-the-art performance of Idylla™ has not gone unnoticed in the market. In 2015, Biocartis signed five new collaborations with leading healthcare industry players, among which Merck and Amgen, who are recognising the unique benefits of our Idylla™ technology. Our partnership strategy is essential for accelerated test development and commercial expansion."

**Rudi Pauwels:** "Besides focus

on commercial and menu expansion we also strengthened our senior management team in view of the next critical steps Biocartis has to take in becoming a world leader in molecular diagnostics. In September 2015, Hilde Windels (our former CFO) was appointed Deputy CEO and Ewoud Welten, bringing in extensive experience as a corporate financier in healthcare, joined as CFO."

**What do you expect for 2016?**

**Rudi Pauwels:** "We are looking forward to 2016 as we aim to have our core menu for oncology on the market by the end of the year. We expect this to be an important driver in the further growth of our installed base. Furthermore, we have high expectations for one of our biomarkers which are relevant for new and booming treatments such as immuno-oncology, requiring fast and accurate MDx.

Also in infectious diseases, the unique Idylla™ multiplexing capacity, allowing simultaneous detection of one or more biomarkers in one single sample, is opening promising doors. The Ebola, MERS and more recently the Zika outbreak show that our world needs better and earlier disease detection and surveillance solutions.

More concretely, we are looking in 2016 to grow our menu of tests



"THE STATE-OF-THE-ART PERFORMANCE OF IDYLLA™ HAS NOT GONE UNNOTICED IN THE MARKET".

RUDI MARIËN, BIOCARTIS CHAIRMAN

with at least four new tests and to expand our installed base of Idylla™ instruments to over 300 by the end of 2016."

**Rudi Mariën:** "Our outlook for 2016 underlines our ambition and confidence in the future, as we focus on becoming a global leading player in molecular diagnostics that generates significant returns for shareholders by providing innovative, personalised healthcare solutions which will make a real difference to the lives of patients."

**Rudi Mariën, Chairman**

**Rudi Pauwels, CEO**

<sup>1</sup> Research Use Only



## Disclaimer and other information

### About this report

The board of directors of Biocartis Group NV is responsible for the contents of this document and declares that, having taken all reasonable care to ensure that such is the case, the information contained in this Biocartis Annual Report 2015 is, to the best of its knowledge, in accordance with the facts and contains no omissions likely to affect it materially and contains the required information in accordance with applicable Belgian Law. In accordance with Article 119 of the Belgian Companies Code, the annual reports on the statutory and consolidated annual accounts have been combined. According to Belgian law, Biocartis must publish its Annual Financial Report in Dutch. Biocartis also provides an English version. In case of difference in interpretation, the English version takes precedence. An electronic version of the Annual Report 2015 is available on the website of Biocartis at [www.biocartis.com](http://www.biocartis.com). Other information on the website of Biocartis or on other websites is not a part of this Report. This report reflects the performance and results of Biocartis in the period between 1 January and 31 December 2015.

### Forward-looking statement

Certain statements, beliefs and opinions in this report are forward-looking, which reflect the Company or, as appropriate, the Company directors' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this report regarding past trends or activities are

not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In 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 update or revisions to any forward-looking statements in this report as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this 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.

### About Biocartis

Biocartis Group NV (the 'Company') is a limited liability company organised under the laws of Belgium and has its registered office at Generaal De Wittelaan 11 bus B, 2800 Mechelen, Belgium. 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 trademark and logo are trademarks belonging to Biocartis and are used and registered in Europe. Idylla™ is a registered trademark in the United States and other countries. Idylla™ trademark and logo are used trademarks belonging to Biocartis. Idylla™ platform, Idylla™ BRAF Mutation Test, Idylla™ KRAS Mutation Test and the Idylla™ Respiratory (IFV-RSV) Panel are CE-marked. The Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay and the Idylla™ ctBRAF Mutation Assay are IVDs for Research Use Only and not for use in diagnostic procedures. Not for sale in the USA and Canada.



CHAPTER 1

# Business Section

“

“IDYLLA™ GIVES YOU AN  
ANSWER IN AN ABSOLUTELY  
UNPRECEDENTED TIME FRAME.”

FILIP JANKU, M.D., PH.D., ONCOLOGIST AT MD  
ANDERSON, CANCER CENTER, TEXAS



## 1.1. About Biocartis Group

“WITH BIOCARTIS, WE AIM TO DEVELOP AND MANUFACTURE NEW GOLD STANDARD MOLECULAR DIAGNOSTIC SOLUTIONS. THIS APPROACH INSPIRES US TO ENABLE DOCTORS TO TAKE CLINICALLY RELEVANT DECISIONS IN THE BEST POSSIBLE TIME FRAMES. OUR EMPLOYEES CONTINUE TO PURSUE THE SAME DEEPLY ROOTED VISION OF INNOVATING DIAGNOSTIC TESTING TO IMPROVE THE LIVES OF ALL PATIENTS AFFLICTED WITH CANCER WORLDWIDE OR SUFFERING FROM SEVERE INFECTIOUS DISEASES.”

RUDI PAUWELS, CEO BIOCARTIS

### 1.1.1. Our mission and vision: high precision diagnostics for high precision medicine

Biocartis is an innovative commercial stage molecular diagnostics (MDx) company, with the goal to establish a new gold standard in diagnostic testing, by providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry.

Personalised medicine is about every person's unique genetic profile. Understanding and leveraging the molecular mechanisms underlying diseases empowers doctors to shift away from the one-drug-fits-all paradigm and tailor a treatment to the genetic profile of their patient. Specific molecular diagnostics tests can help make treatments more effective, with better outcomes and as such, reduce healthcare costs. For instance, detailed molecular diagnostics information helps a doctor determine what drug is the preferred treatment for a melanoma patient whose tumor carries a specific genetic mutation.

However, for a truly sustainable long term healthcare system, molecular information needs to be accurate, gathered quickly and easily, accessible to all, at the point of need. Today, this is not the case. Many hospitals do not perform molecular tests in-house, but send the test samples out to specialised labs, sometimes even in other countries, where they are processed in batches using a workflow that requires usage of multiple complex instruments and operated by highly trained personnel. This is a time-consuming and labor-intensive process that normally takes several days or even weeks before results are available, thereby delaying treatment decisions, which are often crucial to save patients' lives.

Biocartis' flagship product, its proprietary MDx Idylla™ platform, has been designed specifically to offer fully automated, real time accurate and highly-reliable molecular information, from any biological sample, in virtually any setting. Idylla™ addresses the growing demand for personalised medicine by allowing fast and effective treatment selection and treatment progress monitoring.

### 1.1.2. Our company values and DNA

"IN REALISING ITS VISION, BIOCARTIS WANTS TO FACILITATE AN ENVIRONMENT FOR OUR EMPLOYEES WHERE PEOPLE ARE COMMITTED EVERY DAY TO IMPROVE OTHER PEOPLE'S LIVES. 'SENSE, THINK, SHARE, DO' SUMMARISES THE BIOCARTIS DNA AND HOW WE WORK AS A TEAM."

HILDE WINDELS, DEPUTY CEO BIOCARTIS



think



share



do

- surface tensions, think solutions
- work hard, have fun
- put your heart into what you do
- take responsibility
- respect is an attitude
- dare to fail

### 1.1.3. Strategy

**B**iocartis aims to become a global leading player in molecular diagnostics by providing innovative, personalised healthcare solutions which allow instant, global access to accurate, first time right molecular information from a wide variety of biological sample types, thus enabling fast and effective diagnosis, treatment selection and treatment monitoring.

Biocartis' initial focus is to develop a broad test menu for the Idylla™ platform that best meets its unique features by focusing on addressing key unmet needs in oncology and infectious diseases:

- **Oncology:** Biocartis' first wave of tests is tests for oncology, aimed at pathologists/oncologists. Within oncology, the fastest growing segment of the MDx market, Biocartis aims to valorise the unique ability of the Idylla™ platform to directly process formalin fixed paraffin embedded (FFPE) tumor slides. In addition, the very high sensitivity levels of the Idylla™ tests enable the same system to be used for solid biopsy as well as for liquid biopsy tests. With the rapid turnaround time of the Idylla™ platform, in the future it should be possible to analyse a patient sample and use the diagnostic results in clinical decision making and be able to offer diagnostic results during the same patient visit.
- **Infectious diseases:** Biocartis' second wave of tests is for infectious diseases aimed at rapid response and microbiology laboratories. Within infectious diseases, the largest segment of the MDx market, Biocartis' unique position is driven by combining high sensitivity with the ability to offer syndromic panels (e.g. respiratory tract panel assay) at short turnaround times.

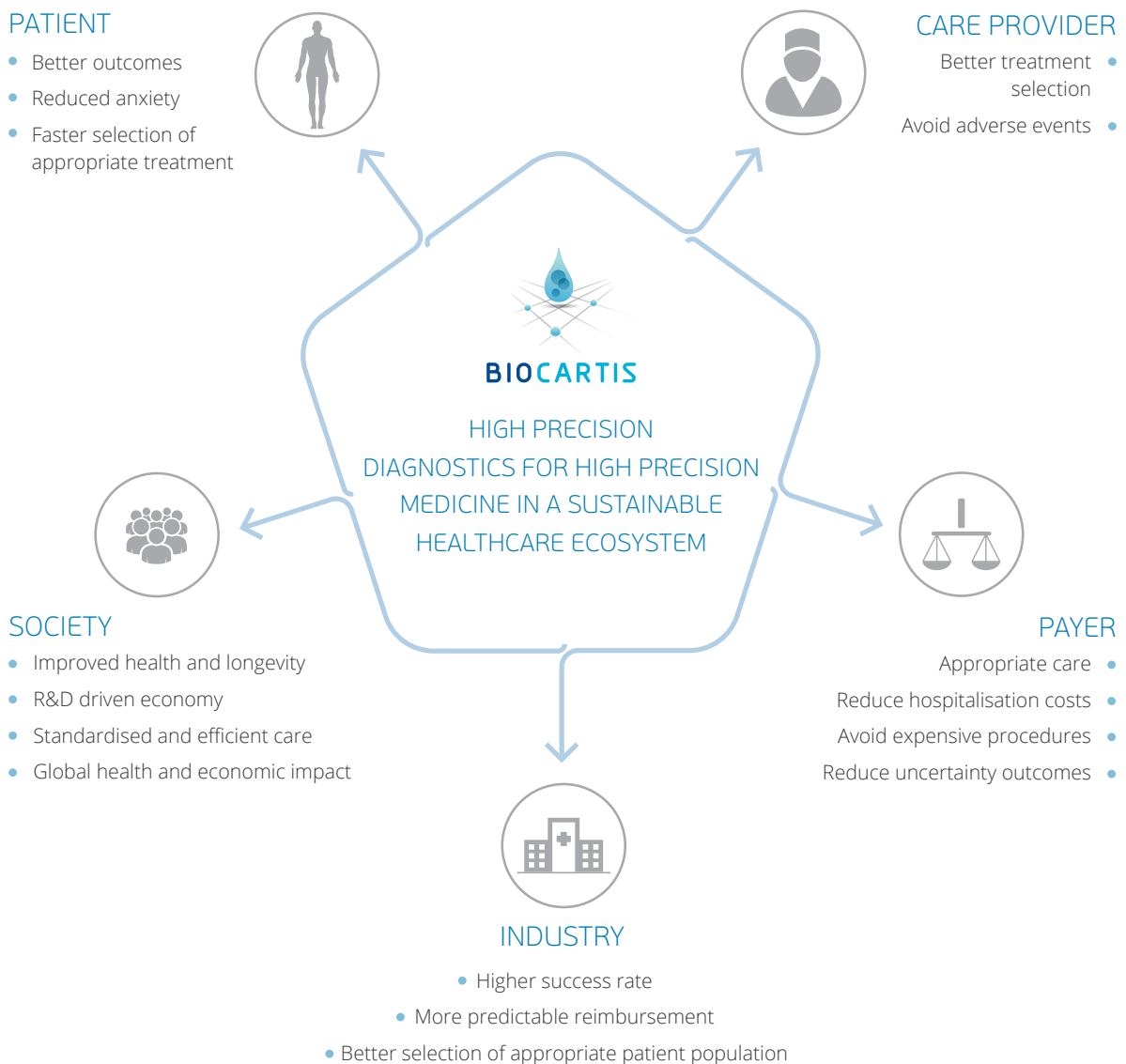


Biocartis intends to launch at least four tests per year. The first tests all involve biomarkers or disease areas for which reimbursement is already established.

To realise its ambitions, partnerships are a key strategic element for Biocartis in ensuring acceleration of its test menu and expansion of our commercial reach. Biocartis currently has strategic partnerships in place with key industry players, such as Johnson & Johnson, Abbott Molecular, Merck KGaA and Amgen. In addition, Biocartis actively pursues collaborations with companies that have considerable knowledge of MDx in specific disease areas such as Microbiome, Fast-Track diagnostics and A\*STAR to (co)develop tests. For this purpose, Biocartis developed a 'Developer's Suite', a unique test development toolkit, for partners containing all required information to develop Idylla™ compatible tests

## High precision diagnostics for high precision medicine in a sustainable healthcare ecosystem

FAST, EARLY AND ACCURATE DIAGNOSES ARE LEADING THE WAY TO APPROPRIATE AND COST EFFECTIVE CARE. BIOCARDIS AIMS TO INCREASE ITS IMPACT BY CREATING BETTER ACCESS TO PERSONALISED MOLECULAR DIAGNOSTIC TESTING TO ALLOW EARLY DETECTION, APPROPRIATE TREATMENTS AND TREATMENT MONITORING FOR ALL PATIENTS. BIOCARDIS BELIEVES THAT ITS APPROACH WILL CREATE LONG TERM POSITIVE IMPACT FOR ALL STAKEHOLDERS IN THE SUSTAINABLE HEALTHCARE ECOSYSTEM, INCLUDING PATIENTS, CARE PROVIDERS, PAYERS, INDUSTRY AND SOCIETY AS A WHOLE. BIOCARDIS' GOAL IS TO IMPROVE CLINICAL PRACTICE AND ULTIMATELY, CONTRIBUTE TO BETTER PATIENT OUTCOME.



## 1.1.4. History

Foundation **Biocartis** in Lausanne, Switzerland by Dr. Rudi Pauwels, Prof Philippe Renaud and Nader Donzel.

Acquisition of **patent rights** from the University of Ghent (Belgium) and Tibotec-Virco (a Johnson & Johnson company) for the development of a **multiplex detection platform** called **Evaluation™**.

First proof of concept for **multiplexed molecular detection of DNA and RNA-based biomarkers**.

Establishment of a subsidiary at a **high tech campus in Eindhoven** (The Netherlands).

First proof of concept for **multiplexed immunoassays** using its proprietary digitally encoded **micro particle technology**.

Acquisition of '**Apollo**' (now trademarked as **Idylla™** platform) from **Koninklijke Philips Electronics NV**.

Strategic partnership with **bioMérieux** to co-develop and co-distribute tests.

Strategic licensing, development and commercialisation agreement with **Johnson & Johnson** to co-develop tests.



2011

Relocation R&D activities and establishment of pilot cartridge manufacturing production line in Mechelen (Belgium).

Biocartis received the **2012 Technology Pioneer Award** by the World Economic Forum.

2013

Biocartis MDx platform was named **Idylla™**

New collaborations and license agreements with **Hospital del Mar** and the **Vlaams Instituut voor Biotechnologie/ Flemish Institute for Biotechnology (VIB)**, in connection with its aim to develop tests for several cancers using new biomarkers.

2012

Launch of collaboration with **Philips, Genome Research Limited** and the **Wellcome Trust** for the development of technology for an automated blood based test-system for monitoring tumour load.

2014

Strategic collaboration with **Abbott Molecular** to develop and commercialise companion diagnostics tests.

Spin out of the multiplex detection platform **Evaluation™** into a separate company **MyCartis NV** to enable Biocartis to focus on the **Idylla™** platform.

Launch of the **Idylla™** platform and its first oncology test, the **Idylla™ BRAF Mutation Test as CE-IVD** in September 2014.

Establishment of Biocartis Group NV, a Belgian holding company, as the group's new holding company.

## 1.2. Risks related to our business

THE FOLLOWING RISK FACTORS MAY AFFECT THE FUTURE OPERATING AND FINANCIAL PERFORMANCE OF BIOCARTIS. THESE RISKS AND UNCERTAINTIES ARE NOT THE ONLY ONES BIOCARTIS FACES. ADDITIONAL RISKS AND UNCERTAINTIES NOT PRESENTLY KNOWN, OR THAT MANAGEMENT CURRENTLY BELIEVES TO BE IMMATERIAL, MAY ALSO AFFECT BIOCARTIS' BUSINESS, FINANCIAL CONDITION AND RESULTS OF OPERATIONS. THE RISKS HAVE BEEN SUBDIVIDED IN FOUR CATEGORIES: STRATEGIC AND COMMERCIAL RISKS, OPERATIONAL RISKS, REGULATORY RISKS AND FINANCIAL RISKS.

### Strategic and commercial risks

**The MDx industry is highly competitive and subject to rapid technological changes.**

The MDx industry is characterised by rapidly and continuously changing technology, evolving market standards, changes in customer needs, emerging competition and new product launches. Biocartis may need to develop or in-licence new technologies and solutions to remain competitive. Current or future competitors may succeed, or may have already succeeded, in developing solutions or services that are more effective or affordable which could render Biocartis' present or future solutions obsolete or uneconomical.

Biocartis faces intense competition from a number of companies that offer solutions and technologies in its target markets. The Idylla™ platform is a sample-to-result platform, and several other companies have brought such platforms to the market. Some of Idylla's™ key competitors in this field are Cepheid (with its GeneXpert system), bioMérieux (BioFire with its FilmArray system), Luminex (GenturaDx with its Aries system), Roche (IQuum with its LIAT analyser) and Becton Dickinson (HandyLab with its BD-Max system). Furthermore, several smaller companies are developing platforms that try to achieve similar goals for sample-to-result functionality (such as Nanosphere, Curetis, Enigma Diagnostics, GenMark Dx, Great Basin, Rheonix, and Atlas Genetics). Some competitors have substantially greater financial resources and larger, more established marketing, sales and service organisations than those of Biocartis.

**The commercial success of Biocartis will depend on commercial market acceptance of the Idylla™ platform and its menu of tests.**

Biocartis launched its Idylla™ platform and its first test, the Idylla™ BRAF Mutation Test, for commercial sale in countries recognising CE-marked in vitro diagnostic ("IVD") devices in September 2014. Since that date, Biocartis has launched four additional tests and so far they have only generated limited revenue. There can be no assurance that these products or any further products launched by Biocartis will gain acceptance by the market as many factors can influence market acceptance.

**Biocartis faces uncertainties over the reimbursement for its products by third parties and may be subject to strict price controls.**

The commercial success of Biocartis' Idylla™ platform and menu of tests depends, in part, on the degree to which they are reimbursed by public health administrations, private health insurers, managed care organisations and other organisations in the countries in which Biocartis operates. Although Biocartis' first wave of tests predominantly involve biomarkers for which reimbursement is already established, reimbursement procedures in most countries where Biocartis is or will be active are highly complex and third-party payer health plans are fragmented, which makes systematic reimbursement arrangements difficult to establish. As a result, Biocartis will need to continue to expend significant effort and expense to establish, and may never succeed in establishing, widespread or systematic reimbursement arrangements.

## Operational risks

### **Delays in the development of tests may occur resulting in a slower development of a broad and clinically relevant menu of tests.**

To date, the Idylla™ platform has only been commercialised on a limited basis with a limited number of tests. The availability of a broad and clinically relevant menu of tests is an important decision factor to acquire and use a diagnostic platform, and management believes that offering a compelling, broad menu of tests will be a key driver of demand for the Idylla™ platform. The continued development and commercialisation of additional tests is therefore a key part of Biocartis' strategy. In addition, Biocartis intends to seek regulatory approval for the Idylla™ platform and its menu of tests in a broad range of jurisdictions (including in the United States). Biocartis may experience unexpected delays or difficulties in the remaining stages of development and commercialisation of its menu of tests, which may jeopardise and/or delay market acceptance of the Idylla™ platform. Such delays may occur due to a variety of factors.

### **Biocartis has only limited experience in commercialising MDx platforms and tests and therefore may not be successful in further growing its commercialisation infrastructure.**

Biocartis has limited experience in deploying a commercialisation infrastructure in diagnostics markets and may not succeed in hiring additional and/or retaining key personnel, or making appropriate arrangements with distributors and other parties, to execute the commercial deployment of the Idylla™ platform and tests. Furthermore, Biocartis will need to continue to build a maintenance and service organisation in order to ensure adequate installation and servicing of instruments and consoles.

### **Biocartis may not be able to manufacture or outsource manufacturing of its products in sufficient quantities, in a timely manner or at a cost that is economically attractive.**

Biocartis' revenues and other operating results going forward will depend, in large part, on its ability to manufacture and deliver its Idylla™ platform in

sufficient quantities and quality, in a timely manner, and at a cost that is economically attractive. The Idylla™ platform comprises three components: the instrument, the console and the cartridge. The manufacturing or assembly of the instrument and the console has been outsourced in the course of 2015 to Biocartis' manufacturing partner (CMO). The manufacturing or assembly of the cartridge to date is performed in-house at Biocartis' facilities in Mechelen (Belgium).

Management believes that Biocartis' current in-house production line for Idylla™ cartridges will provide it with sufficient capacity to meet volume projections to early 2017 by adding work stations and operating in multiple shifts. In order to meet expected demand thereafter, Biocartis has started construction of a more automated and higher volume production line for Idylla™ cartridges in partnership with a global, top tier CMO. In parallel, Biocartis is also preparing the execution of its longer term strategic plan by working on the design of a high volume, fully automated production line for Idylla™ cartridges. Such design work is also prepared in collaboration with a CMO.

There can be no assurance that the contracted CMO's will deliver manufacturing facilities and services in time, or in compliance with the standards that are required by the relevant regulatory authorities, or that they will be able to manufacture Biocartis' products in sufficient quantities, to the same standards and at an economically attractive cost compared to Biocartis' competitors, or at all. However, in selecting the CMO's Biocartis has followed a thorough process (backed by external experts) that has led to the appointment of world class CMO partners. Furthermore, Biocartis has set up internal project teams to monitor all outsourced production activities on a regular basis.

### **Biocartis relies on multiple suppliers to produce the individual components required for its Idylla™ platform and Idylla™ tests, some of whom are single source suppliers.**

The nature of Biocartis' products requires customised components that are currently available from a limited number of sources. For a few components Biocartis is exposed to single source risk. There can be no assurance that the suppliers will at all times be able to continue to provide the components Biocartis needs,

at suitable prices or in sufficient quantity or quality. If Biocartis needs alternative sources for key components, for any reason, these alternative component parts may not be available on short notice, on acceptable terms, or at all. Furthermore, alternative components may require Biocartis to modify its products which is likely to result in important re-design and approval costs and delays in supply. Where possible, Biocartis tries to identify whether secondary sources are available for certain components. However, as this is not always possible, Biocartis tries to establish close relationships with its key suppliers and to perform regular quality checks to quickly identify potential quality issues.

**Biocartis faces an inherent risk of product liability claims.**

Biocartis is exposed to potential product liability claims that are inherent in clinical testing and MDx. Biocartis faces the risk of liability for damages if there are deficiencies with any of its products due to component failures, manufacturing errors, design or labelling defects or other deficiencies and issues. Biocartis cannot be certain that it will be able to successfully defend any product liability lawsuit brought against it. Regardless of merit or eventual outcome, product liability claims may result in decreased demand, reputational damage, litigation costs and potential monetary awards. Biocartis has entered into a product liability insurance with an overall cover that it believes to be market conform.

**Biocartis cannot provide assurance that patients, hospitals, surgeons or other parties will not try to hold it responsible for all, or part, of the medical decisions underlying the treatment of patients.**

Biocartis' MDx products are designed solely to detect the levels of certain, specified biomarkers and are not designed to specify the treatment necessary for each patient, which remains the responsibility of relevant medical personnel. Although Biocartis makes this very clear when it markets its products and on its labelling (which indicates, among other things, the relevant test's accuracy rate), Biocartis cannot provide assurance that patients, hospitals, surgeons or other parties will not try to hold Biocartis responsible for all or a part of the medical decisions underlying the treatment of patients,

exposing Biocartis to potential litigation or civil and criminal liability.

**If Biocartis fails to obtain patent protection for the products it develops or otherwise fails to maintain and adequately protect its intellectual property rights, Biocartis' business could suffer.**

Biocartis' intellectual property rights form the basis of its products and technologies. Biocartis invests in different forms of intellectual property right development and has set up an internal IP department that overlooks the different IP related activities. Currently, the patent portfolio of Biocartis consists of 36 proprietary families comprising issued and pending patents worldwide. The portfolio further includes multiple in-licensed patent families. In addition to patents, Biocartis also relies on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements, non-exclusive licences and other contractual provisions and technical measures. Protecting the intellectual property rights may be critical to Biocartis' success, but will depend on a number of complex legal and factual questions.

**Biocartis is dependent on (sub)licences for key technologies from third parties and may require additional licences.**

Biocartis relies on key technologies from third parties and has entered into (sub)licence agreements with a number of (sub)licensors. Various licence agreements impose on Biocartis various development obligations, payment of royalties and fees obligations, as well as other obligations. If Biocartis fails to comply with any of its obligations under these agreements, the (sub) licensor may have the right to terminate the (sub) licence. In addition, if the sublicensor fails to comply with its licence or the licensor fails to enforce its intellectual property, the (sub)licenced rights may not be adequately maintained. The termination of any (sub) licence agreements, or the failure to adequately protect the intellectual property rights which are the subject matter of such (sub)licence agreements, could prevent Biocartis from commercialising products covered by the (sub)licenced intellectual property or have another negative impact on such commercialisation. In addition, Biocartis may require access to additional

third-party technologies for which an additional (sub) licence, or (sub)licences, needs to be obtained in order to be able to sell certain of its products. If Biocartis is unable to sustain or enter into adequate (sub)licensing agreements to access these technologies, either on acceptable terms or at all, it may be unable to sell all, or certain of, its products, or access some geographic or industry markets. Finally, certain technologies and patents have been developed with collaboration partners, and Biocartis may be limited by restrictions on this jointly developed intellectual property.

**Intellectual property infringement claims from third parties could be time-consuming and costly to defend and may result in liability for damages, or prevent Biocartis from commercialising its products.**

The MDx industry is characterised by a large number of patents, claims of which appear to overlap in certain cases. As a result, there is a degree of uncertainty regarding the extent of patent protection and infringement. Biocartis may thus have unknowingly infringed in the past, and may still be infringing, the proprietary rights of third parties. In addition, third parties may have pending patent applications, which are typically confidential for the first eighteen months following filing, and which may cover technologies Biocartis and/or its partners incorporate in their MDx platforms and tests. In the event that third parties accuse Biocartis of infringing their patents, Biocartis could incur substantial costs and consume substantial resources in defending against these claims. If such claims prove to be valid, this could lead to significant damages, royalty payments or an injunction preventing the sale of certain of Biocartis' products. In order to mitigate these risks, Biocartis' IP team tries to get a good understanding of the IP landscape and to take action where required.

**If Biocartis fails to attract or retain key personnel, its ability to conduct and expand its business would be negatively affected.**

Competition for skilled personnel is intense and may limit Biocartis' ability to hire and retain highly qualified personnel on acceptable terms or at all. Many of the

competitors have greater financial and other resources, different risk profiles and a longer history than Biocartis. Attracting, retaining and training personnel with the requisite skills is therefore challenging. If, at any point, Biocartis is unable to hire, train and retain a sufficient number of qualified employees to match its growth, this could have a material adverse effect on its ability to implement its business strategy. Therefore, Biocartis has set up an HR team that is not only focused on attracting the right employees but also on overall employee satisfaction.

**A breach of security in Biocartis' products or computer systems may compromise the integrity of Biocartis' products, harm Biocartis' reputation, create additional liability and have a material adverse impact on Biocartis' results of operations.**

Like all software products and computer systems, Biocartis' software products and computer systems are vulnerable to such cyber-attacks. The impact of cyber-attacks could disrupt the proper functioning of Biocartis' software products and computer systems (including Idylla™ Connect), cause errors in the output of Biocartis' systems, allow unauthorised access to sensitive, proprietary or confidential information of Biocartis, its customers or the patients that Biocartis and Biocartis' customers serve. In order to try to mitigate this risk, Biocartis' IT system uses a universal threat management system (UTM) that combines different levels of protection measures from generic firewalls to intrusion detection and data analysis (deep package inspection) for suspicious packets of data. This UTM works closely together with protection measures at the client side (e.g. anti-virus and spam detection programs). Furthermore, Biocartis has implemented rules governing access and use of the systems aimed at further reducing the risk of cyber-attacks.

**Potential liability related to the privacy and security of personal information Biocartis collects.**

Biocartis may, in the future, inadvertently gain access, or be determined to have access to personal information that is subject to a number of US federal and state, EU and other applicable foreign laws protecting the confidentiality of certain patient health

or other private information, including patient records, and restricting the use and disclosure of that protected information. In order to minimise this risk, all of the data on the Idylla™ platform is designed to be anonymised as much as possible and patient details should only be available at the point of test. Furthermore, Biocartis tries to accurately anticipate the application or interpretation of the above mentioned laws when developing its products.

## Regulatory risks

### **Failure to comply with regulations of the MDx market**

Regulatory agencies (such as the US Food and Drug Administration ('FDA')) strictly regulate the promotional claims that may be made about medical devices.

If Biocartis is found to have made false or misleading claims about its products, or otherwise have violated promotion or advertising restrictions, Biocartis may become subject to significant fines and/or other liabilities. The Regulatory and Marketing teams within Biocartis work closely together following up specific regulations and their implementation.

### **If Biocartis' products are defective, or otherwise pose safety risks, the relevant governmental authorities could require their recall, or Biocartis may initiate a recall of Biocartis' products voluntarily.**

The relevant governmental authorities may require the recall of commercialised products in the event of material deficiencies, or defects in design or manufacture, or in the event that a product poses an unacceptable risk to health. Manufacturers, on their own initiative, may recall a product if any material deficiency in a device is found. A government mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labelling defects or other deficiencies and issues. Recalls of any of Biocartis' products would divert managerial and financial resources and have a material adverse effect

on Biocartis' business, financial condition and results of operations. In addition, any product recall may result in irreparable harm to Biocartis' reputation. Biocartis has set up a quality department that controls different quality related procedures throughout the Group. The most important procedures are further described in this report under Corporate Governance.

**Biocartis' business could be significantly and negatively affected by substantial government regulations, particularly in the European Union and the United States.**

In line with its strategy, Biocartis launched its Idylla™ platform and its first tests, for commercial sale in the European Union and countries recognising CE-marked IVD devices. It intends to launch its products in other regions over the next few years. In each country in which Biocartis is currently active, or may become active in the future, Biocartis' products, including the Idylla™ platform and its menu of tests, are subject to material government regulation and review by a number of governmental authorities. Such regulations govern activities such as product development, testing, labelling, storage, premarket clearance or approval, manufacturing, advertising, promotion sales, reporting of certain product failures and distribution. If Biocartis fails to receive necessary approvals to commercialise Biocartis' products in relevant jurisdictions on a timely basis, or at all, Biocartis' business, financial condition and results of operations could be adversely affected. In addition, it is possible that the current regulatory framework could change, or additional regulations could arise, at any stage during development or marketing, which may adversely affect Biocartis' ability to obtain or maintain approval of its products, or to comply with ongoing regulations in the countries in which it operates. The Regulatory team in Biocartis tries to follow up these evolutions in order to anticipate in time on any projected changes.

**Healthcare policy changes, including legislation to reform the US healthcare system, could have a material adverse effect on Biocartis.**

From time to time, legislation is enacted that could significantly change the statutory provisions governing

the clearance or approval, manufacture, marketing or taxation of Biocartis' products. In addition, regulations and guidance are often revised or reinterpreted in ways that may significantly affect Biocartis' products (e.g. healthcare systems related legislation). It is impossible to predict whether legislative changes will be enacted or regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Biocartis tries to follow these evolutions through different channels (including outside counsel, industry journals, attendance of relevant industry conferences, etc.).

## Financial risks

**Biocartis has incurred operating losses, negative operating cash flow and an accumulated deficit since inception and may never become profitable.**

Biocartis has incurred operating losses and negative operating cash flow in each period since it was founded in 2007. There can be no assurance that Biocartis will achieve profitability, which could impair its ability to sustain operations or obtain any required additional funding. If Biocartis does achieve profitability in the future, it may not be able to sustain profitability in subsequent periods, and it may suffer net losses and/or negative operating cash flows in subsequent periods.

**Biocartis might require substantial additional funding to respond to business challenges or take advantage of new business opportunities, which may not be available on acceptable terms, or at all.**

Biocartis intends to continue to make appropriate investments to support its growth. Existing sources of financing and any funds generated from operations may not provide Biocartis with sufficient capital. Biocartis may require additional equity or debt funding from time to time to respond to business challenges, or to take advantage of new business opportunities. Equity and debt financing, however, might not be available when needed or, if available, might not be available on acceptable terms. In addition, to the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in the dilution of the

interests of Biocartis' existing shareholders. In addition, these securities may be sold at a discount from the market price of Biocartis' common stock. If Biocartis is unable to obtain adequate financing, its ability to continue to support its business growth and to respond to business challenges could be significantly limited. Existing sources of cash and any funds generated from operations may not provide Biocartis with sufficient capital and may result in delays in its operations.

**Biocartis' operating results could be materially adversely affected by unanticipated changes in tax laws and regulations, adjustments to its tax provisions, exposure to additional tax liabilities, or forfeiture of its tax assets.**

The determination of Biocartis' provision for income taxes and other tax liabilities requires significant judgment, including the adoption of certain accounting policies and Biocartis' determination of whether its deferred tax assets are, and will remain, tax effective. Although management believes its estimates and judgment are reasonable, they remain subject to review by the relevant tax authorities. Biocartis cannot guarantee that its interpretation will not be questioned by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof by the relevant tax authorities, will not be subject to change.

Biocartis is subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing and tax regulations for the compensation of personnel and third parties. Biocartis' tax structure involves a number of transfers and transfer price determinations between its parent company and its subsidiaries or other affiliates. Furthermore, Biocartis' increasing international business may make it subject to income tax and other taxes in countries where it was previously not the case.

**Biocartis may face risks associated with the spin-out of its Evaluation™ business unit into MyCartis NV (further commented in the financial notes 5.2.12) and continued minority shareholding, or any other previous or future acquisitions and disposals of companies, solutions and technologies.**

Since its incorporation, Biocartis has grown through significant licensing and asset acquisition transactions with third parties. If, in the future, Biocartis is presented with appropriate opportunities, it may acquire or make other investments in complementary companies, solutions or technologies. Biocartis may not be able to realise the anticipated benefits of the assets it secured, or may fail to secure or assess, through its past or future licensing transactions or acquisitions the actual value of the assets or technology, or may fail to further use and develop or integrate these assets or technology into its existing business, or may face claims from third parties. Moreover, Biocartis may have to incur debt or issue further equity to pay for any additional future acquisitions or investments, the issuance of which could dilute the interests of its existing shareholders.

Biocartis has also made disposals of assets that it deemed no longer core, and may decide to do so in the future with other assets. For example, in November 2014, Biocartis spun out its former Evaluation™ business into MyCartis NV for a gain on disposal of EUR 26.6 m, distributing the shares to Biocartis' shareholders. Following a capital increase of MyCartis in December 2015 Biocartis holds approximately 9,53% of the share capital in MyCartis NV. When disposing of assets, Biocartis may not be able to complete the disposal at terms deemed acceptable, may be required to give guarantees, and may expose itself to claims from purchasers, as well as creditors of the transferred business.

**Biocartis has no fixed dividend policy.**

Biocartis has not declared or paid dividends on its shares. In the future, Biocartis' dividend policy will be determined and may change from time to time by proposal of the Biocartis board of directors. Any declaration of dividends will be based upon Biocartis' earnings, financial condition, capital requirements and other factors considered important by the board of directors. Belgian law and the Company's articles of association do not require Biocartis to declare dividends.

Further financial risks are identified in the IFRS financial notes under note 'Financial Risk Management' that can be found in this annual report.

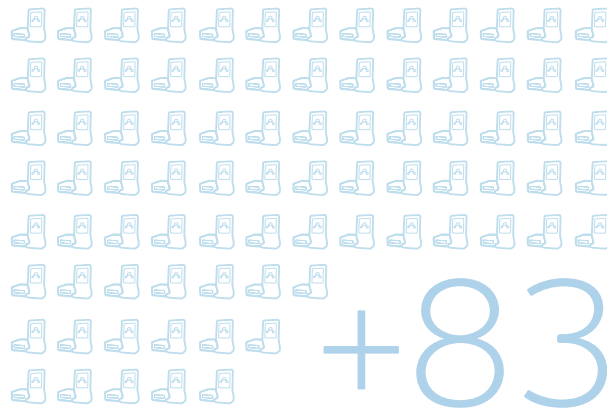


# 1.3. Review 2015

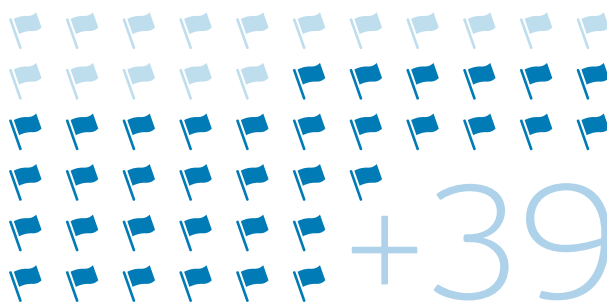
AFTER THE LAUNCH IN SEPTEMBER 2014, 2015 WAS THE FIRST FULL COMMERCIALISATION YEAR OF BIOCARTIS' MOLECULAR DIAGNOSTICS PLATFORM IDYLLA™. BIOCARTIS' COMMERCIAL STRATEGY IS BASED ON DIRECT REPRESENTATIONS IN KEY EUROPEAN COUNTRIES AND INDIRECT SALES VIA DISTRIBUTION PARTNERS IN GEOGRAPHIES ACCEPTING THE CE-MARK.

## 1.3.1. Commercial highlights

**Installed base:** In 2015, Biocartis added a total of 83 instruments to its installed base with customers worldwide. Consequently, Biocartis exceeded its target of 75 instruments for 2015. Based on the 82 instruments sold in 2014, the installed base of instruments amounted to 165 as per 31 December 2015, underlining a successful initial market adoption of the Idylla™ platform.



**Commercial footprint:** Biocartis strengthened its commercial footprint in 2015 by adding 39 countries. This was realised by expanding the direct sales force in Europe to 14 commercial representatives and the signing of 19 distribution agreements. At the end of 2015, Biocartis' commercial footprint covered over 55 countries worldwide.



**Sales & Marketing:** By the end of 2015, Biocartis' sales and marketing organisation amounted to 32 FTEs, an increase of 12 FTEs compared to 2014 to support ramp-up in commercialisation.



### 1.3.2. Test menu highlights

DURING 2015, BIOCARTIS FURTHER ADVANCED THE DEVELOPMENT OF NEW TESTS FOR ITS IDYLLA™ PLATFORM WITH A FOCUS ON ADDRESSING CLINICAL UNMET NEEDS IN ONCOLOGY AND INFECTIOUS DISEASES, BEING RESPECTIVELY THE FASTEST GROWING AND LARGEST SEGMENT OF THE WORLDWIDE MOLECULAR DIAGNOSTICS MARKET. BIOCARTIS AIMS TO LAUNCH AT LEAST FOUR IDYLLA™ TESTS PER YEAR.



#### Oncology menu

BIOCARTIS' INITIAL FOCUS WITHIN ONCOLOGY IS DEVELOPING A CORE MENU CONSISTING OF FOUR SOLID BIOPSY AND FOUR LIQUID BIOPSY TESTS FOR MELANOMA, COLON AND LUNG CANCER. THE MAJORITY OF THIS CORE MENU IS EXPECTED TO BE ON THE MARKET BY THE END OF 2016:

**Solid biopsy menu:** Biocartis launched two new solid biopsy tests for metastatic colorectal cancer (mCRC): the CE-marked Idylla™ KRAS Mutation Test (June 2015) and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay (December 2015, Research Use Only). Together, these tests provide for a complete mCRC mutation analysis of 39 KRAS and NRAS mutations, from two slices of so-called formalin-fixed paraffin embedded (FFPE) tumour tissue, at high sensitivity. For the first time in the molecular pathology field, these tests allow to perform a complete RAS analysis on a same-day basis,

opening up the route towards faster and more accurate treatment selection, based on a single patient visit.

**Liquid biopsy menu:** In December 2015, Biocartis launched the Idylla™ ctBRAF Mutation Assay (Research Use Only), the world's first and only fully automated liquid biopsy test that can potentially act as a substitute for tissue biopsy testing in melanoma, colorectal and lung cancers, as well as conditions such as hairy cell leukaemia and histiocytosis<sup>2</sup>. The commercial market for liquid biopsy testing, that allows for diagnostic testing based on circulating tumour (ct) DNA fragments in the blood, has grown significantly in 2015. This has, amongst others, driven Biocartis' decision to accelerate the development of liquid biopsy versions of its solid biopsy tests.

**Performance studies:** During 2015, multiple studies to analyse performance of the Idylla™ BRAF and RAS

<sup>2</sup> Histiocytosis is a general name for a group of disorders or "syndromes" that involve an abnormal increase in the number of immune cells that are called histiocytes. Source: <https://www.nlm.nih.gov/medlineplus/ency/article/000068.htm>, December 2015.



products were conducted, where the number of tests amounted to over 3,000. In general, these studies demonstrated high concordance with reference methodologies and higher sensitivity and specificity of the Idylla™ tests compared to competing In Vitro Diagnostic (IVD) solutions. Furthermore, these studies underlined Idylla™'s capability of offering very rapid turnaround times, based on a fully automated sample-to-result solution. More information on these studies can be found on the Biocartis website.

### Infectious disease menu

BIOCARTIS' INITIAL FOCUS WITHIN INFECTIOUS DISEASES IS ON OFFERING HIGHLY SENSITIVE SYNDROMIC PANEL TESTS:

**Idylla™ Respiratory (IFV-RSV) Panel:** In November 2015, the first infectious disease test on the Idylla™ platform was launched. The CE-marked Idylla™ Respiratory (IFV-RSV) Panel has been developed by Janssen Diagnostics. This test is intended for the detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV) from nasopharyngeal swabs of adult and paediatric patients (the test is compatible with both dry

NPS swabs as well as with a viral transport medium). The Panel combines, in one single product, the speed of rapid tests (turnaround time of as little as 50 minutes with less than one minute hands-on time) with the quality and sensitivity standards of central lab tests.

**MERS test:** During Q3 2015, Biocartis and Fast-track diagnostics initiated the development of a test aimed at detecting MERS-CoV. MERS-CoV is a type of coronavirus that was first identified in Saudi Arabia in 2012 and is the cause of Middle East Respiratory Syndrome (MERS). A large outbreak of this disease occurred in South Korea in 2015 and approximately 36% of patients with MERS reported to date have died<sup>3</sup>. The MERS test will further complement Biocartis' offering of respiratory tests.

**Ebola test:** Biocartis submitted the required documentation for an emergency use authorisation (EUA) application to the Federal Drug Administration (FDA) of its Rapid Ebola Virus Triage Test, which the Company is developing in association with Janssen Diagnostics and the Institute for Tropical Medicine in Antwerp (Belgium).

<sup>3</sup> Source: World Health Organisation, Fact sheet N°401

## Collaborations

TO ENSURE A RAPID EXPANSION OF THE TEST MENU AND RELATED COMMERCIALISATION, BIOCARTIS HAS AN ACTIVE PARTNERSHIP STRATEGY TO DEVELOP AND/OR COMMERCIALISE TESTS IN COLLABORATION WITH EXTERNAL PARTNERS. BIOCARTIS SIGNED THE FOLLOWING COLLABORATIONS IN 2015:



**Microbiome:** Biocartis signed an agreement with Microbiome, a spin-off of the VU University Medical Center Amsterdam (the Netherlands), aimed at developing a test for the rapid detection of bloodstream infections, such as sepsis.



**Merck:** Biocartis and Merck KGaA ('Merck'), a leading science and technology company in healthcare, life science and performance materials, signed a collaboration agreement for the development and commercialisation of a new liquid biopsy RAS biomarker test for patients with metastatic colorectal cancer (mCRC). The aim of the collaboration is to support clinical practice in performing integrated liquid biopsy RAS biomarker tests, independently of the laboratories' volume of testing or level of expertise. Both parties plan to implement the Idylla™ liquid biopsy RAS test in numerous medical centres across the world<sup>5</sup>. The test is expected to be available for Research Use Only (RUO) in Q3 2016 and is shortly thereafter planned to be submitted for a CE mark.



**Fast-track diagnostics:** Biocartis signed an agreement with Fast-track diagnostics (Luxembourg) aimed at the development of a broad range of Idylla™ infectious disease tests based on the approach of 'syndromic multiplex testing', meaning the identification of a broader range of disease pathogens in one single test.



**A\*STAR:** Biocartis signed an agreement with A\*STAR<sup>4</sup>, Singapore's lead public sector agency that spearheads economic oriented research to advance scientific discovery and develop innovative technologies, aimed at the joint development of a range of proprietary tests for the Idylla™ platform, with a main focus on cancer biomarkers.



**Amgen:** Biocartis and Amgen Inc ('Amgen'), one of the world's leading biotechnology companies, signed a collaboration agreement to offer Biocartis' new RAS biomarker tests (i.e. the Idylla™ KRAS Mutation Test and Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay) to hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey. The aim of the collaboration is to accelerate access to RAS biomarker information in the selected countries.

<sup>4</sup> The partnership agreement was signed with ETPL (Exploit Technologies Pte. Ltd.), the commercialisation arm of the Agency for Science, Technology and Research (A\*STAR, based in Singapore).

<sup>5</sup> Excluding the U.S., China and Japan.

### 1.3.3. Operational highlights

THE OPERATIONAL FOCUS IN 2015 WAS ON FURTHER STRENGTHENING THE ORGANISATION TO SUPPORT AND ENABLE THE ENVISAGED TEST MENU EXPANSION AND RELATED COMMERCIAL ROLL-OUT OF THE IDYLLA™ PLATFORM:



**Manufacturing:** During 2015, Biocartis outsourced the manufacturing of its Idylla™ Instrument and Idylla™ Console to a renowned Contract Manufacturing Organisation. This enabled cost efficiencies and scaling of production capabilities for Idylla™ instrumentation. Furthermore, in Q4 2015 Biocartis ordered the equipment and tools for a second manufacturing line that will provide an additional annual cartridge capacity of over one million Idylla™ cartridges (expected completion H2 2017).



**Strengthening management team:** In view of the next critical steps Biocartis has to take in becoming a world leader in molecular diagnostics, Biocartis strengthened positions at its senior management level in September 2015, to provide the company with the expertise needed for the execution of its strategy.



**Employee base:** Biocartis' employee base included 270 FTEs as per 31 December 2015, compared to 189 FTEs as per 31 December 2014.

### 1.3.4. Financial highlights

FROM A FINANCIAL POINT OF VIEW, 2015 WAS A YEAR MARKED BY SUCCESSFULLY SECURING FUNDING, AS WELL AS INITIATING THE TRANSITION PROCESS FROM REVENUES DRIVEN BY R&D ACTIVITIES, TOWARDS REVENUES DRIVEN BY COMMERCIAL PRODUCT SALES:

**Operating income:** Biocartis increased its total operating income from EUR 10.4m in 2014 to EUR 15.0m in 2015, an increase of 44%. This increase was primarily attributable to an increase in collaboration revenues of EUR 6.5m to EUR 9.7m in 2015. Total product revenues equalled EUR 3.6m in 2015.

**Equity raisings:** In 2015, Biocartis raised a total of EUR 136.5m through the second tranche of its Fround financing of EUR 21.5m in January 2015 and the gross proceeds of EUR 115.0m following a successful initial public offer on Euronext Brussels in April 2015. The IPO attracted a wide interest from a mix of investors across continental Europe, the UK and the US.

**Financial debt:** Biocartis attracted a new financing facility of EUR 5m in Q4 2015 to fund the capital investments in manufacturing. As per 31 December 2015, EUR 1.8m was drawn under this new facility. Following repayment of the Senter Novem loan in October 2015 and ongoing repayments under existing financial lease facilities, the total outstanding amount of financial debt as of 31 December 2015 amounted to EUR 10.8m.

**Cash burn:** Driven by, amongst others, positive movements in working capital of approx. EUR 11.2m (i.e. net movements in inventories, receivables and payables), Biocartis cash flow from operating activities and investing activities amounted to EUR -32.8m in 2015.

**Cash position:** Based on a cash position of EUR 10.9m as of 31 December 2014, a negative cash flow from operating and investment activities of EUR 32.8m and a positive cash flow from financing activities of EUR 125.9m, Biocartis cash position amounted to EUR 104.1m as per 31 December 2015.

### 1.3.5. Financial review 2015

THE TABLE BELOW PROVIDES AN OVERVIEW OF OF THE CONSOLIDATED FINANCIAL RESULTS OF BIOCARTIS GROUP NV. IN ADDITION TO THE REVIEW PROVIDED IN THIS SECTION, REFERENCE IS MADE TO CHAPTER 5 OF THIS ANNUAL REPORT THAT INCLUDES THE FULL CONSOLIDATED ACCOUNTS OF BIOCARTIS GROUP NV INCLUDING NOTES THERETO. A REVIEW OF THE NON-CONSOLIDATED STATUTORY RESULTS OF BIOCARTIS GROUP NV IS PROVIDED IN CHAPTER 6.

| <b>Key figures (EUR 1,000)</b>               | <b>2015</b>    | <b>2014</b>    | <b>% Change</b> |
|--|----------------|----------------|-----------------|
| <b>Total operating income</b>                | <b>14,951</b>  | <b>10,367</b>  | <b>44%</b>      |
| Cost of goods sold                           | -2,642         | -4,251         | -38%            |
| Research and development expenses            | -36,554        | -25,014        | 46%             |
| Marketing and distribution expenses          | -8,747         | -3,095         | 183%            |
| General and administrative expenses          | -6,662         | -7,180         | -7%             |
| <b>Operating expenses</b>                    | <b>-54,606</b> | <b>-39,540</b> | <b>38%</b>      |
| <b>Operational result</b>                    | <b>-39,655</b> | <b>-29,173</b> | <b>36%</b>      |
| Net financial result                         | -790           | -961           | -18%            |
| Income tax                                   | 648            | 947            | -32%            |
| Result from discontinued operations          | -              | 19,472         | -100%           |
| <b>Net result</b>                            | <b>-39,797</b> | <b>-9,715</b>  | <b>310%</b>     |
| Cash flow from operating activities          | -23,357        | -35,884        | -35%            |
| Cash flow from investing activities          | -9,414         | 5,052          | -286%           |
| Cash flow from financing activities          | 125,943        | 12,727         | 890%            |
| <b>Net cash flow</b>                         | <b>93,173</b>  | <b>-18,105</b> | <b>-615%</b>    |
| <b>Cash and cash equivalents<sup>1</sup></b> | <b>104,088</b> | <b>10,919</b>  | <b>853%</b>     |
| Financial debt                               | 10,814         | 13,585         | -20%            |

<sup>1</sup> Including EUR 1.5m of restricted cash (as a guarantee for bank and lease financing).

| <b>Breakdown operating income (EUR 1,000)</b> | <b>2015</b>   | <b>2014</b>   | <b>% Change</b> |
|---|---------------|---------------|-----------------|
| Collaboration revenue                         | 9,686         | 3,174         | 205%            |
| Product sales revenue                         | 3,593         | 5,260         | -32%            |
| Service revenue                               | 54            | 44            | 22%             |
| <b>Total revenue</b>                          | <b>13,334</b> | <b>8,478</b>  | <b>57%</b>      |
| Grants and other income                       | 1,617         | 1,889         | -14%            |
| <b>Total operating income</b>                 | <b>14,951</b> | <b>10,367</b> | <b>44%</b>      |

## Income statement

### Operating income

Biocartis' total operating income increased from EUR 10.4m in 2014 to EUR 15.0m in 2015, an increase of 44%. This increase was primarily attributable to a EUR 6.5m increase in collaboration revenues bringing the total to EUR 9.7m in 2015. Collaboration revenues consisted of revenue recognition from upfront payments that Biocartis received under its license and development agreements with Janssen Pharmaceutica in the amount of EUR 5m, a total of EUR 4m of milestone payments that Biocartis received from Janssen Pharmaceutica in relation to the further commercialisation of the Idylla™ platform, as well as EUR 0.7m of revenues from R&D services.

Total product sales revenues in 2015 amounted to EUR 3.6m, representing a decrease of EUR 1.7m compared to 2014. This is the result of a one-off direct sale of 80 Idylla™ instruments towards Janssen Pharmaceutica in 2014 and lower product sales from R&D activities that were only partially off-set by higher commercial product sales. Idylla™ instrument sales consequently decreased from EUR 3.7m in 2014 to EUR 2.3m in 2015 and Idylla™ cartridge sales decreased from EUR 1.5m in 2014 to EUR 1.3m in 2015.

Other operating income in 2015 amounted to EUR 1.6m and consisted of grants that Biocartis received from the IWT (Institute for Innovation by Science and Technology in Flanders), mainly for R&D in the field of sepsis and liquid biopsy technologies.

### Operating expenses

Total operating expenses in 2015 increased from EUR 39.5m in 2014 to EUR 54.6m in 2015, driven by higher expenses in R&D as well as in marketing & distribution, and lower General & Administrative (G&A) expenses as well as a lower costs of goods sold.

R&D expenses increased from EUR 25.0m in 2014 to EUR 36.6m in 2015 (increase of EUR 11.6m) as the consequence of an expansion of the R&D team with 38FTE, increased R&D activities for test and platform development and additional required support from service providers.

93.2€m

TOTAL NET CASHFLOW  
COMPARED TO EUR -18.1M IN 2014

15€m

TOTAL OPERATING INCOME INCREASED FROM  
EUR 10.4M IN 2014 TO EUR 15.0M IN 2015



125.9 € MILLION

CASH FLOW FROM FINANCING ACTIVITIES  
AMOUNTED IN 2015 TO EUR 125.9M,  
COMPARED TO EUR 12.7M IN 2014



10.8 € MILLION

TOTAL FINANCIAL DEBT DECREASED  
FROM EUR 13.6M AS OF 31 DEC 2014  
TO EUR 10.8M PER  
31 DEC 2015

Marketing and distribution expenses increased from EUR 3.1m in 2014 to EUR 8.7m in 2015 (increase of EUR 5.6m) as the result of an expansion of the marketing & distribution team with 12 FTE, additional external sales force support and increased marketing activities to support the global roll-out of the Idylla™ platform.

G&A expenses decreased from EUR 7.2m in 2014 to EUR 6.7m in 2015. This decrease is the combined result of exceptional expenses that Biocartis incurred in 2014 for its group restructuring and a costs increase because of the expansion of G&A staff with 10 FTE in 2015.

Cost of goods sold decreased from EUR 4.3m in 2014 to EUR 2.6m in 2015, predominantly as the result of lower product sales from R&D activities and a decrease in manufacturing costs for instrumentation and cartridges.

### Operational result

The operational result in 2015 amounted to a loss of EUR 39.7m compared to a loss of EUR 29.2m in 2014.

### Net financial result

Net financial result improved from EUR -1.0m in 2014 to EUR -0.8m in 2015, driven by decreased amounts of interest payable on borrowings.

### Income taxes

Driven by its operational loss in 2015, Biocartis had no taxable income and therefore incurred no income taxes. In 2015, Biocartis received research and development tax credits in Belgium for EUR 0.9m that was partially off-set by tax adjustments relating to prior years of EUR 0.4 m, resulting in a positive tax result of EUR 0.6m as compared to EUR 0.9m in 2014.

### Net result

As a result of the foregoing, the loss for the year after taxes increased from EUR 9.7m in 2014 to EUR 39.8m in 2015. Note that in November 2014, Biocartis SA finalised the spin-off of MyCartis NV that resulted in a gain after taxes from discontinued operations of EUR 19.5m in 2014 (nil in 2015). The result for 2015 after taxes from continuing operations consequently increased from a loss of EUR 29.2m in 2014 to a loss of EUR 39.8m in 2015.

## Balance sheet

### Non-current assets

The Company's intangible assets include patent and technology licenses & software and amounted to EUR 9.0m in 2015, a decrease of EUR 0.7m compared to 2014, driven by EUR 0.4m of additions versus amortisations of EUR 1.0m.

Property, plant & equipment include, amongst others, manufacturing equipment, assets held under lease, Idylla™ systems for internal use and for rent, and laboratory & ICT equipment. In 2015, property, plant & equipment increased with EUR 5.1m from EUR 9.2m in 2014 to EUR 14.2m as the result of EUR 9.2m of additions, predominantly capex for manufacturing equipment and depreciation of EUR 4.2m.

Per 31 December 2015, a financial participation of EUR 5.1m was included on the balance sheet, as the result of the acquisition of a participation in MyCartis NV on 15 January 2015, following the exercise by Debiopharm Diagnostics SA of a put option in December 2014. Biocartis currently holds a 9.53% participation in MyCartis NV. Deferred tax assets per 31 December 2015 amounted to EUR 2.0m and relate to tax credits for research and development in Belgium.

### Current assets

Inventory increased from EUR 3.6m per 31 December 2014, to EUR 5.8m end of 2015, caused by higher inventory levels in view of the further commercialisation of the Idylla™ platform. Trade receivables have decreased significantly with EUR 9.9m to EUR 5.9m per 31 December 2015, because of the collection of receivables of approx. EUR 12.0m from Janssen





Pharmaceutica. Other receivables predominantly relate to VAT receivables. Other current assets include accrued grant income and deferred charges. Driven by the second tranche of the series F financing round of EUR 21.5m in January 2015 and the gross proceeds of EUR 115.0m of the IPO in April 2015, the cash position of the Group increased with EUR 93.2m from EUR 10.9m per 31 December 2014 to EUR 104.1m per 31 December 2015.

## Equity

Biocartis' total equity increased from EUR 20.3m as at 31 December 2014 to EUR 114.9m as at 31 December 2015, mainly driven by a net increase in share capital and premium of EUR 134.3m that was partially offset by an increase in accumulated deficit of EUR 39.8m.

## Financial debt

Total financial debt decreased from EUR 13.6m as of 31 December 2014 to EUR 10.8m per 31 December 2015. This has primarily been the result of the full repayment of the Senter Novem loan of EUR 4.1m, repayments on existing lease facilities of EUR 1.1m and a new financing facility of EUR 5.0m that was obtained from a financial institution end of 2015 under which EUR 1.8m was drawn per 31 December 2015. The current portion of financial debt as of 31 December 2015 amounts to EUR 8.2m and the non-current portion to EUR 2.7m.

## Other liabilities

Trade payables increased from EUR 4.3m per 31 December 2014, to EUR 13.9m per 31 December 2015, mainly driven by prepayment invoices for operating and capital commitments in relation to manufacturing expansion. Deferred income has decreased to EUR 5.1m per 31 December 2015, from EUR 9.6m per 31 December 2014, because of recognised upfront payments from Janssen Pharmaceutica in relation to the strategic licensing, development and commercialisation collaborations. Accrued charges as of 31 December 2015 primarily include accruals for rental charges. Other current liabilities as of 31 December 2015 consist predominantly of provisions for vacation pay.

## Total assets and total equity & liabilities

Total assets as well as total equity & liabilities consequently increased from EUR 53.0m as per 31 December 2014 to EUR 148.4m as per 31 December 2015, representing an increase of EUR 95.4m.

## Cash flow statement

### Cash flow from operating activities

The cash flow from operating activities improved in 2015 to EUR -23.4m compared to EUR -35.9m in 2014, as the result of positive changes in working capital and a higher loss for 2015 as well as an exceptional gain in 2014 on the disposal of MyCartis NV of EUR -26.6m.

### Cash flow from investing activities

The cash flow from investing activities in 2015 amounted to EUR -9.4m compared to EUR 5.1m in 2014, as the result of higher investments in property, plant & equipment, as well as a one-off gain in 2014 of EUR 7.5m as the result of a divestment into MyCartis NV.

### Cash flow from financing activities

The cash flow from financing activities amounted in 2015 to EUR 125.9m, compared to EUR 12.7m in 2014, driven predominantly by the proceeds of the second tranche of the series F financing round and the IPO as well as net payments of borrowings.

### Total net cash flow

Driven by the aforementioned, total net cash flow in 2015 consequently amounted to EUR 93.2m compared to EUR -18.1m in 2014.

### 1.3.6. Important events and announcements after the reporting date

THERE WERE NO IMPORTANT EVENTS BETWEEN 31 DECEMBER 2015 AND THE APPROVAL DATE OF THIS ANNUAL REPORT.

### 1.3.7. Outlook 2016



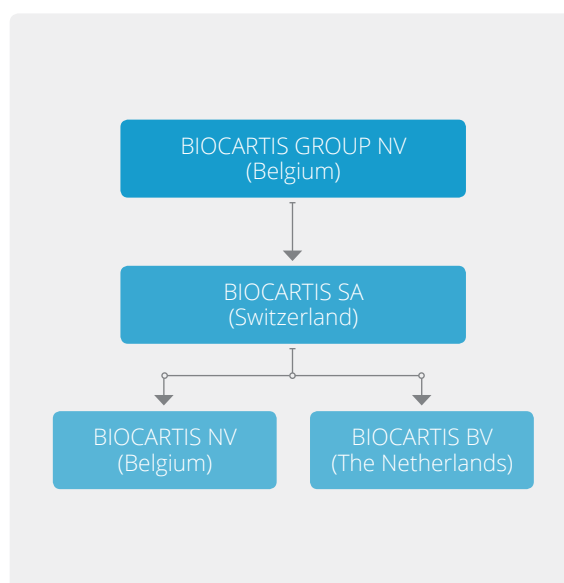
# 1.4. Biocartis as an organisation

## 1.4.1. Legal structure

The Biocartis group consists of the holding company, Biocartis Group NV, and three wholly owned subsidiaries. In addition, Biocartis currently holds 9.53% of the share capital in MyCartis NV.

The chart opposite represents the structure of Biocartis as of 31 December 2015.

Biocartis' headquarters are located in Mechelen, Belgium, incorporated on 24 November 2014 and in Belgium for an unlimited duration under registration number 0505.640.808 (RLP Antwerp, division Mechelen). All functions, including research and development, manufacturing and engineering, are currently centralised on one site in Mechelen, Belgium consisting of approximately 5,400 m2 that is being leased from Intervest.



35

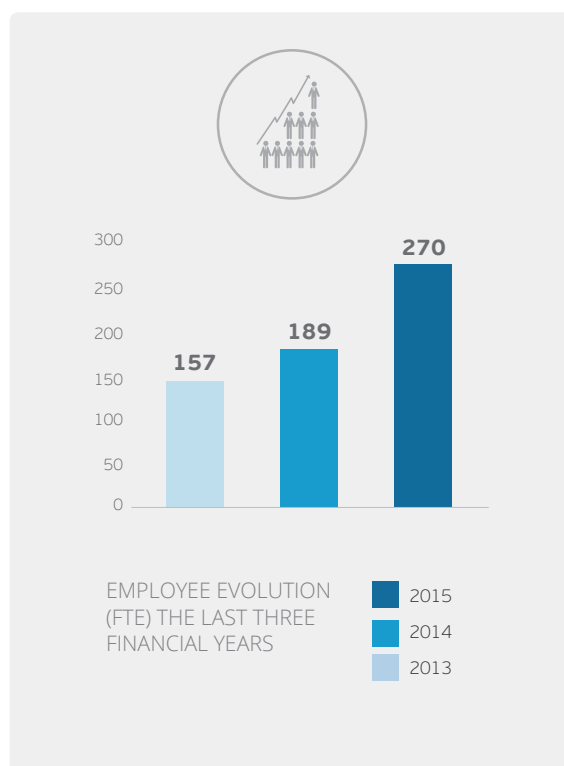
## 1.4.2. Employees

- 270 employees
- 25 nationalities
- 52% male, 48% female

Our employees are key to the success of Biocartis. Currently, its employee base reflects a diverse workforce, mirroring the international markets and society we live and work in. Biocartis' staff consists of 25 different nationalities and has a balanced level of gender diversity with 52% male and 48% female, stable versus 2014. In total, Biocartis employed 270 FTEs on 31 December 2015. The table opposite shows the employee evolution for the last three financial years.

### Training & development

Training and development is an essential part of Biocartis' HR management as it supports our employees to develop their full potential. It includes different training & development initiatives:



**Induction training:** all new employees receive an Induction Training within the first few weeks after joining Biocartis. A Welcome Package document is provided for all new employees, containing a wide range of information varying from travel policy, to health, safety & environment topics.

**Biocartis School:** this initiative stimulates continuous learning at Biocartis, by providing regular 'lunch & learn sessions' for employees on a wide variety of topics. In 2015, key topics included the basics of molecular biology and cartridge production.

**Specific job training:** depending on the specific job requirements, additional training needs are discussed.

Biocartis furthermore engages with its employees in a participative manner, in which regular and two-way communication is crucial. Internal communication with employees takes place through several channels:

- Monthly staff meetings with all employees, at which different operational topics, company updates on key progress and projects are presented
- Roundtable meetings to discuss important topics across different departments
- Department meetings
- Project team meetings
- Intranet

'Work hard, have fun' is one of the key values at Biocartis. In 2015, Biocartis organised an annual Family Day for employees and their families, and a Corporate Day at which Biocartis reflects on its strategy and progress made.

As serving the patient is part of our DNA as a molecular diagnostics company, Biocartis employees organised a fundraising in December 2015 for Music for Life, resulting in a fundraising of over 12.000 EUR, which was donated to the not-for-profit Kinderkankerfonds.

## Health & safety

Biocartis is committed to providing a safe and healthy work environment for all of its employees, contractors and visitors. Our measures include:

- A risk management system to identify, monitor and manage all environmental, health and safety (EHS) aspects.
- Prevention and protection steering team, responsible for implementing and overseeing our risk management system. They meet on a monthly basis.
- Internal prevention advisor, an environmental coordinator and a biosafety advisor.
- Biocartis has Roundtable Meetings in place, consisting of representatives of the different teams, to discuss cross departmental topics. These roundtable meetings take place every month and meeting reports including improvement actions and action points are made available for all employees.

### 1.4.3. Quality Management

Biocartis has established, documented and implemented a quality management system ('QMS') compliant with the international standards and regulations for design and development, for manufacturing and testing and for customer facing processes. The quality system covers all of Biocartis' products and tests. In the future, Biocartis intends to further develop the quality system to cover the regulatory requirements of other major territories, including China, US, Japan, Brazil, Australia, Russia, the Middle East, South Korea and Singapore.

More information can be found in the chapter 'Corporate Governance', under 'internal and external control'.

#### 1.4.4. Environment

One of the key aspects of our environmental impact as a company manufacturing MDx materials is related to our cartridge and instrument production. As a producer of equipment, Biocartis complies with two directives that have been installed to address environmental impact:

- The RoHS directive regarding the Restriction of Hazardous Substances in electrical and electronic equipment;
- The WEEE directive (Waste of Electrical and Electronic Equipment) to improve the environmental management of electrical and electronic waste, contribute to a circular economy and enhance resource efficiency.

Biocartis also complies with the REACH regulation which restricts the use of chemical substances that could have an impact on human health and the environment.<sup>6</sup>

#### 1.4.5. Production facilities

##### 1.4.5.1. Idylla™ platform production

During 2015, Biocartis outsourced the manufacturing of its Idylla™ Instrument and Idylla™ Console to a renowned Contract Manufacturing Organisation. More information can be found under 'Review 2015', 'Operational highlights'.



<sup>6</sup> REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and is a European Union regulation dated 18 December 2006.

##### 1.4.5.2. Cartridge production

Biocartis currently has one commercial production line for cartridges that has been fully operational since the first quarter of 2014. This is a custom made, semi-automated manufacturing line that is located in Biocartis' facilities in Mechelen (Belgium).

In Q4 2015, Biocartis ordered the equipment and tools for a second manufacturing line that should provide an additional annual cartridge capacity of over one million Idylla™ cartridges.

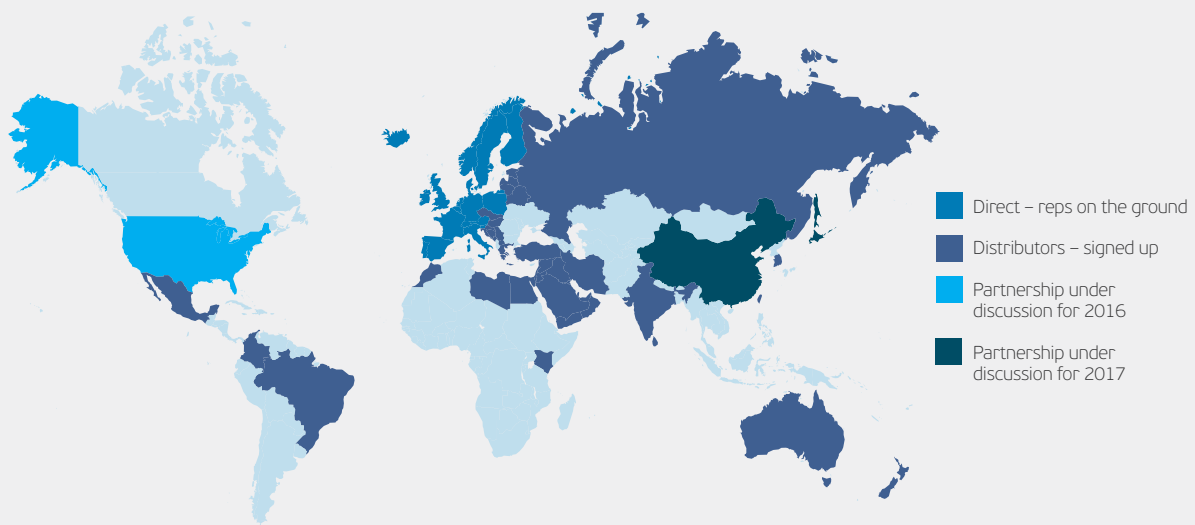
#### 1.4.6. Market access strategy

Healthcare policy makers, governments, insurers and other payers are implementing price control systems that favour early diagnosis, better screening and monitoring and cost-effective therapies driven by rising healthcare costs and budget constraints. As such, diagnostic testing is increasingly being accepted as a critical tool to reduce healthcare costs.

Thanks to their unique features such as flexibility, versatility, multiplexing and rapid response time, the fully automated Idylla™ platform and Idylla™ tests are used by the current central, highly skilled laboratories as well as by a growing number of more decentralised, non-expert settings such as smaller hospitals. In order to further increase our market access, our activities are focused on:

- Reimbursement: initially focus on tests that are already reimbursed by third-party payers in most developed countries
- Competitive pricing: with price levels competitive to existing regulator-approved tests in the European Union
- Health economics and outcomes research: the Idylla™ platform and tests provide clinicians with accurate and fast information, which allows for improved care, higher precision treatment and more effective treatment monitoring. For payers and care providers this will result in better outcomes, reduced hospitalisation costs and faster, appropriate and affordable care.

Biocartis is developing a worldwide commercial footprint that is currently covering 55 countries in 2015 through direct and indirect sales channels:



**Direct sales channels:** Biocartis has a direct sales force in Europe that covers key European countries. At the end of 2015, Biocartis' direct sales force counted 14 commercial representatives.

**Indirect sales channels:** outside Europe, Biocartis aims to commercialise through collaborations with distributors and strategic partners. In 2015, 21 distribution agreements were signed with renowned distributors. Biocartis' distribution partners cover over 40 countries.

### 1.4.7. Regulation

In each of the countries in which Biocartis markets its products, it must comply with local regulations affecting, among other things, design and product standards, packaging and labelling requirements.

In the European Union, Biocartis is compliant with the IVD Directive for manufacturers who place IVD devices on the EU market. The Idylla™ platform, the Idylla™ BRAF and KRAS Mutation Test and the Idylla™ Respiratory (IFV-RSV) Panel are CE-IVD marked, allowing Biocartis to market these products in European Union, as well as in countries accepting CE-marked IVD devices.

In the European Union, devices without the CE-conformity mark are called 'RUO' or Research Use Only, meaning they may be used for clinical investigations. In the United States, certain IVD products may be sold (subject to certain restrictions) as RUO products, without so-called 510(k) clearance or Pre-Market Approval (PMA). Many producers introduce RUO products first, and only later obtain the necessary approvals needed for introduction in the US market.

Regarding countries outside of the European Union and the United States, Biocartis will develop a country specific regulatory strategy, for which Biocartis will, amongst others, conduct regulatory auditing to gain maximum efficiency in product registrations.

### 1.4.8. Intellectual property (IP)

Biocartis considers the protection of its intellectual property rights, which form the basis of its products and technologies, to be a critical factor for its success. In order to protect its proprietary technologies and products, Biocartis has developed, and continues to develop and maintain, a strong intellectual property position. Biocartis has built its current patent portfolio through acquisitions of third-party patents, patent applications and know-how, as well as through internal creation. It has also exclusively licenced specific third-party technologies.

In addition to patents, Biocartis also relies on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements, non-exclusive licences and other contractual provisions and technical measures that help it maintain and develop its competitive position with respect to intellectual property. Based on these protections, competitors are not able to produce tests or cartridges that operate on the Idylla™ system. Biocartis' intellectual property is predominantly held by Biocartis NV.

Biocartis' intellectual property rights form the basis of its products and technologies. Biocartis invests in different forms of intellectual property right development and has set up an internal IP department that overlooks the different IP related activities. Currently, the patent portfolio of Biocartis consists of 36 proprietary families comprising of issued and pending patents worldwide. The portfolio further includes multiple in-licensed patent families.

# 1.5. Activities

## 1.5.1. The molecular diagnostics market

Since the unravelling of the human genome in the 2000's, the study of human health and diseases has been continuously leading to the discovery of specific genes, proteins and other molecular variations associated with specific diseases or drug response. These macro-molecules, called biomarkers, can be detected in patient samples such as blood, urine, sputum, saliva or tissue such as tumour tissue. The presence of a biomarker can be related to a particular disease and can help better define the exact type, status or stage of a disease or treatment response. Molecular diagnostics is the primary tool used to identify such biomarkers, paving the way for high-precision personalised medicine.

Due to the technical complexity of MDx testing and the fact that most current systems rely on batch-based testing (meaning that a large number of samples requiring the same test are tested in parallel), MDx testing is currently centralised in specialised molecular laboratories. Consequently, smaller hospitals (lacking the volume of tests for which batch-based systems are designed) or laboratories that are not specialised in MDx testing, typically send out their samples for analysis by external reference centres. In Biocartis' view, a key element of successful implementation of personalised medicine is that accurate diagnostic information is made available in a timely manner, near the patient instead of in specialised molecular laboratories, which are often located further away.

A number of key trends and drivers are expected to lead to accelerated development of diagnostic tools, further expanding the market over the next few years:

**Increased adoption of personalised medicine and growth of companion diagnostics:** society is progressively experiencing a shift from the "one drug fits all" paradigm and "trial-and-error-practice" of medicine, to a more, personalised medicine, driven by a better understanding of diseases, health economic studies, access to advanced technologies and better informed patients. This shift also resulted in a paradigm shift from diagnostics that traditionally helped to confirm or screen the presence of a disease, towards

predicting for example the course of a disease or the response to a specific treatment (companion diagnostics).

**Enhanced biomarker identification and molecular techniques:** certain key developments over the last decade, particularly the rise of NGS, have significantly accelerated biomarker discovery in clinical research, the elaboration of the tumour genome atlas, the growing availability of "big data" solutions, the discovery of the relevance of circulating tumour DNA, and growing insights in targeted and immunotherapies. These are expected to continue to boost the development of innovative diagnostic tests that are able to analyse a multitude of biomarkers in a single sample.

**Decentralisation of molecular testing:** accurate diagnostic information needs to be made available in a timely manner, near the patient and away from testing by the often further located specialised molecular laboratories. This is expected to require the development of sample-to-result solutions that can be used in non-expert settings by healthcare workers with no special laboratory training.

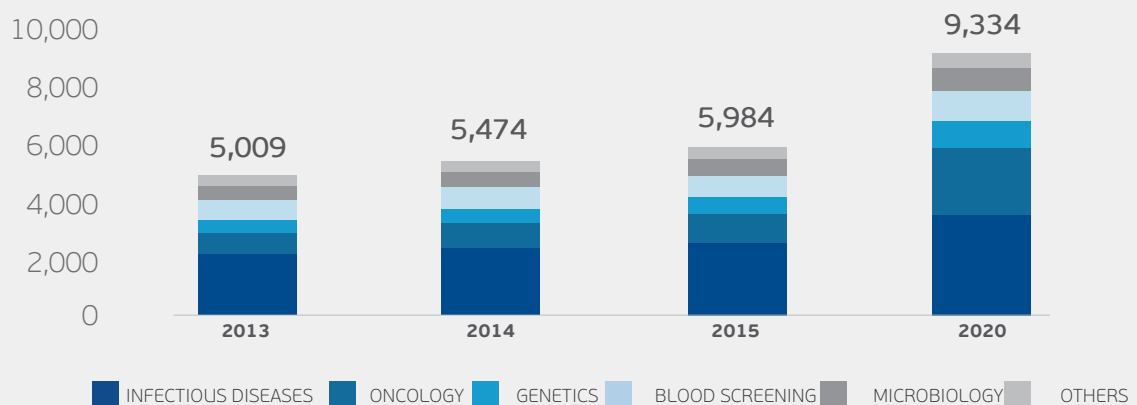
Having more sample-to-result solutions should also allow for molecular testing in less developed areas of the world. Currently, only a tiny fraction of the global population has access to MDx tests.

**Growing prevalence and management of chronic illness:** chronic illnesses increase the importance of monitoring disease, for which diagnostic testing is crucial.

**Expected shift of healthcare spending from treatment to more pro-active diagnosis:** rising healthcare costs and budget constraints push towards a more intelligent approach where MDx provides clinicians with more and better information, enhancing diagnosis capabilities, leading to better treatment outcomes. Healthcare policy makers, governments, insurers and other payers are implementing price control systems that favour early diagnosis, better screening and monitoring and cost-effective therapies. As such, diagnostic testing is increasingly being accepted as a critical tool to reduce healthcare costs.

The MDx market is estimated to be one of the fastest growing segments<sup>7</sup> of the approximately US\$57 billion (2015 estimate) IVD market<sup>8</sup>. The global MDx market is expected to grow from approximately US\$6 billion in 2015 to approximately US\$9.3 billion in 2020, representing a compound annual growth rate (CAGR) of 9.3%<sup>8</sup>.

*The molecular diagnostics market size, by application, 2015–2020 (USD MILLION)<sup>8</sup>*



By application, the largest MDx segment in 2015 was infectious disease, representing 44% of the MDx market, followed by oncology (17%), blood screening (13%), genetics (10%), microbiology (9%) and others (7%)<sup>8</sup>. Biocartis focuses on the two largest fields: oncology and infectious diseases.

### 1.5.2. Biocartis' focus on the molecular diagnostics market

Biocartis' primary focus is oncology, the fastest growing segment of the MDx market<sup>8</sup>. Oncology diagnostics are being driven by increasing incidences of certain cancers and the growing acceptance of companion diagnostics to improve treatment efficacies, while containing healthcare costs. In terms of healthcare costs, cancer remains a major direct and indirect burden on society. The US Agency for Healthcare Research and Quality (AHRQ) estimated that for 2012, the direct medical costs for cancer in the US, including all health care expenditures, were US \$87.5 billion<sup>9</sup>.

As a result of the foregoing, oncology, the second largest MDx segment in 2015, is expected to show the highest growth rate, resulting in a CAGR of 17% in the period 2015-2020<sup>8</sup>.

Biocartis' second focus is on the infectious disease market, as the MDx infectious disease segment is expected to continue to dominate the MDx market and to grow with a CAGR of 7% in the period 2015-2020<sup>8</sup>. MDx tests can help detect viruses and bacteria more rapidly and with far greater sensitivity and specificity. Particularly in this segment, sample-to-result systems and the development of new advanced tests such as syndromic panels, are expected to continue to drive growth and the adoption of MDx in decentralised settings.

<sup>7</sup> <https://www.alliedmarketresearch.com/ivd-in-vitro-diagnostics-market>

<sup>8</sup> MarketsandMarkets: In Vitro Diagnostics (IVD) Market by Product Technology (Immunoassay, Clinical Chemistry, Molecular Diagnostics, Hematology) by Application (Diabetes, Cancer, Cardiology, Autoimmune Diseases) - Forecast to 2020. See <http://www.marketsandmarkets.com/Market-Reports/ivd-in-vitro-diagnostics-market-703.html>

<sup>9</sup> [http://www.cdc.gov/cancer/npcr/uscs/technical\\_notes/#4](http://www.cdc.gov/cancer/npcr/uscs/technical_notes/#4). Last accessed on 4 March 2016.



BIOCARTIS LAUNCHED THE IDYLLA™ PLATFORM IN SEPTEMBER 2014 AS A CE-MARKED PRODUCT. THE IDYLLA™ PLATFORM IS A FULLY-AUTOMATED, SELF-CONTAINED REAL-TIME PCR-BASED COMPACT LABORATORY THAT INTEGRATES ALL THE SAMPLE PROCESSING AND ANALYTICAL PROCEDURES REQUIRED TO PROVIDE HIGH QUALITY MDX RESULTS AT THE POINT-OF-IMPACT. THE IDYLLA™ PLATFORM WORKS ON-DEMAND IN VIRTUALLY ANY SETTING, ALLOWING EVEN DECENTRALISED LABORATORIES TO RAPIDLY REPORT RESULTS. THE IDYLLA™ PLATFORM COVERS THE ENTIRE PROCESS FROM SAMPLE-TO-RESULT IN A TIMEFRAME OF BETWEEN 35 MINUTES (FOR GENETIC TESTS) AND 150 MINUTES (FOR HIGHLY COMPLEX TESTS). THE IDYLLA™ PLATFORM IS COMPOSED OF THREE PHYSICAL COMPONENTS: A CONSOLE, AN INSTRUMENT AND A DISPOSABLE CARTRIDGE.

### 1.5.3. Products

#### 1.5.3.1. The Idylla™ platform

**The console:** This is a touch-screen operated computer, with integrated barcode scanning and communication capabilities. This is where clinical sample information is entered, tests are initiated, results are displayed and, when required, test results are communicated to the Idylla™ Connect central data centre and/or the user's laboratory information system.

**The instrument:** This is a stackable, independent unit that executes the entire test procedure within the cartridge through a limited number of multipurpose instrument-cartridge interfaces. Multiple instruments can be connected to an Idylla™ console to match a range of throughput needs. A single instrument measures only around 30 x 50 x 20 cm and weighs approximately 20 kg.

**The cartridge:** This is a single use, disposable, self-contained plastic consumable with all of the necessary reagents on board to process a clinical sample and to detect the molecular biomarkers of interest. All cartridges share a common hardware design, but are made application-specific by their reagent content, test execution protocol (software) and labelling.

The Idylla™ platform provides unsurpassed ease of use, making the system suitable for use by non-expert personnel (such as nurses) in a non-specialised laboratory environment close to the patient<sup>10</sup>. The simplified 4-step workflow of Idylla™ drastically limits the number and duration of operator steps that have traditionally led to high labour costs and risks of errors for MDx tests, and generally take no longer than two minutes:



SCAN SAMPLE



SCAN CARTRIDGE



LOAD SAMPLE



INSERT CARTRIDGE

**Step 1:** The patient sample information is entered via the console. This can be accomplished either by scanning the barcode on the sample container, or by manual entry of the patient sample identification code.

**Step 2:** The patient sample is linked to the cartridge by subsequently scanning the barcode of the cartridge. The console automatically recognises which test the user intends to perform.

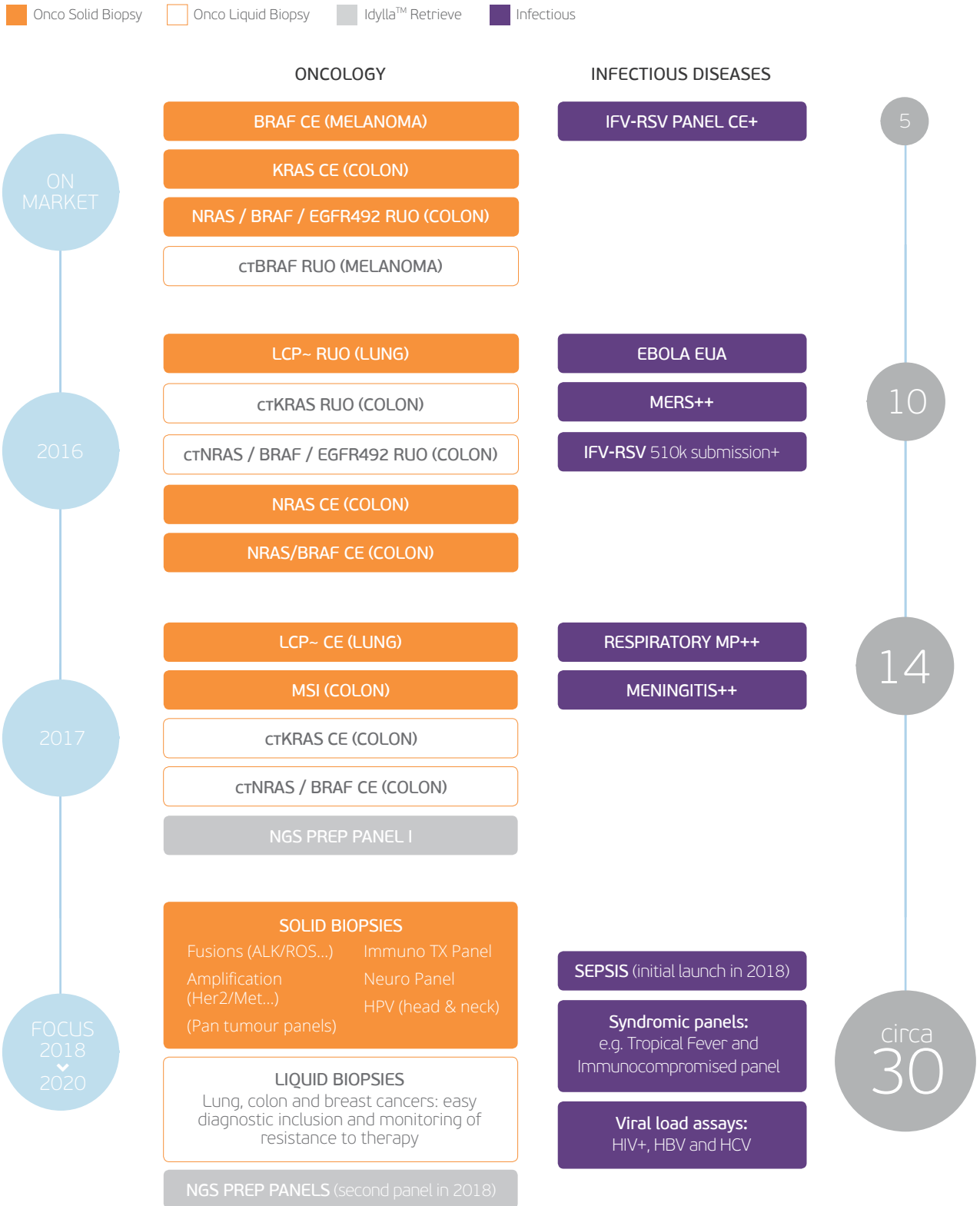
**Step 3:** The patient sample is added into the cartridge. By closing lid, the cartridge is hermetically sealed to prevent contamination of the instrument or laboratory.

**Step 4:** The cartridge is inserted into one of the available instruments, which will subsequently execute the appropriate test protocol. After completion of the test, results are displayed on the console.

<sup>10</sup> Biocartis believes Idylla™ has the potential to become a CLIA-Waived platform, i.e., a platform that, in accordance with applicable US rules and regulations (including the CLIA), is authorised for use in the United States outside of specialised, dedicated laboratory environments and without the need for technically specialised and highly trained staff.

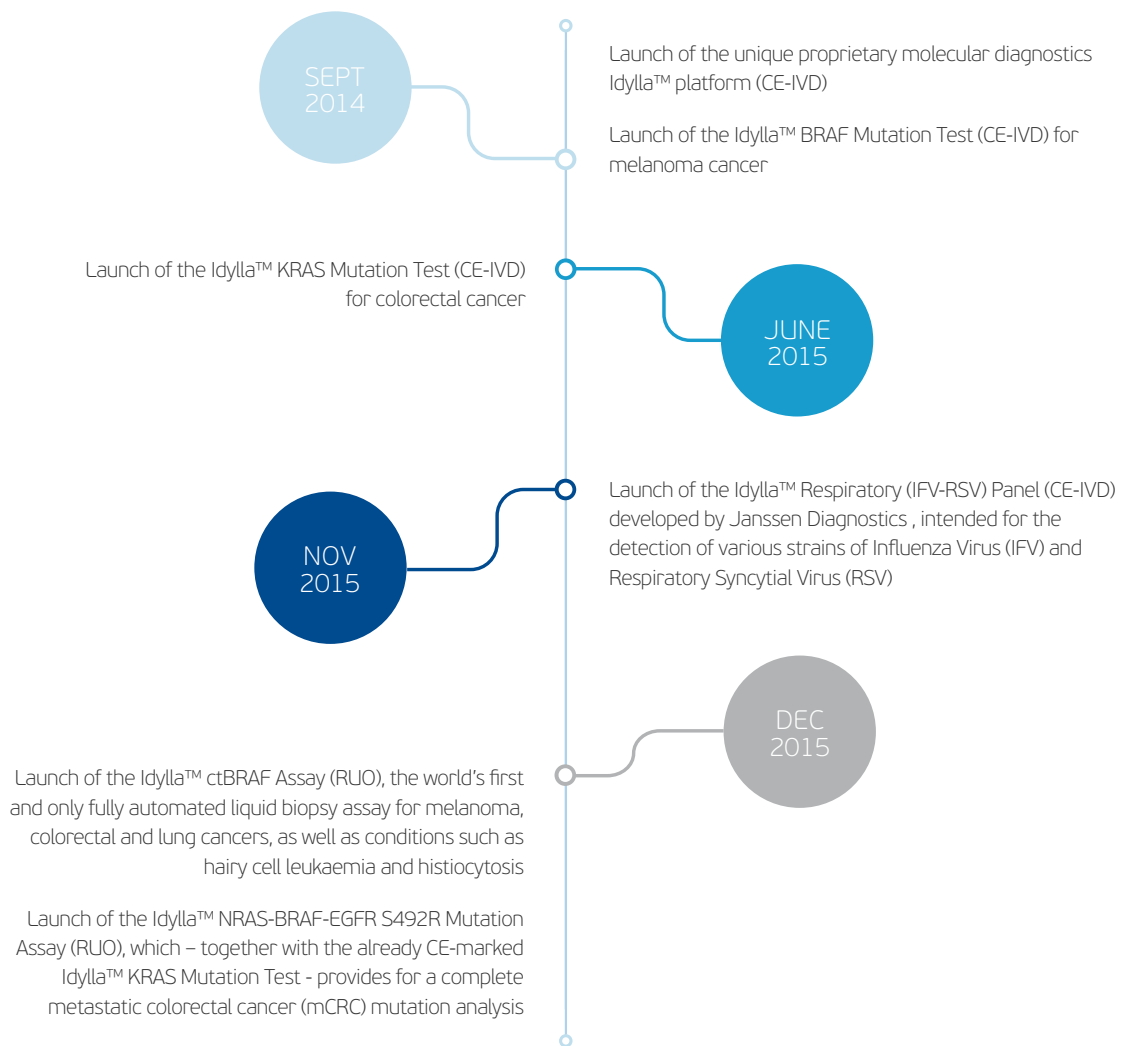
### 1.5.3.2. Menu of tests

Biocartis is developing a range of rapid and accurate tests for use on the Idylla™ platform focusing on oncology and infectious diseases as disease areas with significant unmet needs, where the Idylla™ solution can make a real difference thanks to its unique features. Biocartis intends to launch minimum four tests per year.



CE = CE-marked tests. RUO = Research Use Only. EUA = Emergency Use Authorisation label + Jn] test ++ Fast-track Diagnostics development. ~ LCP = lung cancer panel  
 Note: overview is subject to changes in prioritisation of test development driven by several factors such as commercial and operational considerations. Overview excludes regional expansion (as of 2017), life cycle management and potential partner tests.

The following products are currently commercialised:



## Oncology

Tumor mutation status is usually assessed starting from FFPE tumor tissue material. Currently the process from sample to result is labor-intensive, requiring multiple steps. Most laboratories do not perform these tests in-house, but send them out to specialised centers, where samples are batched in order to optimise costs. This leads to long turnaround times from sample to result.

Idylla™ tests are specifically designed for used on the Idylla™ platform, allowing rapid and accurate testing close to the point of care.

## Solid tissue tests

### 1. Idylla™ BRAF Mutation Test (CE-IVD)



About 50 percent of all melanomas harbor mutations in the BRAF oncogene.

The Idylla™ BRAF Mutation Test detects BRAF mutations directly from FFPE tissue sections in 90 minutes with less than 2 minutes hands-on time, in a fully contamination-controlled design.

The Idylla™ BRAF Mutation Test has demonstrated excellent analytical sensitivity during clinical performance studies. It can detect BRAF V600E, E2, D, K, R and M mutations at an analytical sensitivity of 1% of mutant in wild type background in FFPE samples. Studies demonstrated excellent concordance with Illumina MiSeq deepsequencing technology (100%), with Roche's Cobas® BRAF V600 Mutation Test (96.7%) and with CLIA laboratory PCR-based sequencing and Sequenom™ MassARRAY (98%). A clinical validation study comparing Idylla™ with Pyrosequencing showed 97.9% agreement between both tests. Similar comparison of the Idylla™ BRAF Mutation Test with standard testing in the MD Anderson CLIA laboratory (Houston, Tx) showed 97.2% concordance with discordancy analysis all in favor of Idylla™.

The Idylla™ BRAF Mutation Test has achieved CE-IVD marking. The Idylla™ system and the Idylla™ BRAF Mutation Test are currently only sold in countries accepting the CE certification.

### 2. Idylla™ KRAS Mutation Test (CE-IVD)



About 45 percent of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the KRAS oncogene. Idylla™ KRAS Mutation Test detects KRAS mutations directly from FFPE tissue sections in approx. 2 hours with less than 2 minutes hands-on time, in a fully contamination-controlled design.

The Idylla™ KRAS Mutation Test, performed on the Biocartis Idylla™ system, is an in vitro diagnostic test for the detection of 21 relevant KRAS mutations in codons 12 and 13 (exon 2), codons 59 and 61 (exon 3) and codons 117 and 146 (exon 4).

The Idylla™ KRAS Mutation Test directly liberates DNA from FFPE tissue of human colorectal cancer for subsequent real-time PCR amplification and detection. The clinical validation study comparing the Idylla™ KRAS Mutation Test with a real-time PCR based reference method showed an agreement of 96.7% (95% CI 93.0% - 98.5%) for codons 12 and 13.

The Idylla™ KRAS Mutation Test has achieved CE-IVD marking. The Idylla™ system and the Idylla™ KRAS Mutation Test are currently only sold in countries accepting the CE certification.



### 3. Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay (RUO)



“WITH OUR NEW IDYLLA™ NRAS-BRAF-EGFR S492R MUTATION ASSAY, WE CAN NOW OFFER A COMPLETE RAS-BRAF ANALYSIS FOR ALL CLINICALLY ACTIONABLE BIOMARKERS, IN LINE WITH THE NEWEST CLINICAL GUIDELINES IN MCRC, TO BE PERFORMED ON A SAME-DAY BASIS. IN ADDITION, THE ASSAY INCLUDES THE RECENTLY DISCOVERED EGFR S492R MUTATION, ILLUSTRATING BIOCARTIS' CONTINUOUS DRIVE FOR INNOVATION.”

GEERT MAERTENS, CHIEF SCIENTIFIC OFFICER  
BIOCARTIS

46

Together with the CE-marked Idylla™ KRAS Mutation Test, the tissue biopsy Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay<sup>11</sup> provides for a complete metastatic colorectal cancer (mCRC) mutation analysis, from two slices of so-called formalin-fixed paraffin embedded (FFPE) tumour tissue. For the first time in the molecular pathology field, this assay allows to perform a complete RAS analysis on a same-day basis, opening up the route towards faster treatment selection<sup>12</sup>.

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.

The Idylla™ KRAS Mutation Test and new Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay together are able to detect 39 KRAS and NRAS mutations ('extended RAS') at high sensitivity, in line with the novel clinical guidelines as recently issued by ASCO/AMP/NCI (including 5% limit of detection). The new assay detects 18 NRAS mutations as well as five BRAF mutations, for which testing is now mandatory in patients with mCRC<sup>13</sup>. The assay also uniquely detects the so-called EGFR S492R mutation, which is associated with resistance to certain anti-EGFR therapies.

The Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, performed on the Biocartis Idylla™ system, is an in vitro diagnostic test for the qualitative detection of mutations in codons 12, 13, 59, 61, 117, 146 of the NRAS oncogene, codon 600 of the BRAF oncogene and codon 492 of the EGFR gene. The Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay directly liberates DNA from FFPE tissue of human colorectal cancer for subsequent real-time PCR amplification and detection.

<sup>11</sup> The Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay is intended for Research Use Only. Not for sale in the USA and Canada.

<sup>12</sup> At the 40th European Cancer Congress in September 2015 (Vienna, Austria), Biocartis presented a study called 'A solution for same-day extended RAS testing'.

<sup>13</sup> Diaz and Bardelli, Liquid Biopsies: Genotyping Circulating Tumor DNA. J clin Oncol (2014) 32: 579-586.

## Liquid biopsy

RESEARCH OVER THE LAST FEW YEARS<sup>14</sup> HAS SHOWN THAT FRAGMENTS OF TUMOUR DNA ARE SHED INTO THE BLOOD FROM PRIMARY TUMOURS OR METASTATIC SITES. THESE CIRCULATING DNA FRAGMENTS CAN BE USED FOR DIAGNOSTIC PURPOSES, SUCH AS PROVIDING MOLECULAR INFORMATION FOR TREATMENT SELECTION, OR FOR MONITORING DISEASE PROGRESSION IN PATIENTS UNDERGOING TREATMENT. THIS OBSERVATION HAS LED TO THE DEVELOPMENT OF TECHNOLOGIES FOR LIQUID BIOPSY TESTING. ACCORDING TO J.P. MORGAN, THE GLOBAL MARKET OF LIQUID BIOPSY TESTS IS ESTIMATED TO REACH \$20 BILLION BY 2020.

### 4. Idylla™ ctBRAF Mutation Assay (RUO), a revolution in liquid biopsy cancer research



47

The Idylla™ ctBRAF Mutation Assay is the world's first and only fully automated liquid biopsy assay.

The use of liquid biopsies has the potential to transform cancer diagnostics and extend the application from disease confirmation to patient monitoring and even early diagnosis.

Taking a tissue biopsy is an invasive method of obtaining a patient sample, with an increased risk for complications compared to a blood draw. Moreover, a tissue biopsy only represents a single location of the primary tumor or a single metastasis and doesn't represent heterogeneity found in different nodules or areas of the tumor. A less invasive, more convenient, rapid and cost-effective way of obtaining

this information is using plasma samples for the diagnosis and management of cancer. In the plasma of most cancer patients, circulating tumor DNA (ctDNA) can be found with the same biomarker profile as the tumor tissue, making this the ideal sample type for a wide range of applications like mutation detection and disease monitoring<sup>15</sup>.

Some tissue biopsies are difficult to reach or provide insufficient material for genotyping<sup>16</sup>. In these cases, liquid biopsies could become the primary solution for proper diagnosis. During or after effective treatment, where the tumor is hardly or not detectable, liquid biopsies would be exquisitely suited for monitoring treatment efficacy and early detection of relapse<sup>17</sup>.

<sup>14</sup> Diaz and Bardelli, Liquid Biopsies: Genotyping Circulating Tumor DNA. J clin Oncol (2014) 32: 579-586

<sup>15</sup> Genotyping cell-free tumor DNA in the blood to detect residual disease and drug resistance. Giulia Siravegna and Alberto Bardelli; Genome Biology 2014, 15:449.

<sup>16</sup> Detection of Circulating Tumor DNA in Early- and Late-Stage Human Malignancies. Chetan Bettegowda et al.; Science Translational Medicine 2014, Vol 6 Issue 224.

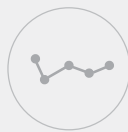
<sup>17</sup> Actionable Mutations in Plasma Cell-Free DNA in Patients with Advanced Cancers Referred for Experimental Targeted Therapies. Janku et al; Oncotarget 2015, Vol. 6 No. 15. Liquid biopsy: monitoring cancer-genetics in the blood. Crowley E. et al.; Nature Reviews Clinical Oncology 2013 10, 472-484. Analysis of circulating DNA and protein biomarkers to predict the clinical activity of regorafenib and assess prognosis in patients with metastatic colorectal cancer: a retrospective, exploratory analysis of the CORRECT trial. Tabernero et al.; The Lancet Oncology 2015, Vol. 16 No. 8.

“THE IDYLLA™ PLATFORM HAS THE POTENTIAL TO ALLOW THE START OF TARGETED THERAPY WITHIN A TIME WINDOW OF LESS THAN 24 HOURS FOLLOWING THE DIAGNOSIS OF METASTASIS BY ANALYSING TUMOR OR ctDNA, THUS SAVING PRECIOUS TIME.”

PROF. B. NEYNS, M.D., PH.D, MEDICAL ONCOLOGY, UZ BRUSSELS, BELGIUM



**Mutation detection:** detection of mutated ctDNA in plasma can complement, or even replace, in certain situations, tissue mutation detection.



**Monitoring:** monitoring of treatment by means of ctDNA in plasma is a convenient way of regular testing of genetic changes, which is not practically feasible by means of solid biopsies. First, the rate of reduction of targeted mutations can be analysed and patients can be categorised in rapid and slow responders to treatment. Secondly, the emergence of the original targeted mutations and/or new upcoming resistance mutations can be monitored in responding patients. Finally, patients with complete responses can be further monitored for minimal residual disease.

The test can potentially act as a substitute for tissue biopsy testing in melanoma, colorectal and lung cancers, as well as conditions such as hairy cell leukaemia and histiocytosis<sup>18</sup>. The assay has a turnaround time of approximately 90 minutes with less than one minute of hands-on time. With an earlier prototype of the assay, Schreuer et al. have shown that analysis of BRAF mutant circulating tumour DNA (ctDNA) from plasma using Idylla™ allows for a rapid determination of the BRAF status in samples from patients with advanced melanoma, and that the amount of mutant BRAF ctDNA may be an indication of tumour growth. The ability to rapidly analyse BRAF mutations in plasma of patients holds promise as a therapeutic monitoring tool for patients with advanced BRAF V600 mutant melanoma.

<sup>18</sup> Histiocytosis is a general name for a group of disorders or “syndromes” that involve an abnormal increase in the number of immune cells that are called histiocytes. Source: <https://www.nlm.nih.gov/medlineplus/ency/article/000068.htm>, December 2015.



## Infectious diseases

### 5. Idylla™ Respiratory (IFV-RSV) Panel (CE-IVD)



Less than 1 minute hands-on time



50 minute turnaround time



Samples can be obtained directly from nasopharyngeal swab in viral transport media (VTM)

On 30 November 2015, Biocartis launched its first infectious disease test on the Idylla™ platform. The Idylla™ Respiratory (IFV-RSV) Panel has been developed by Janssen Diagnostics and is intended for the detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV). The Idylla™ Respiratory (IFV-RSV) Panel received CE-IVD marking on 18 November 2015 and was being launched for commercial use in Europe and other geographies recognising the CE-mark. Janssen Diagnostics has appointed Biocartis as co-exclusive worldwide distributor of the test.

Respiratory viruses are one of the most important causes of morbidity and mortality throughout the world with the influenza virus killing at least 50 million and up to 100 million people in the last century alone<sup>19</sup>. The majority of diagnostic tests currently used for this market are rapid immunoassays which are chosen due to their low cost and convenience. However, one of the key downsides of these rapid tests is their poor sensitivity. Negative samples are typically re-tested in a central lab with a more sensitive molecular test, delaying time-to-result by many hours. The new Idylla™ Respiratory (IFV-RSV) Panel, running on the Idylla™ platform, combines in one single product the speed of rapid tests with the quality and sensitivity standards of central lab tests.

The Idylla™ Respiratory (IFV-RSV) Panel is designed for the qualitative detection of nucleic acids of Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, H275Y mutation of Influenza A subtype 2009 H1, Influenza B and Respiratory Syncytial Virus (RSV) subtype A and RSV subtype B from nasopharyngeal swabs (NPS) of adult and pediatric patients, using the Idylla™ molecular diagnostics platform to aid in the diagnosis of respiratory viral infection.

Each Single-use cartridge can identify:

- Influenza A or B
- For Influenza A, the panel can discriminate between H1, H3, 2009-H1N1, and H275Y oseltamivir resistance mutation
- RSV A or B

#### Example: Idylla™ IFV-RSV results

|                               |              |
|-------------------------------|--------------|
| Influenza A                   | Detected     |
| AH1                           | Not detected |
| AH3                           | Not detected |
| 2009-H1N1                     | Detected     |
| H275Y                         | Detected     |
| Influenza B                   | Not detected |
| Respiratory Syncytial Virus A | Not detected |
| Respiratory Syncytial Virus B | Not detected |

The Idylla™ Respiratory (IFV-RSV) Panel is the first of a series of infectious disease tests that Biocartis and its partners are developing for use on the Idylla™ platform.

<sup>19</sup> WHO: The global burden of disease: 2004 update. WHO Press, Geneva, Switzerland



CHAPTER 2

# The Biocartis Share

“

FAST DIAGNOSTICS INFORMATION IS ALL ABOUT PATIENT IMPACT: THE POSSIBILITY TO OBTAIN TEST RESULTS AND TREATMENT ON THE SAME DAY IS WHAT TRULY MAKES A DIFFERENCE.”

PROF. CLARA MONTAGUT, CHIEF MEDICAL ONCOLOGIST GASTROINTESTINAL CANCER UNIT, MEDICAL ONCOLOGY DEPARTMENT, HOSPITAL DEL MAR (BARCELONA, SPAIN)

| Name          | Last     |
|---------------|----------|
| BIOCARTIS AIW | 3 808.   |
| BEL 20        | 14.      |
| AB INBEV      | 19.3     |
| GDF SUEZ      | 58       |
| KBC           | 134.     |
| SOLVAY        | 34.      |
| AGEAS         | 17.4     |
| DELTA LLOYD   | 81.      |
| DELHAIZE GROU | 69.      |
| UCB           | 79.      |
| GACOM         | 34.0     |
| CORE          | 41       |
| INIMMO        | 100      |
| INDEX CAC 40  | Last     |
|               | 504.58   |
|               | Last     |
|               | 5 196.75 |

BRUSS

|     | %Chng | Time     | Turnover   |
|-----|-------|----------|------------|
| 18  | 23.30 | 09:09:55 | 7 169 098  |
| 39  | 0.22  | 09:09:45 | 14 343 309 |
| 3.4 | -0.18 | 09:09:55 | 3 603 543  |
| 35  | 0.23  | 09:09:55 | 2 974 595  |
| 3.5 | -0.07 | 09:09:54 | 1 508 232  |
| 95  | 0.22  | 09:09:55 | 1 421 947  |
| 23  | 0.53  | 09:09:55 | 1 164 959  |
| 95  | 0     | 09:09:53 | 978 799    |
| 33  | 0.10  | 09:09:55 | 863 874    |
| 02  | 0     | 09:09:54 | 586 039    |
| 94  | 0.20  | 09:09:55 | 406 239    |
| 35  | -0.28 | 09:09:55 | 422 415    |
| .8  | 0.34  | 09:09:52 | 364 326    |
| .1  | -0.30 | 09:09:55 | 313 669    |

| PSI 20 | EURONEXT 100 | NEXT 150 | BEL MID INDE |
|--------|--------------|----------|--------------|
| Last   | Last         | Last     | Last         |
| 6 048  | 1 013.65     | 2 480.68 | 4 542.41     |



## 2. The Biocartis share

### 2.1. Outstanding shares and share capital

Biocartis shares are traded on Euronext Brussels following the company's IPO in April 2015 under symbol BCART (ISIN code BE0974281132). On 31 December 2015, a total of 40,544,188 shares were outstanding (each share entailing one voting right) that represent a total share capital of EUR 405,441.88.

Given the company's stock options plans and outstanding warrants, an additional number of 5,411,935 shares (each share entailing one voting right) can still be issued, of which:

- 904,172 shares can be issued upon the exercise of 904,172 outstanding stock options (each stock option having the form of a warrant) that are still outstanding under the '2013 Plan' for employees, consultants and management members, entitling the holders thereof to acquire one new share per option;
- 262,934 shares can be issued upon the exercise of 262,934 outstanding stock options (each stock option having the form of a warrant) that are still outstanding under the '2015 Plan' for employees, consultants, management members and directors, entitling the holders thereof to acquire one new share per option;
- 67,000 shares can be issued upon the exercise of 67,000 warrants, called 'WHC Warrants', granted to Whitemarsh Capital LLC, a commercial partner of Biocartis, with each warrant exercisable into one share;
- 4,177,829 shares can be issued pursuant to a conversion option agreement entered into between Koninklijke Philips NV (Philips) and the Company<sup>20</sup>.

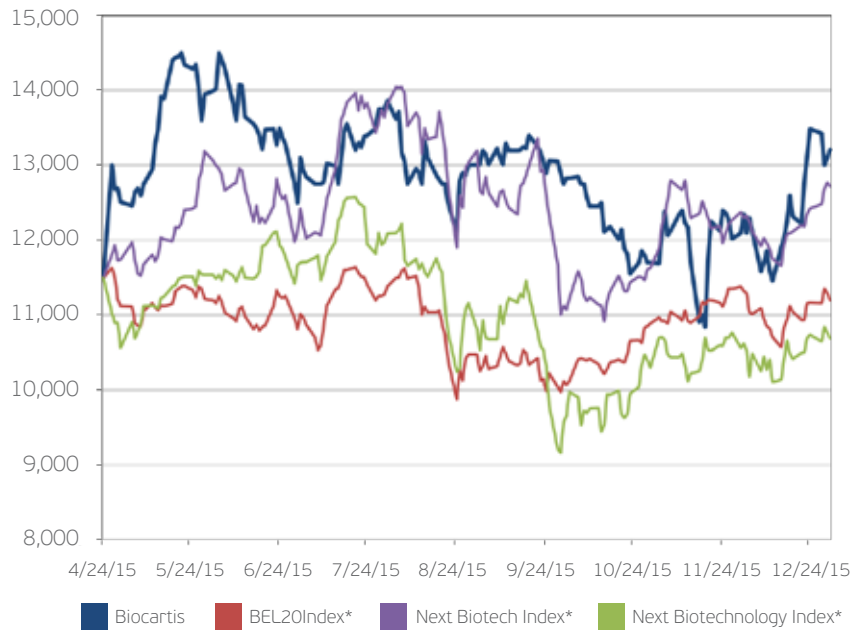
The total number of fully diluted shares consequently amounted to 45,956,123 as of 31 December 2015. More information on the stock option plans can be found in chapter 4, 'Remuneration report'. More information on the outstanding warrants can be found under 'Warrant plans' in this chapter.

<sup>20</sup> The conversion option agreement allows Philips to convert certain royalty and other payments due to it up to a maximum of 10% of the then outstanding capital of the Company on a fully diluted post-money basis, but only if the Company has not yet made a lump sum payment in lieu of such royalty and other payments, and the conversion can only be exercised by Philips upon the acceptance of the exercise by the Company at its sole discretion. The number of 4,177,829 shares that can still be issued assumes that all outstanding warrants (entailing the issue of up to 1,234,106 new shares) have been exercised, it being understood that the actual number of shares issuable depends on a number of factors.

## 2.2. Share performance

Biocartis' IPO was priced at EUR 11.50 on April 24 2015. The closing price of the Biocartis share on 31 December 2015 was equal to EUR 13.21. Please find below an overview of Biocartis' share price performance compared to three relevant stock indices:

- BEL20 Index (Belgium focused): the benchmark stock market index for Euronext Brussels;
- Next Biotech Index (European focused): composed of companies listed on Euronext and Alternext markets, classified (according to the ICB classification) as 4573 being Biotechnology; and
- Nasdaq Biotechnology Index (US focused); a stock market index made up of securities of NASDAQ-listed companies classified according to the Industry Classification Benchmark as either Biotechnology or Pharmaceuticals.



\* Rebased at Biocartis' IPO price of EUR 11.5 on 24 April 2015

Source: Bloomberg

## 2.3. Trading volume

Please find opposite a summary of the trading volumes in 2015 of Biocartis' share:

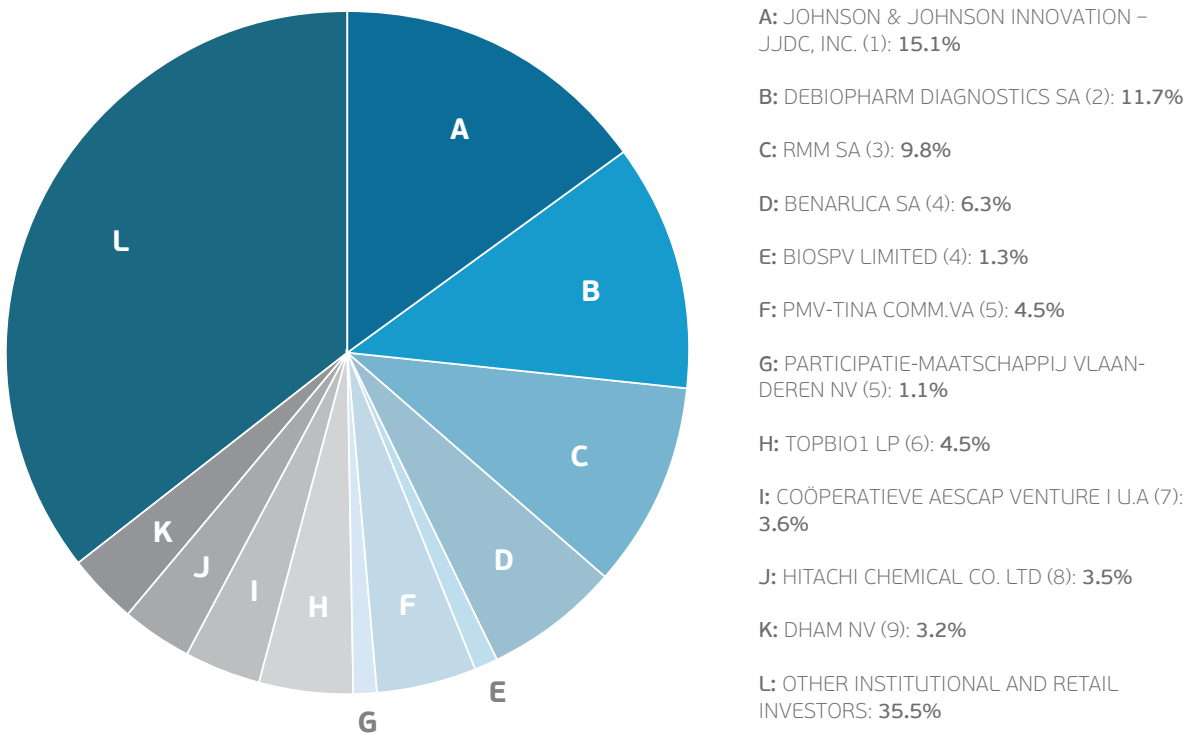
| BCART                | 2015        |
|----------------------|-------------|
| Average daily volume | 45,800      |
| Average daily value  | 12.87       |
| Total traded volume  | 8,152,448   |
| Total traded value   | 106,367,526 |

Source: Euronext

## 2.4. Shareholders

### 2.4.1. Major shareholders

Biocartis has an international shareholder structure with both large and smaller specialised shareholders in pharma and life sciences as well as a broad base of more local retail investors. Based on the most recent number of shares and transparency notifications, the shareholder structure of Biocartis is as follows:



The Articles of the Association of BIOCARTIS NV provide for shareholders notification threshold of 3%, 5% or a multiple of 5% (i.e. 10%, 15%, 20% etc) of the total number of existing voting rights. In 2015, threshold notifications were published on 5 June 2015, 30 June 2015, 21 October 2015 and 23 December 2015.

#### Notes:

(1) Johnson & Johnson Innovation--JJDC, Inc., is a wholly owned subsidiary of Johnson & Johnson. Johnson & Johnson is not a controlled entity.

(2) Debiopharm Diagnostics SA is controlled by Debiopharm Holding SA, which is controlled by Rolland-Yves Mauvernay.

(3) Rudi Mariën controls RMM SA. RMM SA entered into a stock lending agreement with KBC Securities NV, as Global Coordinator with respect to the Offering, to allow KBC Securities NV to over-allot shares in the Offering within the framework of an over-allotment facility consisting of up to a maximum of 15% of the number of new shares that were effectively placed in the Offering (representing 1,304,347 shares). The 3,989,058 voting rights and the 10.19% of shares before exercise of the Over-allotment Option include the number of voting rights attached to shares that were lent to KBC Securities NV in application of the stock lending agreement. On the date hereof, the stock lending agreement has ended and the shares that were lent to KBC Securities NV have been returned to RMM SA.

(4) Rudi Pauwels controls BioSPV Limited and Benaruca SA.

(5) Het Vlaams Gewest controls ParticipatieMaatschappij Vlaanderen nv. ParticipatieMaatschappij Vlaanderen nv owns 100% of the shares of PMV-TINA Comm.VA and hence controls PMV-TINA Comm.VA.

(6) Topbio 1 LP is not a controlled entity.

(7) Aescap Venture I Management BV controls Cooperatieve Aescap Venture I U.A. Aescap Venture I Management BV is not a controlled entity.

(8) 51.2% shares of Hitachi Chemical Co., Ltd. is directly held by Hitachi, Ltd., which is a parent company of Hitachi Chemical Co., Ltd. Hitachi Ltd is not a controlled entity.

(9) DHAM NV is controlled by Halse Investeringsmaatschappij NV, which is controlled by Korys NV, which in turn is controlled by Stichting Administratiekantoor Cozin. Stak Cozin is not a controlled entity.

## 2.4.2. Warrant plan

### 2.4.2.1. Stock based incentive plans

The Company has a number of stock based incentive plans, consisting of:

- the 2008 Plan
- the 2013 Plan
- the 2015 Plan

The options under the 2013 Plan and 2015 Plan have the form of a warrant with respect to new shares. The options under the 2008 Plan are options in relation to existing shares and do not have the form of a warrant. The 2008 is therefore a non-dilutive plan. The details of these plans are further described in the remuneration report.

### 2.4.2.2. Philips conversion option agreement

On 15 August 2011, Biocartis SA and Koninklijke Philips NV ('Philips') entered into a conversion option agreement, as amended and restated, on the basis of which shares of Biocartis may be acquired subject to the terms and conditions of that conversion option agreement. The conversion option is stipulated as follows: "At Biocartis' sole discretion, Philips shall be granted the right to convert all or part of the Third Milestone Payment, Royalties and Initial Revenue Sharing Payments, all as specified in the Polaris IP Agreement, into Biocartis shares it being understood that:

- Under all circumstances Philips can only convert up to a maximum of 10% of the then outstanding capital of the Company on a fully diluted post-money basis, and Philips hereby accepts the options pursuant to the terms and conditions of the conversion option agreement.
- The conversion of the Initial Revenue Sharing Payments and/or Royalty Payments as specified under the Polaris IP Agreement can only take place in so far as the Company has not exercised the buy-out right granted to it under clause 3.2 of the Polaris IP Agreement." The Polaris IP Agreement refers to the intellectual property assignment and intellectual property license agreement pursuant to which Philips assigned certain patents and patent applications and know-how in relation to the Idylla™-Enrich technology to Biocartis, and the buy-out right refers to the option of Biocartis to make a lump sum payment in

lieu of all further revenue sharing payments and royalties to Philips under this agreement.

On 25 November 2014, the conversion option agreement was rolled up in order to relate to the Company and the Company's shares. This conversion right can only be exercised by Philips upon acceptance of the exercise by the Company. The price to be paid in relation to the shares upon conversion shall be the underlying stock price of the Biocartis shares.

### 2.4.2.3. Whitemarsh capital warrants

In execution of a decision of the board of directors of Biocartis SA of 24 April 2014, 100,000 options on shares of the Company were granted by Biocartis SA to Whitemarsh Capital LLC, a commercial partner of Biocartis that assists in brokering agreements for Biocartis with US governmental institutions for the payment of its products. On 25 November 2014, the option grant was rolled up in order to relate to the Company and the Company's shares instead of shares in Biocartis SA. The options, called 'WHC Warrants', were formally granted by an award letter on 14 April 2015. The WHC Warrants have the following features: (i) each WHC Warrant can be exercised into one share, (ii) the WHC Warrants were granted for no additional consideration, (iii) the WHC Warrants have a term of five years, (iv) the exercise price of the WHC Warrants is EUR €8.1308, and (v) the WHC Warrants are not transferable by Whitemarsh Capital LLC. The WHC Warrants will vest as follows: (i) 33,000 WHC Warrants can be exercised when Biocartis enters into a first agreement with a US governmental institution as a result of the intermediation by Whitemarsh Capital LLC before 18 April 2015, (ii) 33,000 WHC Warrants can be exercised if Biocartis has effectively realised a turnover of at least US \$1 million before 18 April 2016 under the agreements that Biocartis has entered into with US governmental institutions as a result of the intermediation by Whitemarsh Capital LLC, and (iii) 34,000 WHC Warrants can be exercised if Biocartis has effectively realised a turnover of at least US \$3 million before 1 January 2017 under the agreements that Biocartis has entered into with US governmental institutions as a result of the intermediation by Whitemarsh Capital LLC. The board of directors can decide to accelerate the vesting of the WHC Warrants in the event of a change of control. None of the WHC Warrants have vested to this date and the first 33,000 WHC Warrants will not vest, thus at the date of this annual report, 67,000 shares are covered by this agreement.

## 2.5. Analyst coverage

The Biocartis share is actively covered by three renowned brokers as shown in the table below.

| <b>BROKER</b>    | <b>ANALYST</b>    | <b>RATING END 2015</b> | <b>TARGET PRICE END 2015</b> |
|------------------|-------------------|------------------------|------------------------------|
| KBC Securities   | Jan De Kerpel     | Buy                    | EUR 16.50                    |
| Kempen & Co      | Anastasia Karpova | Buy                    | EUR 16.00                    |
| Degroof Petercam | Roderick Verhelst | Buy                    | EUR 17.20                    |

## 2.6. Financial calendar

### **BCART**

|  |                  |
|--|------------------|
| Q1 Business Update                     | 12 May 2016      |
| Annual General Meeting Biocartis Group | 13 May 2016      |
| Half year results H1 2016              | 6 September 2016 |
| Q3 Business Update 2016                | 17 November 2016 |

## 2.7. Investor relation details

For any investor relation related questions, please contact:

Renate Degrave

**Biocartis**

Generaal De Wittelaan 11 B3

2800 Mechelen (Belgium)

tel. +32 15 631 729

[rdegrave@biocartis.com](mailto:rdegrave@biocartis.com)







CHAPTER 3

# Corporate Governance

58

“

“FAST, RELIABLE AND ACCURATE. THESE ARE THREE CHARACTERISTICS OF IDYLLA™ THAT CAN THOROUGHLY CHANGE THE LIFE OF A PATIENT.”

PROF. PATRICK PAUWELS, PROFESSOR PATHOLOGY AND DIRECTOR OF THE MOLECULAR PATHOLOGY UNIT AT ANTWERP UNIVERSITY HOSPITAL



# 3. Corporate Governance

## 3.1. Introduction

The Company applies the Belgian Code on Corporate Governance as published on 12 March, 2009 (the 'Code'), that can be consulted on the website of the Corporate Governance Committee ([www.corporategovernance-committee.be](http://www.corporategovernance-committee.be)). In accordance with the Code, the Company has adopted a corporate governance charter on 13 April 2015 that came into effect upon the public listing of the shares of the Company on 27 April 2015.

The corporate governance charter was updated at the meeting of the board of directors of 25 November 2015 to reflect the new governance structure of the Company.

The corporate governance charter describes the main aspects of the corporate governance of the Company, including its governance structure, the terms of reference of the board of directors and its committees and other important topics. The corporate governance charter must be read together with the articles of association of the Company. Furthermore, the Company applies the flexibility provided by the Code and thus complies in general with the corporate governance provisions set forth in the Code, except in relation to the following two matters;

- The Company awards stock based incentives to the independent directors, upon advice of the remuneration and nomination committee. This is contrary to provision 7.7 of the Code that provides that non-executive directors should not be entitled to performance-related remuneration such as (amongst others) stock related long-term incentive schemes. The Company justifies this as it allows to limit the portion of remuneration in cash that it would otherwise need to pay to attract or retain (internationally) renowned experts with the most relevant skills, knowledge and expertise, and as this is customary for directors active in companies in the biotech and life sciences industry, and as the portion of the remuneration payable in options is limited.

- The audit committee of the board of directors is composed exclusively of non-executive directors, of which two are independent directors. However, as the audit committee is composed of four members it does not have a majority of independent directors. This is contrary to provision 5.2/4 of the Code which provides that at least a majority of the audit committee's members should be independent. The chairman of the audit committee, however, is an independent director and has a casting vote. The Company justifies this as it allows the audit committee to draw on the additional (sector) expertise of members of the board of directors that have financial and auditing expertise.

The articles of association and the corporate governance charter are made available on the Company's website ([www.biocartis.com](http://www.biocartis.com)).

## 3.2. Internal & External control

### 3.2.1. External control

The Company's current statutory auditor is Deloitte Bedrijfsrevisoren BV owe CVBA, represented by Gert Vanhees, auditor. The statutory auditor performs the external audit of the consolidated and statutory accounts of the Company and of its Belgian subsidiary (Biocartis NV). The statutory auditor has been appointed for the statutory term of three years at the Company's incorporation on 24 November 2014 and thus the auditor's term will end at the annual general assembly in 2018.

In 2015 a total amount of EUR 396,882 was paid to Deloitte. This amount includes the following elements: EUR 95,750 for audit fees, EUR 278,217 for work performed in the framework of the IPO of the Company

(of which EUR 250,000 was pre-approved by the audit committee in accordance with article 133 §6 of the Company Code), EUR 2,915 for work performed in relation to legal mission work of the Company (warrant plans), EUR 2,625 for tax related work and EUR 17,375 for IFRS accounting advice.

### 3.2.2. Internal control

Biocartis has taken different steps to identify the most important risks that it is exposed to and to keep these risks at an acceptable level. The different risks have been identified in this report under the section 'Risks related to our business'. The control activities of Biocartis include the measures taken by it to ensure that the most important risks, which were identified, are controlled or mitigated. Biocartis manages some of its risks, e.g. property and material damage, business interruption, cyber risk by entering into insurance contracts covering such risks.

As indicated in this report the board of directors set up an audit committee that gives guidance and controls the financial reporting of the Group. It ensures the presence of sufficient internal control mechanisms and, in co-operation with the statutory auditor of the Group, investigates questions which are in relation to accounting and valuation rules. The audit committee more specifically reviews the management reporting and budget and gives its recommendation with regards to these documents to the board of directors.

Biocartis has set up control policies and risk management systems to ensure that the main business risks are properly identified, managed and disclosed. The objectives of the Biocartis internal control framework are achieving effectiveness and efficiency of operations, reliability of financial reporting, compliance with applicable laws and regulations and the safeguarding of assets. Hereto, Biocartis has established a number of instruments that are discussed on a regular basis in the audit committee and are presented to the board of directors:

- Long term financial planning and annual budgets: at least once per year the management of Biocartis



prepares the annual budget. This is a very important instrument to control activities of the Group and combines strategy, risk, business plans and intended results. The budget is also used as a basis to define the most important company goals for the financial year. The performance against the budget and company goals is monitored monthly by the finance team and discussed in management meetings. It is also presented to the audit committee and the board of directors. In addition, the management and board of directors also prepare and update a longer term financial plan to crystallise the longer term strategy of Biocartis.

- Monthly management information reports and financial accounts to monitor (actual) performance versus (budget) objectives: Every month management prepares a detailed management information report (MIR) covering all activities of the Group (commercial, development, strategic, IP, HR, etc.). The MIR also maps the company's ongoing progress against the yearly budget and longer term strategic and R&D development goals.
- Statutory financial and tax reporting per legal entity, and IFRS financial accounts on a consolidated level: management prepares and presents to the audit committee and the board of directors the above mentioned accounts on at least a half year basis.

In order to ensure the quality and reliability of the financial information, Biocartis has established different standardised information flow processes, consistent throughout the entire organisation. The most important financial processes are designed to ensure data consistency and comparability as well as to detect potential anomalies; they include the following processes; expenditure, revenue, inventory, fixed assets, financial closing and treasury processes.

Management defines the values as well as the skills and job descriptions needed for all functions and tasks within the organisation. Biocartis is organised around four key activities and for all functions, clear areas of responsibilities are defined as well as horizontal communication processes ensuring involvement of different functions in more complex and multilayered issues.

In addition to the foregoing, Biocartis has also developed a vast set of procedures and workflows on key business cycles that are all documented through a unique IT system. The system is designed to help meet the quality levels required for the Company's products and is one of the elements used by the quality department to ensure product and process compliance with the regulatory framework. Further details on the quality management system are provided below.

Before commercialising its products, Biocartis performs the necessary tests to reach the level of quality acceptance. In order to try to assure the best possible quality standards during production, Biocartis has installed an in-house quality team that is present in the different stages of product development and manufacturing.

### 3.2.3. Quality management system

Biocartis has established, documented and implemented a quality management system ('QMS') compliant with the international standards and regulations for design and development, for manufacturing and testing and for customer facing processes. The quality system covers all of Biocartis' products and tests. In the future, Biocartis intends to further develop the quality system to cover the regulatory requirements of other major territories, including China, US, Japan, Brazil, Australia, Russia, the Middle East, South Korea and Singapore.

Biocartis currently holds ISO 13485:2012 (Medical devices—Quality Management Systems—Requirements certification for regulatory purposes), ISO 13485:2003 as for CMDCAS (Medical Devices and QMS for Canadian Medical Devices Conformity Assessment System) and ISO 9001:2008 (Quality Management Systems) certificates covering its design and development activities, its manufacturing and testing activities and its customer related processes, in Mechelen (Belgium)

and has elected TÜV Rheinland as its registrar and notified body. Biocartis also complies with the following standards:

- The IVD Directive;
- EN ISO 14971:2012(C) (Medical devices—Application of risk management to medical devices);
- EN IEC 62304:2006 (Medical device software—Software life cycle processes); and
- EN IEC 62366:2008 (Medical devices—Application of usability engineering to medical devices).

In addition, Biocartis is implementing the requirements of FDA QSR 21 CFR chapter 820 (Quality System Regulation) to comply with the FDA regulations governing IVD devices.

All processes needed for the QMS and their application throughout the organisation are defined in the QMS process. This process-based model describes the sequence and interaction between these processes and illustrates that customers are of significant importance for defining requirements as inputs in Biocartis' quality management processes as well as in monitoring its effectiveness. Each of the underlying key processes is described in procedures and work instructions that are deployed throughout the organisation.

Biocartis has established an Internal Audit Program to verify compliance with the QMS, planned arrangements for product realisation, requirements from standards and regulations for QMS (like ISO13485 and 21CFR820), and internal requirements established as per Biocartis' Quality Manual and Quality Policy.

All feedback loops within Biocartis' process model for measurement, analysis and improvement have been set up to interface with the determination of corrective and preventive actions to eliminate the cause of (potential) nonconformities and feed the continuous improvement process.

## 3.3. Protection schemes

### 3.3.1. Introduction

All the shares of the Company belong to the same class of securities and are in registered or dematerialised form. With the exception of what is stated below under 'Lock-up', the shares of the Company are freely transferable.

### 3.3.2. Lock-up

A number of the shareholders of the Company and some members of the executive management team have entered into a lock-up arrangement with the KBC Securities (at the time of the IPO the Global Coordinator) in respect of (i) the shares and all other instruments with the characteristics of a share ('effecten met een aandelenkarakter') as defined in article 6 of the Belgian Prospectus Act, (ii) securities, certificates and contractual rights (including options, futures, swaps and other derivatives) issued or contracted by the Company, an affiliate of the Company or in cooperation with the Company or any of its subsidiaries and representing, giving right to or being exchangeable for, any of the financial instruments referred to in (i), and (iii) securities issued in exchange for the financial instruments referred to in (i) and (ii) in the framework of a merger, demerger, spin-off of the Company (together 'Locked Financial Instruments') in each case, as outstanding from time to time and whether held now by a person or acquired in the future. Pursuant to the lock-up arrangement they will not directly or indirectly, except as set forth below, for a period of 6 months from the 'Listing Date' (i.e. 27 April 2015): (i) sell, exchange, pledge, assign by way of security, grant any right "in rem", deliver or offer or market, a Locked Financial Instrument whether for consideration or for free, (ii) enter into any option or any future (whether or not settled in cash) or otherwise dispose of or agree to dispose of (whether conditionally or unconditionally, now or in the future) any Locked Financial Instrument, (iii) enter into any swap, any arrangement, any derivative transaction (whether or not settled in cash) or issue any instruments that transfer (conditionally or unconditionally, now or in the future) to a third party all or part of the economic risk, benefits, rights or ownership of a Locked Financial Instrument, and (iv) announce any of the above or the intention thereto.

Following this 6 month-period, a new period of 6 months starts during which the shareholders and executive management members may only transfer the shares provided that (i) one or more shareholders that hold in the aggregate at least 3% of the outstanding share capital at the time the request is made, shall have requested and obtained the prior approval of KBC Securities and (ii) any such transfer shall solely be effected through a coordinated sale.

None of the restrictions for the shareholders and executive management members referred to above apply to (i) transfers to legal successors or other transferees in case of death of a natural person or in case of liquidation, concursus, merger or demerger (provided, however, that the legal successor or transferee of such person adheres to the lock-up agreement and assumes the relevant transfer restriction obligations for the remaining term thereof), (ii) transfers between the shareholders and their affiliates (provided, however, that the affiliate adheres to the lock-up arrangement and assumes the relevant transfer restriction obligations for the remaining term thereof), (iii) acceptance of a public tender offer, (iv) any transfer of shares subscribed for or acquired after the IPO of the Company (except if those shares are acquired pursuant to one of the other exemptions), (v) any transfer of shares pursuant to the shadow option agreements entered into by the Company, Benaruca SA, Mr. Ferdinand Verdonck and Mr. Philippe Renaud dated 2 July 2009, as amended, in relation to the 2008 Plan (the details of which are further explained below), and (vi) any transfer of shares under a stock lending agreement to a financial institution for market making and liquidity providing purposes.

### 3.3.3. Appointment of directors

The directors are appointed for a term of no more than four years by the general shareholders' meeting. They may be re-elected for a new term. In the event the office of a director becomes vacant, the remaining directors can appoint a successor temporarily filling the vacancy until the next general shareholders' meeting. The general shareholders' meeting can dismiss the directors at any time.

### 3.3.4. Modifications to the articles of association

Amendments to the articles of association (other than an amendment of the corporate purpose) require the presence or representation of at least 50% of the share capital of the Company and a majority of at least 75% of the votes cast. An amendment of the Company's corporate purpose requires the approval of at least 80% of the votes cast at a general shareholders' meeting, which can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special majority requirements, however, remain applicable.

### 3.3.5. Right of the board of directors to increase the capital of the Company

On 13 April 2015, the general shareholders' meeting authorised, subject to and with effect as from the closing of the IPO, the board of directors to increase the share capital of the Company within the framework of the authorised capital with a maximum of 100%.

The general shareholders' meeting further decided that the board of directors, when exercising its powers under the authorised capital, is authorised to restrict or cancel the statutory preferential subscription rights of the shareholders (within the meaning of article 592 and following of the Belgian Companies Code). This authorisation includes the restriction or suppression of preferential subscription rights for the benefit of one or more specific persons (whether or not employees of the Company or its subsidiaries). The authorisation is valid for a term of five years as from the date of the publication of the authorisation in the Annexes to the Belgian State Gazette (*Belgisch Staatsblad/Moniteur belge*).

### 3.3.6. Public takeover bids

Public takeover bids for the Company's shares and other securities giving access to voting rights (such as warrants) are subject to supervision by the FSMA.

Any public takeover bid must be extended to all of the Company's voting securities, as well as all other securities giving access to voting rights. Prior to making a bid, a bidder must publish a prospectus which has been approved by the FSMA prior to publication.

The Belgian Takeover Act provides that a mandatory bid must be launched if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting for their account, directly or indirectly holds more than 30% of the voting securities in a company having its registered office in Belgium and of which at least part of the voting securities are traded on a regulated market or on a multilateral trading facility designated by the Belgian Takeover Decree. The mere fact of exceeding the relevant threshold through the acquisition of shares will give rise to a mandatory bid, irrespective of whether the price paid in the relevant transaction exceeds the current market price. The duty to launch a mandatory bid does not apply in certain cases set out in the Belgian Takeover Decree such as (i) in case of an acquisition if it can be shown that a third party exercises control over the company or that such party holds a larger stake than the person holding 30% of the voting securities or (ii) in case of a capital increase with preferential subscription rights decided by the Company's general shareholders' meeting.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose significant shareholdings and merger control, that may apply to the Company and may create hurdles to an unsolicited tender offer, merger, change in management or other change in control. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of the Company's shares. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their shares at a premium.

Pursuant to Belgian company law, the board of directors of Belgian companies may in certain circumstances, and subject to prior authorisation by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (pursuant to the 'authorised capital') or through share



buy-backs (i.e., purchase of own shares). In principle, the authorisation of the board of directors to increase the share capital of the Company through contributions in kind or in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the securities of the Company. The general shareholders' meeting can, however, under certain conditions, expressly authorise the board of directors to increase the capital of the Company in such case by issuing shares in an amount of not more than 10% of the existing shares of the Company at the time of such a public takeover bid. Such authorisation has not been granted to the board of directors of the Company.

The Company's articles of association do not provide for any specific protective mechanisms against public takeover bids.

The Company (or its subsidiaries) is a party to the following most significant agreements or instruments which, upon a change of control of the Company or following a takeover bid can either be terminated or limited by the other parties thereto, or give the other party the ability to accelerate certain rights under such agreements or instruments (such as an early repayment of debt):

- EUR 10,000,000 subordinated loan agreement dated 25 June 2010 entered into between PMV and Biocartis SA;
- outstanding WHC Warrants (see also 2.4.2.3. Warrants—Whitemarsh capital warrants);
- ISDA 2002 Master Agreement dated 31 October 2013 between KBC Bank NV and Biocartis SA and between KBC Bank NV and Biocartis NV;
- EUR 500,000 credit facility dated 14 November 2013 between KBC Bank NV and Biocartis NV;
- patent licence and exploitation agreement dated 1 December 2012 entered into between Wellcome Trust Limited and Biocartis SA, subsequently assigned by Biocartis SA to Biocartis NV on 30 June 2014;
- amended and restated license and development agreement dated 9 October 2014 entered into between Janssen Pharmaceutica NV and Biocartis NV;
- co-promotion agreement dated 1 October 2014

entered into between Janssen Pharmaceutica NV and Biocartis NV;

- development agreement dated 21 September 2011 entered into between Philips Medisize BV and Biocartis NV;

In addition, the Company's warrant plans (2013 Plan and 2015 Plan) also contain take over protection provisions. The 2013 Plan and 2015 Plan are described in more detail in the remuneration report (see further).



## 3.4. Board of Directors

### 3.4.1. Composition

The board of directors is composed of 7 directors. The table below gives an overview of the members of the Company's board of directors and their terms:

| NAME                            | AGE | POSITION                                 | START OF TERM | END OF TERM |
|---------------------------------|-----|--|---------------|-------------|
| Rudi Mariën <sup>(1)</sup>      | 70  | Chairman, Non-Executive Director         | 2015          | 2016        |
| Rudi Pauwels <sup>(2)</sup>     | 56  | Chief Executive Officer, Director        | 2015          | 2018        |
| Hilde Windels <sup>(3)</sup>    | 50  | Deputy Chief Executive Officer, Director | 2015          | 2018        |
| Roald Borré                     | 43  | Non-Executive Director                   | 2015          | 2016        |
| Peter Piot                      | 67  | Non-Executive , Independent Director     | 2015          | 2018        |
| Renaat Berckmoes <sup>(4)</sup> | 50  | Non-Executive, Independent Director      | 2015          | 2016        |
| Mark Shaffar                    | 60  | Non-Executive, Independent Director      | 2015          | 2018        |

#### Note:

<sup>1</sup> Acting through Gengest BVBA.

<sup>2</sup> Acting through Valetusan Ltd.

<sup>3</sup> Acting through Hilde Windels BVBA.

<sup>4</sup> Renaat Berckmoes resigned after the meeting of the board of directors held on 10 September 2015. Following his resignation Be@vised BVBA, represented by Renaat Berckmoes was coopted as director of the Company.

**Rudi Mariën** is President and Managing Director of Gengest BVBA and Biovest Comm.VA. He was the Vice President of Cerba European Lab. Through his management company, Gengest BVBA, Mr. Mariën has board mandates in different listed and private biotech companies. Mr. Mariën was co-founder, reference shareholder and Chairman of Innogenetics, and has been the founder, shareholder and Managing Director of several clinical reference laboratories including the Barc Group, a leading international centralised clinical laboratory, exclusively dedicated to pharmaceutical studies. Mr. Mariën holds a degree in pharmaceutical sciences from the University of Ghent, Belgium and a degree in clinical biology from the University of Ghent, Belgium.

**Rudi Pauwels** founded Biocartis in 2007. Mr. Pauwels is a serial entrepreneur who also co-founded several other European biotech companies, including Tibotec, Virco and Galapagos Genomics. Starting his career as a researcher at the internationally renowned Rega Institute for Medical Research in Leuven, Mr. Pauwels has focused for more than two decades

on the search and development of anti-HIV drugs and the development of diagnostic tools that enable personalised HIV treatment. He is (co)-author or more than 150 papers in peer-reviewed journals and is the recipient of several awards for his scientific and entrepreneurial accomplishments. Mr. Pauwels holds a PhD in Pharmaceutical Sciences from the Katholieke Universiteit Leuven, Belgium.

**Hilde Windels** has close to 20 years of experience in biotech with a track record of building and structuring organisations, private fundraising, M&A, public capital markets and business and corporate strategy. She joined Biocartis as CFO mid-2011 and transitioned in the role of Deputy CEO as of September 2015. From 2009 to mid-2011, she worked as independent CFO for several private biotech companies. From 1999 to 2008, Mrs. Windels was CFO of publicly-listed DevGen. She also served on the boards of DevGen, MDxHealth and FlandersBio and currently serves as a board member of VIB and Erytech SA. Mrs. Windels holds a Masters in Economics from the University of Leuven, Belgium.

**Roald Borré** started his professional career at the *Financieel Economische Tijds* newspaper as a financial analyst specialised in high-tech companies, particularly in the ICT and biotech fields. He was responsible for the launch of *Wall Street Invest*, a weekly with a focus on Nasdaq-listed (mainly) biotech and ICT companies. In 1999, he joined *Puilaetco Private Bankers* as Senior Fund Manager, where he was in charge of the Biotechnology Fund and managed various investments in the therapeutics and diagnostics field, a position he held until 2006. In 2011, after five years as an entrepreneur, Mr. Borré joined the *ParticipatieMaatschappij Vlaanderen* as Business and Fund Manager of the TINA fund that focuses on industrial projects with a high degree of innovation and the potential to transform, now adding co-Head of Venture Capital and permanent representative of PMV NV, statutory manager of PMV-TINA Comm.VA to his responsibilities. He is on the board of different TINA portfolio companies and a member of several advisory boards. Mr. Borré holds a Master in Financial and Commercial Sciences (specialisation Accountancy) from EHSAL Management School, Belgium.

**Peter Piot** is Director at the London School of Hygiene & Tropical Medicine. He was the founding Executive Director of UNAIDS and Under Secretary-General of the United Nations from 1995 until 2008, and was an Associate Director of the Global Programme on AIDS of the WHO. Under his leadership, UNAIDS became the chief advocate for worldwide action against AIDS, also spear heading UN reform by bringing together 10 UN systems organisations. In 1976 he co-discovered the Ebola virus in Zaire. Mr. Piot also led research on HIV/AIDS, sexually transmitted diseases and women's health and has held positions as professor of microbiology and of public health at various institutions. Mr. Piot has received numerous scientific and civil awards and has published over 550 scientific articles and 16 books. He holds amongst others an M.D. from the University of Ghent, Belgium, a Ph.D. in Microbiology from the University of Antwerp, Belgium and a Diploma of Tropical Medicine from the Antwerp Institute of Tropical Medicine, Belgium.

**Renaat Berckmoes** is non-executive director at *Primacom AG* and *FPIM-SFPI* and partner at *Fortino CVA*. Mr. Berckmoes also has held finance positions at *Telnet*, being CFO from 2006 to 2013. Mr. Berckmoes holds a Master in Business Economics and a Master in Maritime Economics from the University of Antwerp,

Belgium and a Master in Political & Social Sciences from the Katholieke Universiteit Leuven, Belgium.

**Mark Shaffar** has 38 years of experience in the biotechnology sector, having held numerous positions at *Abbott Laboratories* from 1977 to 2014, including Divisional Vice-President of Acquisitions and Licensing. Mr. Shaffar holds an MM in Management Policy, Finance from Northwestern University—Kellogg Graduate School of Management, the United States and a BS in Biochemistry the University of Wisconsin-Madison, the United States.

The business address of each of the directors for the purpose of their mandate is Generaal De Wittelaan 11 bus B, 2800 Mechelen, Belgium.

### 3.4.2. Changes to the composition of the board of directors

As indicated above *Renaat Berckmoes* resigned as director after the meeting of the Board of Directors held on the 10th of September 2015. As a result of the vacancy that was created by this resignation, the Board of Directors coopted *Be@dvised BVBA*, organised and existing as a private company with limited liability under Belgian law, with registered office at *Berchemboslaan 16, 2600 Berchem*, with as permanent representative *Renaat Berckmoes*, as independent director within the meaning of Article 526ter of the Belgian Code of Companies and provision 2.3 of the Belgian Code on Corporate Governance. It was further decided that *Be@dvised BVBA*, aforementioned, with as permanent representative *Renaat Berckmoes*, succeed in the roles and positions that were held before by *Renaat Berckmoes*, i.e. Chairman of the Audit Committee and member of the Remuneration and Nomination Committee. The Board of Directors will therefore propose to the annual general meeting to confirm the nomination of *Be@dvised BVBA* for the term of the mandate of the resigning director, Mr. Berckmoes, who was appointed for a term until the closing of the annual general meeting to be held in 2018 which will have resolved on the financial statements for the financial year ending on December 31, 2017; and further that the mandate will be remunerated in accordance with the decision of the extraordinary meeting of shareholders held on 13 April 2015. The business address of the director for the purpose of this mandate will be *Generaal de Wittelaan 11 bus B, 2800 Mechelen*.



The mandate of Rudi Mariën<sup>21</sup> and Roald Borré will end after the annual general meeting that has to resolve on the financial statements for the financial year ending on December 31, 2015 (i.e. the annual general meeting that is scheduled to take place on the 13th of May 2016). The board of directors will propose to the annual general meeting that the mandate of Roald Borré be renewed for a term of 2 years as non-executive director and that the mandate of Rudi Mariën (through Gengest BVBA) be renewed for a term of 1 year as non-executive director. The board of directors will further propose the appointment of Hilde Eylenbosch as independent, non-executive director for a term of 2 years, as she satisfies the independence criteria set forth in Article 526ter of the Companies Code and in provision 2.3 of the Belgian Code on Corporate Governance. Hilde Eylenbosch is a Senior Business Executive with over 25 years of experience in marketing, product innovation, cross functional businesses and organisational leadership in the life sciences industry. Over the last 5 years, she held the roles of Chief Commercial Officer at Alere Inc and was President of Alere International reporting to the COO.

<sup>21</sup> Acting as permanent representative of Gengest BVBA.

### 3.4.3. Gender diversity

Going forward the board of directors must be composed in a manner compliant with the principles of gender diversity as well as of diversity in general. The board of directors is currently composed of six men and one woman with very diverse and complementary knowledge bases and fields of experience.

The board of directors is well aware of the recommendations of the Corporate Governance Committee with regard to the representation of women on boards of directors of listed companies and of the provisions of Article 518bis of the Companies Code. In order to ensure compliance with this provision, the board of directors will make every effort to propose female candidate directors for nomination by the general meeting going forward. More information on diversity at Biocartis can be found under 'Biocartis as an organisation', 'Employees'.

### 3.4.4. Activity report

The Company went through a successful IPO process following which its shares were listed on Euronext Brussels on 27 April 2015. Between that day and the end of 2015 the board of directors met 3 times in person and 1 time via conference call.

All board members attended to all four board meetings, resulting in a 100% attendance rate for the board of directors meetings. During these meetings the board reviewed the Group's overall strategy, discussed the regular updates of the financial data and reviewed the budget for the current financial year (2016). The board further reviewed the development of the different activities of the Group (research, development, manufacturing and commercial) on the basis of reports prepared by the executive management team.

The Board also discussed the recommendations made by the advisory committees with regards to financial matters, the half year report and related communication, as well as the strengthening of the executive management team. As the board of directors has only been officially installed since the IPO (27 April 2015), it has not yet carried out an internal evaluation procedure to discuss its size, composition, performance and interaction with the executive management and committees.

## 3.5. Committees of the board of directors

THE BOARD OF DIRECTORS HAS ESTABLISHED TWO BOARD COMMITTEES, WHICH ARE RESPONSIBLE FOR ASSISTING THE BOARD OF DIRECTORS AND MAKING RECOMMENDATIONS IN SPECIFIC FIELDS: THE AUDIT COMMITTEE (IN ACCORDANCE WITH ARTICLE 526BIS OF THE BELGIAN COMPANIES CODE AND PROVISION 5.2 OF THE BELGIAN CODE ON CORPORATE GOVERNANCE) AND THE REMUNERATION AND NOMINATION COMMITTEE (IN ACCORDANCE WITH ARTICLE 526QUATER OF THE BELGIAN COMPANIES CODE AND PROVISION 5.3 AND 5.4 OF THE BELGIAN CODE ON CORPORATE GOVERNANCE). THE TERMS OF REFERENCE OF THESE BOARD COMMITTEES ARE PRIMARILY SET OUT IN THE CORPORATE GOVERNANCE CHARTER.

### 3.5.1. Audit committee

#### 3.5.1.1. Composition

The audit committee consists of four directors. All members of the audit committee are non-executive directors. According to the Belgian Companies Code, at least one member of the audit committee must be independent and must have the necessary competence in accounting and auditing. The following directors are the members of the audit committee: Renaat Berckmoes (chairperson)<sup>22</sup>, Roald Borré, Rudi Mariën and Mark Shaffar. While the audit committee of the board of directors is composed exclusively of non-executive directors, of which two are independent directors, the audit committee does not have a majority of independent directors. This is contrary to provision 5.2/4 of the Belgian Code on Corporate Governance which provides that at least a majority of the audit committee's members should be independent. The chairperson of the audit committee, however, is an independent director and has a casting vote. The Company justifies this as it allows the audit committee to draw on the additional expertise of the members of the board of directors that combine their experience in Biocartis with financial and auditing expertise.

The members of the audit committee have sufficient expertise in financial matters to discharge their functions. The chairperson of the audit committee is competent in accounting and auditing as evidenced by his previous and current roles. The other members of the audit committee also satisfy this requirement, as evidenced by the different senior management and director mandates that they have held in the past and currently hold.

#### 3.5.1.2. Activity Report

The Company went through a successful IPO process following which its shares were listed on Euronext Brussels on 27 April 2015. Between that day and the end of 2015 the audit committee met 2 times in person and 1 time via conference call.



All four members of the audit committee attended all three meetings, resulting in a 100% attendance rate for the audit committee meetings. During its meetings the audit committee reviewed and discussed the financial reporting process, and analyzed the half year financial statements and communication in relation to these figures. The external auditor of the Company attended the meeting of the Audit Committee that reviewed the half year figures and reporting. The audit committee further reviewed during its meetings the performance of the Group presented through the management reporting documentation and it discussed the draft budget prepared by the executive management team. The audit committee reported systematically to the board of directors and furthermore the committee was ensured the co-operation of the executive management team and the financial department of the Company where required.

<sup>22</sup> Renaat Berckmoes resigned after the meeting of the board of directors held on 10 September 2015. Following his resignation Be@vised BVBA, represented by Renaat Berckmoes was coopted as director of the Company. Following this change Be@vised, represented by Renaat Berckmoes, was also nominated as chair of the audit committee.

## 3.5.2. Remuneration and nomination committee

### 3.5.2.1. Composition

The remuneration and nomination committee consists of three directors: Rudi Mariën (chairperson), Renaat Berckmoes<sup>23</sup> and Mark Shaffar. All members of the remuneration and nomination committee are non-executive directors. In line with the Belgian Companies Code, the remuneration and nomination committee consists of a majority of independent directors. Pursuant to the Belgian Companies Code, the remuneration and nomination committee must have the necessary expertise on remuneration policy, which is evidenced by the experience and previous roles of its current members. The chief executive officer and deputy chief executive officer participate to the meetings of the remuneration and nomination committee in an advisory capacity each time the remuneration of another member of the executive management is being discussed.

### 3.5.2.2. Activity report

The Company went through a successful IPO process following which its shares were listed on Euronext Brussels on 27 April 2015. Between that day and the end of 2015 the remuneration and nomination committee met 2 times in person and one time via conference call.

One member of the remuneration and nomination committee was unable to attend the conference call of the committee but did reach out to the chair of the committee to briefly consult and discuss the topics on the agenda prior to the meeting of the committee. As a result the attendance rate for the remuneration and nomination committee is 89%.

During its meetings the remuneration and nomination committee reviewed and discussed the composition of the executive management team, conducted interviews with potential candidates for the executive team, reviewed the compensation of the new members of the management team as well as a companywide incentive scheme set up in accordance with the

Collective Bargaining Agreement N° 90, non-recurrent performance-related bonuses applicable to all the employees of Biocartis and whereby the employees can obtain a variable compensation of max. EUR 1.500 upon completion of pre-defined goals.

The remuneration and nomination committee reported systematically to the board of directors and furthermore the committee was ensured the co-operation of the executive management team and the financial department of the Company where required.

## 3.6. Other information

### 3.6.1. Conflicts of interest

Directors are expected to arrange their personal and business affairs so as to avoid conflicts of interest of a monetary nature. Any director with a conflicting financial interest (as contemplated by article 523 of the Belgian Companies Code) on any matter before the board of directors must bring it to the attention of both the statutory auditor and fellow directors, and take no part in any deliberations or voting related thereto. The corporate governance charter contains the procedure for transactions between Biocartis and the directors which are not covered by the legal provisions on conflicts of interest. The corporate governance charter contains a similar procedure for transactions between Biocartis and members of the executive management (other than the chief executive officer and the deputy chief executive officer).

The conflict of interest procedure was applied once in 2015 during the preparations of the IPO of the Company at the meeting of the board of directors held on 13 April 2015. The extract of the minutes of that meeting is as follows:

*Prior to the deliberation and resolutions by the Board of Directors, Rudi Pauwels and Rudi Mariën, each Director of the Company, made the following declarations as far as needed and applicable in accordance with Article 523 of the Belgian Companies Code.*

<sup>23</sup> Renaat Berckmoes resigned after the meeting of the board of directors held on 10 September 2015. Following his resignation Be@vised BVBA, represented by Renaat Berckmoes was coopted as director of the Company. Following this change Be@vised, represented by Renaat Berckmoes, was also nominated as chair of the audit committee.



*The meeting of the Board of Directors will deliberate and resolve in relation to the contemplated capital increase by the Company with the issuance of new shares of the Company with admission of the Company's shares to listing on the regulated market of Euronext Brussels (the 'IPO'). The resolution to increase the Company's share capital and a number of additional resolutions in connection therewith were approved by the extraordinary general shareholders' meeting of the Company held on 13 April 2015, prior the meeting of the Board of Directors (the 'EGM').*

*In the context of the IPO and in execution of the resolutions of the EGM a number of existing shareholders of the Company (the 'Participating Shareholders') will be able to subscribe for new shares of the Company for an aggregate amount (including issue premium) of EUR 21,512,800.00 in execution of existing commitments vis-a-vis the Company, as provided for in the Investment Agreement of 25 August 2014, as amended on 25 November 2014, which (amongst others) was entered into by the Company and certain shareholders mentioned therein (the 'Investment Agreement').*

*Mr. Rudi Pauwels informed the Board of Directors that Benaruca SA (a company under his control) is a Participating Shareholder which shall subscribe for new shares of the Company in execution of the Investment Agreement. Benaruca SA and BIOSVP Limited (another company under the control of Mr. Pauwels) will also commit not to transfer their shares in the Company during a certain period after the IPO. The same commitment will also be made by other shareholders of the Company.*

*Mr. Rudi Mariën informed the Board of Directors that RMM SA (a company under his control) will commit to*

*lend certain of its shares in the Company to one of the Underwriters within the framework of the IPO in order to allow overallocments of shares. RMM SA will also commit not to transfer its shares in the Company during a certain period after the IPO.*

*As a result, Rudi Pauwels and Rudi Mariën potentially each have a financial interest that is in conflict with the resolutions that will be passed by the Board of Directors. Both, however, are of the opinion that the contemplated resolutions in connection with the IPO are in the interest of the Company, as it will allow the Company to attract new capital with a view to the further development of its activities and at the same time to reinforce its net equity.*

*Rudi Pauwels and Rudi Mariën will each inform the Statutory Auditor of the Company of the foregoing as far as needed and applicable in accordance with the provisions of Article 523 of the Belgian Companies Code."*

### 3.6.2. Dealing code

The board of directors has established a dealing code describing the declaration and conduct obligations of directors, members of the executive management, certain other employees and certain other persons with respect to transactions in shares or other financial instruments of the Company. The dealing code sets limits on carrying out transactions in shares of the Company and allows dealing by the above mentioned persons only during certain windows. The dealing code is attached to the Company's corporate governance charter.

### 3.6.3. Other mandates

The directors hold the following directorships (apart from their functions within Biocartis) and memberships of administrative, management or supervisory bodies and/or partnerships:

|                                    |  |
|------------------------------------|--|
| <b>Rudi Pauwels<sup>(1)</sup></b>  | Valetusan Ltd.<br>Benaruca<br>Cambenes SA<br>Riverwells Investments SA<br>Calimontes SL<br>Caruso Inversiones SL   |
| <b>Rudi Mariën<sup>(2)</sup></b>   | Gengest BVBA<br>Biovest Comm.VA<br>DSJ Bruxelles NV<br>LMA BVBA<br>Immo St-Michel NV<br>MyCartis NV <sup>(3)</sup><br>MDxHealth <sup>(3)</sup><br>myoscience <sup>(3)</sup><br>Quest For Growth NV <sup>(3)</sup><br>Oystershell NV <sup>(3)</sup><br>Bio-Incubator Gent NV <sup>(3)</sup><br>Argon CVA<br>Jenalvalve<br>4Tech<br>Agrosavfe NV |
| <b>Roald Borré</b>                 | High Wind NV <sup>(4)</sup><br>MyCartis NV <sup>(5)</sup><br>miDiagnostics NV<br>PMV-TINA Comm.VA <sup>(5)</sup><br>Trividend CVBA<br>Capricorn Cleantech Fund NV<br>Future Foundations NV<br>Laboratoria Smeets NV<br>Newtec Cy NV<br>Zoefffl! BVBA   |
| <b>Hilde Windels<sup>(5)</sup></b> | Hilde Windels BVBA<br>Erytech<br>VIB   |
| <b>Peter Piot</b>                  | N/A  |
| <b>Renaat Berckmoes</b>            | Savaco NV<br>FPIIM-SFPI<br>Fortino   |
| <b>Mark Shaffar</b>                | Shaffar LLC  |

Notes:

(1) Acting as permanent representative of Valetusan Ltd. (2) Acting as permanent representative of Gengest BVBA. (3) Acting through Gengest BVBA. (4) Acting as permanent representative of ParticipatieMaatschappij Vlaanderen. (5) Acting as permanent representative of Hilde Windels BVBA.

## 3.7. Executive management

### 3.7.1. Composition

Biocartis' executive management is composed of the chief executive officer and the other members of the executive management. On the 31st of December 2015 the team was composed as follows:

| Name                               | Age | Function                            |
|------------------------------------|-----|-------------------------------------|
| <b>Rudi Pauwels<sup>(1)</sup></b>  | 55  | Chief Executive Officer (CEO)       |
| <b>Hilde Windels<sup>(2)</sup></b> | 50  | Deputy Chief Executive Officer      |
| <b>Ewoud Welten</b>                | 32  | Chief Financial Officer (CFO)       |
| <b>Ulrik Cordes</b>                | 45  | Chief Commercial Officer (CCO)      |
| <b>Erwin Sablon</b>                | 51  | Head of R&D and Alliance Management |
| <b>Susy Spruyt</b>                 | 48  | Human Resources Director            |
| <b>Caroline Collard</b>            | 42  | Marketing Director                  |
| <b>Patrick Hofkens</b>             | 46  | General Counsel                     |

Notes:

(1) Acting through Valetusan Ltd.

(2) Acting through Hilde Windels BVBA.

**Rudi Pauwels** is the chief executive officer and a director of the Company. See his biography under 'Board of directors - Pre-Offering composition of the board of directors'.

**Hilde Windels** is the deputy chief executive officer of the Company. See her biography under 'Board of directors - Post-Offering composition of the board of directors'.

**Ewoud Welten** is the chief financial officer. He joined Biocartis in September 2015. Coming from international investment bank Kempen & Co where he worked as Vice President Corporate Finance. He has a proven track record in the Life Sciences and Healthcare sector as a corporate financier, in which position he managed numerous international capital market transactions including IPOs, secondary fundraisings and M&A transactions. Ewoud holds a Master Degree in Financial Economics (distinction) from the Erasmus University Rotterdam, the Netherlands.



**Ulrik Cordes** is the chief commercial officer. Mr. Cordes has special experience in strategy, commercial partnering, global go-to market strategies and M&A activities. Prior to joining Biocartis, he held the position of Global Sales & Marketing Director Slides & Specialty Glass at Thermo Fisher Scientific. He has also held a number of positions at Dako, including that of Vice President Marketing Operations and Vice President Asia Pacific & Export Region. At Dako, Ulrik spear-headed M&A transactions including the Dako-Cytomation merger and the Cytologix acquisition. He also successfully led Dako's market expansion through commercial partnering and the establishment of subsidiaries in amongst others China and Brazil. Ulrik holds a Master of Science in Biochemistry from the University of Copenhagen, Denmark and a Bachelor of Commerce from Copenhagen Business School, Denmark.

**Erwin Sablon** is the head of R&D and alliance management. He joined Biocartis as Director of Diagnostics Development and Alliance Management in June 2010. In August 2012, he took on the role of Head of Applied Research and Development. He is now responsible for all Biocartis internal and external life sciences R&D activities, and for managing the relationships with the company's development partners. Prior to joining Biocartis, Erwin held the position of Director Project Management at Ablynx N.V. (Gent, Belgium) from 2008-2010. He also gained extensive experience in in vitro diagnostics (IVD) development of molecular diagnostic tests during his 18 years at Innogenetics NV (Gent, Belgium), where he held various R&D management positions, including at the departments of infectious diseases, virology and microbiology. Erwin holds a PhD in Molecular Biology from the University of Ghent and an Executive MBA from the Vlerick Business School.

**Susy Spruyt** is the human resources director. She joined Biocartis in 2015. Prior to joining Biocartis, Susy held progressive HR roles primarily in the biotech and pharmaceutical industry. Susy holds a Master Degree in Law from VUB University of Brussels.

**Caroline Collard** is the marketing director of the Company. She has a solid expertise in Sales and Marketing in the pharmaceutical and biotech industry. In previous positions, she worked for Roche Pharmaceuticals, Serono, MerckSerono and Teva Pharmaceuticals, heading a wide variety of Sales & Marketing activities. She joined Biocartis

in 2015. Caroline holds a Master Degree in Labour Sociology, Midwifery and an MBA from Vlerick Leuven Ghent Management School.

**Patrick Hofkens** is the General Counsel of the Company. He joined Biocartis in September 2015 from Ericsson where he worked as Director in the Intellectual property and licencing department. Between 2006 and 2013, Patrick worked for telecom company Option as a Corporate Secretary and Chief Development Officer, also overlooking the legal function and licencing activities of the company. Prior to Option, Patrick worked in private practice as Counsel at Loyens&Loeff and as Senior Legal Counsel with Borealis. Patrick holds a Master Degree in Law from the University of Leuven and a Master after Master Degree in Corporate Law from the University of Brussels.

The business address of each of the members of the executive management for the purpose of their mandate is Generaal De Wittelaan 11 bus B, 2800 Mechelen, Belgium.

### 3.8. Share ownership of the members of the executive management team

The table below provides an overview of the number of shares held by each member of the executive management (on 31 December 2015):

| Name                         | Number of shares held |
|------------------------------|-----------------------|
| Rudi Pauwels <sup>(1)</sup>  | 3,064,555             |
| Hilde Windels <sup>(2)</sup> | 21,832                |

Notes:

(1) Acting through Valetusan Ltd. The shares are held by Benaruca (which holds 2,524,721 shares on the 31st of December 2015) and BIOSPV Limited (which holds 539,834 shares on the 31st of December 2015), which are controlled by Rudi Pauwels.

(2) Acting through Hilde Windels BVBA. The shares held by Hilde Windels are held in her own name.

An overview of the number of warrants held by each member of the executive management on 31st of December 2015 is provided below in the Remuneration Report.



CHAPTER 4

# Remuneration report

“

“TODAY WE KNOW SO MUCH MORE ABOUT CANCER. HAVING ROBUST AND ACCURATE TESTS ARE CRITICAL TOWARDS EFFECTIVE TREATMENT AND MONITORING.”

DR. MASSIMO BARBERIS, DIRECTOR CLINIC UNIT OF HISTOPATHOLOGY AND MOLECULAR DIAGNOSTICS, ISTITUTO EUROPEO DI ONCOLOGIA (MILANO, ITALY)



# 4. Remuneration report

## 4.1. Remuneration policy

Biocartis' remuneration policy is designed to enable Biocartis to (i) attract and retain talented employees, (ii) to promote continuous improvement in the business, and (iii) to link remuneration and performance, motivating employees to deliver increased shareholder value through superior business results.

## 4.2. Remuneration of Directors

### 4.2.1. General

The remuneration and compensation of the non-executive directors has been determined by the general shareholders' meeting of 13 April 2015 and is composed of a fixed fee and an attendance fee:

#### Annual fixed fees:

- The chairman of the board of directors receives a fee of EUR 14,000 p/a.
- The chairperson of the audit committee receives a fee of EUR 12,000 p/a.
- The chairperson of the remuneration and nomination committee receives a fee of EUR 10,000 p/a.
- The other non-executive directors receive a fee of EUR 8,500 p/a.

#### Attendance fees:

In addition to the annual fixed fees (mentioned above), each non-executive director receives an attendance fee of EUR 2,000 per meeting of the board of directors attended in person (of EUR 1,000 if the meeting is attended per conference call), EUR 1,000 per meeting of the audit committee of which the director is a member, EUR 500 per meeting of the remuneration and nomination committee of which the director is a member.

#### Share based awards:

Each independent director receives 5.000 warrants on an annual basis. Part of the warrants of the 2015 Plan (further described below) will be used for this purpose.

The Company also reimburses reasonable out of pocket expenses of directors (including travel expenses) incurred in performing their mandate.

The directors that are also a member of the executive management team (Valetusan Ltd and Hilde Windels BVBA, respectively the CEO and Deputy CEO of the Company), are remunerated for the executive management mandate, but not for their director mandate.

## 4.2.2. Remuneration and compensation of the Board of Directors in 2015

The Board of Directors in its current composition started its activities in April 2015 with the final preparation of the IPO of the Company. As a result, the compensation of the board members has been calculated pro rata. Furthermore, in September 2015 the composition of the Board of Directors was adapted as indicated above. This change has also been reflected in the remuneration paid to the board members concerned.

Based on the decision of the general shareholders' meeting of 13 April 2015 the Company has paid for the financial year 2015 the following fees to the board members:

|   | <b>DIRECTOR'S FEES<sup>2</sup></b> | <b>ATTENDANCE FEES</b> |
|---|------------------------------------|------------------------|
| Gengest BVBA, represented by Rudi Mariën                    | EUR 18,000                         | EUR 11,500             |
| Renaat Berckmoes  | EUR 5,500                          | EUR 5,500              |
| Be@vised BVBA, represented by Renaat Berckmoes <sup>1</sup> | EUR 3,500                          | EUR 5,500              |
| Roald Borré   | EUR 6,375                          | EUR 10,000             |
| Mark Shaffar  | EUR 6,375                          | EUR 11,500             |
| Peter Piot  | EUR 6,375                          | EUR 6,000              |

Notes:

(1) Renaat Berckmoes resigned after the meeting of the board of directors held on 10 September 2015. Following his resignation Be@vised BVBA, represented by Renaat Berckmoes was coopted as director of the Company. The directors' fee was proportionally split between Renaat Berckmoes and Be@vised BVBA.

(2) The Director's fee has been calculated on a pro rata basis from April – December 2015.

As indicated above, Valetusan Ltd. and Hilde Windels BVBA are not remunerated for their director mandate. No warrants have yet been granted to the directors.

## 4.3. Remuneration of members of the executive team

### 4.3.1. General

The remuneration of the CEO, the Deputy CEO and the other members of the executive management is based on recommendations made by the remuneration and nomination committee. The CEO and Deputy CEO participate to the meetings of the remuneration and nomination committee in an advisory capacity each time the remuneration of another member of the executive management is being discussed.

The remuneration is determined by the board of directors. As an exception to the foregoing rule, pursuant to Belgian law the general shareholders' meeting must approve, as relevant, (i) in relation to the remuneration of members of the executive management and other executives, an exemption from the rule that share based awards can only vest during a period of at least three years as of the grant of the awards, (ii) in relation to the remuneration of members

of the executive management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years, and (iii) any provisions of service agreements to be entered into with members of the executive management and other executives (as the case may be) providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen months' remuneration).



A proportion of the remuneration package is structured so as to link rewards to corporate and individual performance, thereby aligning the interest of the executive management with the interests of the Company and its shareholders. In the past, approval by the general shareholders' meeting has been obtained in relation to the share plans (see 'Description of share plans').

The remuneration of the executive management consists of the following main remuneration components:

- Annual base salary (fixed)
- Variable remuneration
- Group and hospitalisation insurance
- Other components
- Participation in stock option plans

One member of the executive management has a variable remuneration component. (i.e., remuneration linked to performance criteria). The variable remuneration

of that member of the executive management team amounts to up to 20% of the base salary for on target performance, and the respective criteria to determine eligibility consist of the achievement of individual goals (for 70%) and team goals (30%). The eligibility for the variable remuneration for performance year 2015 was determined by the Remuneration Committee to be at 15%. In 2015, the CEO and Deputy CEO received an exceptional bonus payment related to the successful IPO of the Company.

The members of the executive management are also reimbursed for certain costs and expenses made in the performance of their function. The members of the executive management that have an employee contract also benefit from a group insurance, hospitalisation plan, company car with fuel card, meal vouchers, mobile phone, laptop. Finally, one member of the executive management team also receives certain housing and relocation costs, school allowance, tax assistance and statutory accident and disease insurance.

There are no contractual provisions in place between the Company and the CEO or the other members of the executive management that give the Company a contractual right to reclaim from the executives the variable remuneration that would be awarded based on erroneous financial information.

### 4.3.2. Remuneration and compensation in 2015

The following remuneration and compensation was paid to the chief executive officer and other members of the executive management in 2015:

| AMOUNTS IN EUR              | CEO               | MEMBERS OF THE EXECUTIVE MANAGEMENT TEAM <sup>1</sup> |
|-----------------------------|-------------------|---|
| Annual base salary          | 349,500.00        | 823,786.29  |
| Group insurance             |                   | 16,617.61   |
| Expat expenses              |                   | 72,960.00   |
| Bonus <sup>2</sup>          | 158,750.00        | 151,504.81  |
| Other elements <sup>3</sup> |                   | 43,287.75   |
| <b>Total</b>                | <b>508,250.00</b> | <b>1,108,156.46</b>                                   |

Notes:

(1) The amounts reflect the proportion of the compensation paid to the members of the team for the period during the year when they were part of the management team. It therefore also includes payments made to the former COO of the Company, who left in September 2015. Further the amount includes both (proportional) gross salaries (excluding employer social security contributions) as well as compensation paid to the self-employed members of the executive management team.

(2) As indicated above the bonus payments are linked to i) the exceptional bonus payment related to the successful IPO of the Company in April 2015; and ii) a variable compensation for one member of the executive management team fixed at 15% of the base salary for the performance of 2015.

(3) The other elements include; meal vouchers, medical plan, company car, and other smaller elements of the overall compensation.

The board of directors decides on the granting of warrants to the members of the executive team based on recommendations of the remuneration and nomination committee. The table below provides an overview of the number of warrants under the 2013 and 2015 Plan that are held by the members of the executive management team:

| NAME                         | VESTED  | UNVESTED | TOTAL                 | EXERCISE PRICE | PLAN      |
|------------------------------|---------|----------|-----------------------|----------------|-----------|
| Rudi Pauwels <sup>(1)</sup>  | -       | -        |                       |                |           |
| Hilde Windels <sup>(2)</sup> | 100,000 | 0        | 100,000               | EUR 8.1309     | 2013 Plan |
| Ulrik Cordes                 | 36,458  | 26,042   | 62,500                | EUR 8.1309     | 2013 Plan |
| Erwin Sablon                 | 25,000  | 0        | 30,000 <sup>(3)</sup> | EUR 8.1309     | 2013 Plan |
| Ewoud Welten                 | 5,208   | 57,292   | 62,500                | EUR 13.28      | 2015 Plan |
| Caroline Collard             | 2,292   | 7,708    | 10,000                | EUR 13.28      | 2015 Plan |

Notes:

(1) Acting through Valetusan Ltd.

(2) Acting through Hilde Windels BVBA

(3) 5,000 warrants were exercised in 2015 and the shares obtained through that exercise were sold.

For an overview of the features of the stock options, see also 'Characteristics of the stock options'.

## 4.4. Relative weighting of each component of the remuneration

In 2015 the relative weight of each component of the remuneration in the overall remuneration paid to the members of the executive management team (excluding the CEO) is as follows:

|                            |                |        |
|----------------------------|----------------|--------|
| Annual base salary (fixed) | EUR 823,786.29 | 74.34% |
| Variable remuneration      | EUR 151,504.81 | 13.67% |
| Other components           | EUR 132,865.36 | 11.99% |

## 4.5. Characteristics of the stock options

Biocartis has currently three outstanding stock based incentive plans, namely (i) the 2008 stock option plan (the '2008 Plan'), (ii) the 2013 stock option plan (the '2013 Plan'), and (iii) the 2015 stock option plan (the '2015 Plan') (collectively the 'Stock Based Plans').

### 4.5.1. 2008 Plan

On 2 July 2008, the board of directors of Biocartis SA approved the 2008 Plan, enabling it to grant certain stock options to selected staff members (consisting of employees, consultants and members of the management). On





26 June 2012 the board of directors of Biocartis SA amended and restated certain clauses of the 2008 Plan. On 25 November 2014, the 2008 Plan was rolled up in order to relate to the shares of the Company instead of the shares of Biocartis SA.

The 2008 Plan is a non-dilutive stock option plan, implying that no new shares are issued upon the exercise of the respective stock options. Upon the exercise of the respective stock options, the Company is able to require certain shareholders of the Company (namely Benaruca, which is controlled by Rudi Pauwels, the chief executive officer, Ferdinand Verdonck and Philippe Renaud) to deliver the shares underlying the exercised stock options directly to the staff members who exercised the respective stock options and do so in exchange for the exercise price to be paid by the respective staff members.

The key features of the stock options granted under the 2008 Plan are as follows: (i) each option can be exercised for one share, (ii) the stock options are granted for free, i.e. no consideration is due upon the grant of the stock options, (iii) the stock options have a term of seven years, (iv) the exercise price of the stock option is equal to CHF 4.14, and (v) the stock options vest in 48 monthly instalments.

On 31 December 2015 a total number of 67,702 stock options are still outstanding under the 2008 Plan, entitling the holders to acquire 67,702 shares of the Company. All stock options are vested.

#### 4.5.2. 2013 Plan

On 25 August 2011, the general shareholders' meeting of Biocartis SA approved the 2013 Plan, enabling Biocartis SA to grant a maximum of 1,000,000 stock options (each stock option having the form of a warrant) to selected staff members (consisting of employees, consultants and members of the management). On 25 November 2014, the 2013 Plan was rolled up in order to relate to the shares of the Company instead of the shares of Biocartis SA.

The 2013 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options. Upon the exercise of the respective stock options, the Company will therefore issue a maximum of 1,000,000 shares.

The key features of the stock options under the 2013 Plan are as follows: (i) each option can be exercised for one share, (ii) the stock options are granted for free, i.e. no consideration is due upon the grant of the stock options unless the grant stipulates otherwise, (iii) the stock options have a term of 10 years when they were created but this term is contractually reduced to seven years upon grant of the stock options, (iv) the exercise price of the stock option is determined at the time of the grant of the stock options, and (v) the stock options vest in 48 monthly instalments, subject to acceleration in case of a change of control event.

Prior to the IPO of the Company, a total number of 720,340 stock options have been granted under the 2013 Plan, having an exercise price of EUR 8,1308, entitling the holders to acquire 720,340 shares of the Company.

The exercise price of the stock options that have been granted since the IPO of the Company is determined on the basis of the stock exchange price of the underlying shares at the time of the grant or an average price calculated over a previous period. The exercise windows of the plan are 16-31 March, 16-30 September and 1-15 December.

On 31 December 2015 a total of 750,340 stock options have been granted of which 550,928 are vested and not exercised and, a total number of 249,660 stock options can still be granted under the 2013 Plan.

### 4.5.3. 2015 Plan

On 15 January 2015, an option plan was established, pursuant to which 217,934 options were issued. This plan was cancelled by the general shareholders' meeting of the Company on 13 April 2015 and replaced on the same date by a new stock option plan (the '2015 Plan'), enabling the Company to grant a maximum of 262,934 stock options (each stock option having the form of a warrant) to selected staff members (consisting of employees, consultants and members of the management) and directors.

The 2015 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options. Upon the exercise of the respective stock options, the Company will therefore issue a maximum of 262,934 shares.

The key features of the stock options under the 2015 Plan are as follows: (i) each option can be exercised for one share, (ii) the stock options are granted for free, i.e. no consideration is due upon the grant of the stock options, (iii) the stock options have a term of 10 years when they were created, but this term will be contractually reduced to seven years, (iv) the exercise price of the stock option is determined at the time of the grant of the stock options, and (v) the stock options vest in 48 monthly instalments, subject to acceleration in case of a change of control event. The exercise price of the stock options is determined on the basis of the stock exchange price of the underlying shares at the time of the grant or an average price calculated over a previous period. The exercise windows of the plan are 16-31 March, 16-30 September and 1-15 December.

On 31 December 2015 a total of 72,500 stock options have been granted of which 7,500 are vested and, a total number of 190,434 stock options can still be granted under the 2015 Plan.

## 4.6. Changes to the remuneration policy

The Company will continue to review the remuneration of non-executive directors against market practice. Since the IPO of the Company the composition of the executive team changed. The impact of these changes is reported in this remuneration report. However, since the IPO no significant changes were made to the remuneration policy for the board of directors and for the executive team.

## 4.7. Remuneration policy for the next two financial years (2016-2017)

The board of directors is reviewing the remuneration of the executive team following its new composition. A first step in this direction was made during the meeting of the remuneration committee and the board of directors on 18 February 2016 where it was decided that the remuneration of the management team should include a variable component linked for the majority to the overall Company objectives and for a smaller portion to individual key performance indicators aligned with the overall Company objectives.

## 4.8. Main contractual conditions

The CEO and Deputy CEO are self-employed. Their contracts contain customary provisions regarding remuneration, non-competition and confidentiality, and are entered into for an undetermined period of time.

The services contract of the CEO (acting through Valetusan Ltd.) was entered into for an indefinite period of time, and can be terminated by either the CEO or the Company at any time subject to a prior notice of 12 months. In certain cases, the contract can be terminated by the Company with immediate effect.

The services contract of the Deputy CEO (acting through Hilde Windels BVBA) was entered into for an indefinite period of time, and can be terminated by either the Deputy CEO or the Company at any time subject to a prior notice of 6 months (or, in case of termination by the Company, the payment of an indemnity equal to the pro rata fee for that period). In certain cases, the contract can be terminated by the Company with immediate effect or subject to a prior notice of three months.

The other members of the executive team are employees. Their contracts contain customary provisions regarding remuneration, non-competition and confidentiality, and are entered into for an undetermined period of time, and can be terminated by either the employee or Biocartis at any time subject to a prior notice (or the payment of an indemnity in lieu of notice) in accordance with the provisions of the Belgian Act of 3 July 1978 concerning Employment Contracts and the Belgian Act of 26 December 2013 concerning the Introduction of a Single Status between Workers and Employees on Notice Periods and Carez Day and Accompanying Measures. The contract can be immediately terminated by the Company in case of serious cause. In certain circumstances, in case of termination, one of the members of the executive team will benefit of a relocation fee.



CHAPTER 5

# Consolidated annual accounts

“

“TUMOR DNA CAN FROM NOW ON BE TRACKED IN THE BLOOD OF A PATIENT.”

ROF. DR. BART NEYNS, HEAD OF MEDICAL ONCOLOGY  
AT THE UNIVERSITY HOSPITAL BRUSSELS, BELGIUM



## 5.1. Consolidated financial statements as of and for the years ended 31 December 2015 and 2014

### 5.1.1. Consolidated income statement

| In EUR000  | Notes  | Years ended 31 December, |                      |
|--|--------|--------------------------|----------------------|
|  |        | 2015                     | 2014                 |
| <b>Revenue</b>   |        |                          |                      |
| Collaboration revenue  | 5.2.4  | 9,686                    | 3,174                |
| Product sales revenue  | 5.2.4  | 3,593                    | 5,260                |
| Service revenue  | 5.2.4  | 54                       | 44                   |
|  |        | <u>13,334</u>            | <u>8,478</u>         |
| <b>Other operating income</b>  |        |                          |                      |
| Grants and other income  | 5.2.5  | 1,617                    | 1,889                |
|  |        | <u>14,951</u>            | <u>10,367</u>        |
| <b>Total operating income</b>  |        |                          |                      |
| <b>Operating expenses</b>  |        |                          |                      |
| Cost of goods sold   | 5.2.6  | -2,642                   | -4,251               |
| Research and development expenses  | 5.2.7  | -36,554                  | -25,014              |
| Marketing and distribution expenses  | 5.2.8  | -8,747                   | -3,095               |
| General and administrative expenses  | 5.2.9  | -6,662                   | -7,180               |
|  |        | <u>-54,606</u>           | <u>-39,540</u>       |
| <b>Operating loss for the period</b>   |        |                          |                      |
|  |        | <u>-39,655</u>           | <u>-29,173</u>       |
| Financial income   | 5.2.11 | 107                      | 60                   |
| Financial expense  | 5.2.11 | -819                     | -933                 |
| Foreign exchange gains/(losses), net   | 5.2.11 | -78                      | -88                  |
| <b>Financial result, net</b>   |        | <u>-790</u>              | <u>-961</u>          |
| <b>Loss for the year before taxes from continuing operations</b>             |        |                          |                      |
|  |        | <u>-40,445</u>           | <u>-30,134</u>       |
| Income taxes   | 5.2.29 | 648                      | 947                  |
| <b>Loss for the year after taxes from continuing operations</b>              |        | <u>-39,797</u>           | <u>-29,187</u>       |
| Gain (loss) for the year after taxes from discontinued operations            | 5.2.12 | 0                        | 19,472               |
| <b>Loss for the year</b>   |        | <u><u>-39,797</u></u>    | <u><u>-9,715</u></u> |
| attributable to owners of the Company  |        | -39,797                  | -9,118               |
| attributable to non-controlling interest                                     |        |                          | -598                 |
| <b>Earnings per share</b>  |        |                          |                      |
| basic and diluted loss per share from continuing and discontinued operations | 5.2.13 | -1.07                    | -0.36                |
| basic and diluted loss per share from continuing operations                  | 5.2.13 | -1.07                    | -1.14                |

### 5.1.2. Consolidated statement of other comprehensive income

| In EUR000   | Notes | Years ended 31 December, |               |
|---|-------|--------------------------|---------------|
|   |       | 2015                     | 2014          |
| Loss for the year   |       | -39,797                  | -9,715        |
| Other comprehensive income (loss), not to be reclassified to profit or loss               |       | 0                        | 0             |
| Other comprehensive gain (loss) for the year, that may be reclassified to profit and loss |       | 0                        | 0             |
| <b>Total comprehensive loss for the year</b>  |       | <b>-39,797</b>           | <b>-9,715</b> |
| Attributable to owners of the Company   |       | -39,797                  | -9,118        |
| Attributable to non-controlling interest  |       | 0                        | -598          |

## 5.1.3. Consolidated balance sheet

|   |        |                       |                      |
|---|--------|-----------------------|----------------------|
| <b>Assets</b>   |        |                       |                      |
| <b>Non-current assets</b>                                 |        |                       |                      |
| Intangible assets   | 5.2.14 | 8,987                 | 9,652                |
| Property plant and equipment                              | 5.2.15 | 14,245                | 9,154                |
| Participating interests                                   | 5.2.16 | 5,052                 | 0                    |
| Other long term receivables                               |        | 11                    | 117                  |
| Deferred tax assets                                       | 5.2.17 | 1,986                 | 947                  |
|   |        | <u>30,281</u>         | <u>19,870</u>        |
| <b>Current assets</b>                                     |        |                       |                      |
| Inventory   | 5.2.18 | 5,837                 | 3,583                |
| Trade receivables   | 5.2.19 | 5,852                 | 15,793               |
| Other receivables   | 5.2.19 | 1,063                 | 148                  |
| Other current assets                                      | 5.2.20 | 1,258                 | 2,700                |
| Cash and cash equivalents                                 | 5.2.21 | 104,087               | 10,919               |
|   |        | <u>118,097</u>        | <u>33,142</u>        |
| <b>Total assets</b>                                       |        | <b><u>148,378</u></b> | <b><u>53,012</u></b> |
| <b>Equity and liabilities</b>                             |        |                       |                      |
| <b>Capital and reserves</b>                               |        |                       |                      |
| Legal share capital                                       | 5.2.22 | 405                   | 222,268              |
| Historical share capital adjustment                       | 5.2.22 | -221,232              | -221,232             |
| Share premium   | 5.2.22 | 522,708               | 166,592              |
| Share based payment reserve                               | 5.2.23 | 1,345                 | 1,166                |
| Accumulated deficit                                       | 5.2.22 | -188,310              | -148,513             |
| <b>Total equity attributable to owners of the Company</b> |        | <u>114,916</u>        | <u>20,280</u>        |
| <b>Non-current liabilities</b>                            |        |                       |                      |
| Financial debt  | 5.2.24 | 2,662                 | 8,528                |
| Deferred income   | 5.2.27 | 1,342                 | 4,534                |
| Accrued charges   | 5.2.28 | 1,580                 | 1,955                |
|   |        | <u>5,585</u>          | <u>15,017</u>        |
| <b>Current liabilities</b>                                |        |                       |                      |
| Financial debt  | 5.2.24 | 8,152                 | 5,057                |
| Trade payables  |        | 13,927                | 4,265                |
| Deferred income   | 5.2.27 | 3,812                 | 5,100                |
| Other current liabilities                                 | 5.2.26 | 1,986                 | 3,293                |
|   |        | <u>27,877</u>         | <u>17,714</u>        |
| <b>Total equity and liabilities</b>                       |        | <b><u>148,378</u></b> | <b><u>53,012</u></b> |



## 5.1.4. Consolidated cash flow statement

| In EUR000  | Notes              | Years ended 31 December, |                |
|--|--------------------|--------------------------|----------------|
|  |                    | 2015                     | 2014           |
| <b>operating activities</b>  |                    |                          |                |
| Loss for the period  |                    | -39,797                  | -9,715         |
| <b>Adjustments for</b>   |                    |                          |                |
| Depreciation and amortisation  | 5.2.14 -<br>5.2.15 | 5,021                    | 4,437          |
| Depreciation and amortisation included in discontinued operations                  | 5.2.12             | 0                        | 81             |
| Impairments  | 5.2.15             | 73                       | 37             |
| Tax income in profit and loss  | 5.2.29             | -1,039                   | -947           |
| Financial result, net  | 5.2.11             | 688                      | 897            |
| Net movement in retirement benefit obligation                                      | 5.2.25             | 0                        | 108            |
| Gain on disposal MyCartis NV   | 5.2.12             | 0                        | -26,624        |
| Share based payment expense  | 5.2.23             | 179                      | 143            |
| <b>Changes in working capital</b>  |                    |                          |                |
| Net movement in inventories  | 5.2.18             | -2,254                   | -2,524         |
| Net movement in trade and other receivables and other current assets               | 5.2.19 -<br>5.2.20 | 10,574                   | -2,736         |
| Net movement in trade payables & other current liabilities                         | 5.2.26             | 7,981                    | 1,860          |
| Net movement in deferred income  | 5.2.27             | -4,479                   | -746           |
| Interests paid   |                    | -304                     | -155           |
| <b>Cash flow used in operating activities</b>                                      |                    | <b>-23,357</b>           | <b>-35,884</b> |
| <b>Investing activities</b>  |                    |                          |                |
| Interest received  |                    | 106                      | 60             |
| Purchases of property, plant & equipment   | 5.2.15             | -9,241                   | -1,927         |
| Purchases of intangible assets   | 5.2.15             | -371                     | -840           |
| Proceeds from sale and lease back of property, plant and equipment                 | 5.2.15             | 18                       | 0              |
| Proceeds from the sale of fixed assets   | 5.2.15             | 74                       | 0              |
| Disposal shares in other companies   |                    | 0                        | 245            |
| Acquisition of a subsidiary  | 5.2.12             | 0                        | 7,514          |
| <b>Cash flow from / (used in) investing activities</b>                             |                    | <b>-9,414</b>            | <b>5,052</b>   |
| <b>Financing activities</b>  |                    |                          |                |
| Proceeds from borrowings   | 5.2.24             | 1,817                    | 0              |
| Proceeds from issue of preference shares F   | 5.2.22             | 21,513                   | 21,244         |
| Disposal of MyCartis NV to capital owners of the parent                            | 5.2.12             | 0                        | -5,138         |
| Proceeds from the issue of common shares, net of transaction costs                 | 5.2.22             | 107,688                  | 0              |
| Repayment of borrowings  | 5.2.24             | -5,057                   | -3,378         |
| Bank charges   |                    | -18                      | -1             |
| <b>Cash flow from financing activities</b>   |                    | <b>125,943</b>           | <b>12,727</b>  |
| <b>Net increase / (decrease) in cash and cash equivalents</b>                      |                    | <b>93,173</b>            | <b>-18,105</b> |
| Cash and cash equivalents at the beginning of the period                           |                    | 10,919                   | 29,047         |
| Effects of exchange rate changes on the balance of cash held in foreign currencies |                    | -4                       | -23            |
| <b>Cash and cash equivalents at the end of the period</b>                          |                    | <b>104,088</b>           | <b>10,919</b>  |
| <b>Supplementary cash flow disclosures</b>   |                    |                          |                |
| new finance leases   |                    | 1,216                    | 0              |

## 5.1.5. Consolidated statement of changes in equity

| In EUR000                             | Notes  | Legal share capital | Historical share capital adjustment | Attributable to owners of the Company |                             |   |                     | Total equity attributable to the owners of the Company | Non-controlling interest | Total equity |
|---------------------------------------|--|---------------------|-------------------------------------|---------------------------------------|-----------------------------|---|---------------------|--|--------------------------|--------------|
|                                       |  |                     |                                     | Share premium                         | Share based payment reserve | Gains and losses on defined benefit plans | Accumulated deficit |  |                          |              |
| <b>Balance as at 31 December 2013</b> |  |                     |                                     |                                       |                             |   |                     |  |                          |              |
|                                       |  | 926                 |                                     | 175,946                               | 1,023                       | -309                                      | -145,631            | 31,955   |                          | 31,955       |
|                                       | Loss for the period  |                     |                                     |                                       |                             |   | -9,118              | -9,118   | -598                     | -9,716       |
|                                       | Non-controlling interest of 20% in Mycartis NV   |                     |                                     |                                       |                             |   | 6,057               | 6,057  | 1,443                    | 7,500        |
|                                       | Capital increase by incorporation of share premium                                     | 30,488              |                                     | -30,488                               |                             |   |                     |  |                          |              |
|                                       | Disposal of interest in Mycartis NV through capital decrease                           | -30,488             |                                     |                                       |                             | 309                                       | 178                 | -30,000  | -845                     | -30,845      |
|                                       | Issue of preference shares   | 110                 |                                     | 21,403                                |                             |   |                     | 21,513   |                          | 21,513       |
|                                       | Cost related to capital increase   |                     |                                     | -269                                  |                             |   |                     | -269   |                          | -269         |
|                                       | Share-based payment expense  |                     |                                     |                                       | 143                         |   |                     | 143  |                          | 143          |
|                                       | Change in reporting entity   | 221,232             | -221,232                            |                                       |                             |   |                     |  |                          |              |
| <b>Balance as at 31 December 2014</b> |  |                     |                                     |                                       |                             |   |                     |  |                          |              |
|                                       |  | 222,268             | -221,232                            | 166,592                               | 1,166                       |   | -148,513            | 20,280   |                          | 20,280       |
|                                       | Loss for the period  |                     |                                     |                                       |                             |   | -39,797             | -39,797  |                          | -39,797      |
|                                       | Share issue - tranche 2 of round F on 15 January 2015                                  | 20,488              |                                     | 1,025                                 |                             |   |                     | 21,513   |                          | 21,513       |
|                                       | Share issue - contribution in kind of the participation in Mycartis on 15 January 2015 | 4,812               |                                     | 241                                   |                             |   |                     | 5,052  |                          | 5,052        |
|                                       | Capital increase by incorporation of share premium on 15 January 2015                  | 8                   |                                     | -8                                    |                             |   |                     | -  |                          | -            |
|                                       | Capital decrease by conversion into share premium on 13 April 2015                     | -247,272            |                                     | 247,272                               |                             |   |                     | -  |                          | -            |
|                                       | Share issue - Initial Public Offering on 28 April 2015                                 | 87                  |                                     | 99,913                                |                             |   |                     | 100,000  |                          | 100,000      |
|                                       | Share issue - exercise of over-allotment warrant on 19 May 2015                        | 13                  |                                     | 14,987                                |                             |   |                     | 15,000   |                          | 15,000       |
|                                       | Cost related to Initial Public Offering  |                     |                                     | -8,124                                |                             |   |                     | -8,124   |                          | -8,124       |
|                                       | Share issue - exercise of stock options on 3 June 2015                                 | 0                   |                                     | 171                                   |                             |   |                     | 171  |                          | 171          |
|                                       | Share issue - exercise of stock options on 6 October 2015                              | 0                   |                                     | 313                                   |                             |   |                     | 313  |                          | 313          |
|                                       | Share issue - exercise of stock options on 23 December 2015                            | 0                   |                                     | 295                                   |                             |   |                     | 295  |                          | 295          |
|                                       | Costs related to capital increase  |                     |                                     | 33                                    |                             |   |                     | 33   |                          | 33           |
|                                       | Share-based payment expense  |                     |                                     |                                       | 179                         |   |                     | 179  |                          | 179          |
| <b>Balance as at 31 December 2015</b> |  |                     |                                     |                                       |                             |   |                     |  |                          |              |
|                                       |  | 405                 | -221,232                            | 522,708                               | 1,345                       |   | -188,310            | 114,916  |                          | 114,916      |

## 5.2. Notes to the consolidated financial statements

### 5.2.1. General Information

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

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

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

The consolidated financial statements have been authorised for issue on 14 March 2016 by the board of directors of the Company (the 'board of directors').

### 5.2.2. Summary of significant accounting policies

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

#### 5.2.2.1. Statement of compliance

The consolidated financial statements of the Group for the year ended 31 December 2015 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.

#### 5.2.2.2. Change in reporting entity

Biocartis Group NV was created in November 2014 by the shareholders of Biocartis SA, by means of a contribution in kind (in two consecutive stages, on 24 November 2014 and 25 November 2014, respectively) of all shares in Biocartis SA on a share-for-share basis for a total amount of EUR 222m. This contribution in kind is considered in the IFRS consolidated financial statements of Biocartis Group NV to be a transaction between entities under common control and consequently does not fall within the scope of IFRS 3 'Business combinations'. The Group has applied the guidance as referred to in the US Accounting Standard Codification 805-50 with regard to the 'Pooling-of-Interest method'. In this context, the continuity of the book values method is applied.

The consolidated financial statements for the year ended 31 December 2015 include Biocartis Group NV and its subsidiaries. Prior to the incorporation of Biocartis Group NV the consolidation was performed at the level of Biocartis SA. The consolidated financial statements of Biocartis Group NV have therefore been presented as if Biocartis Group NV has been in existence and control of the Group since 1 January 2014.

The aforementioned transaction between entities under common control did not have a significant impact at the consolidated group level (applying the continuity of the book values method, the increase in share capital for EUR 222m was offset by an identical, opposite entry in the capital distributed for EUR -222m). Therefore, the activities of the consolidated group are given for 12 months for 2015, with comparative information for 2014.

### 5.2.2.3. Basis of preparation

The consolidated financial statements have been prepared on the historical cost basis except for available for sale financial assets and non-cash distribution that are measured at fair value at the end of each reporting period as further explained in the accounting policies. The acquired assets and assumed liabilities in a business combination are also measured initially at fair value at the date of acquisition.

Historical cost is generally based on the fair value of the consideration given in exchange for assets.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

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

The Group has adopted the following new and revised standards and interpretations issued by the IASB and IFRIC that are relevant to its operations and effective for accounting periods beginning on 1 January 2015:

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

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

Standards and interpretations published, but not yet applicable for the annual period beginning on 1 January 2015, are listed in note 5.2.36.



#### 5.2.2.4. Consolidation principles

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries as at 31 December 2015. Control is achieved when the Company is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee.

Specifically, the Group controls an investee if, and only if, the Company has:

- Power over the investee (i.e., existing rights that give it the current ability to direct the relevant activities of the investee)
- Exposure, or rights, to variable returns from its involvement with the investee
- The ability to use its power over the investee to affect its returns

The Company has 100% of the shares in its subsidiaries at the end of the reporting date.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction. If the Group loses control over a subsidiary, it derecognises the related assets (including goodwill), liabilities, non-controlling interest and other components of equity while any resultant gain or loss is recognised in profit or loss. Any investment retained is recognised at fair value.

All transactions between Group companies have been eliminated upon consolidation.

#### 5.2.2.5. Foreign currency translation

The items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which each entity operates ('Functional Currency'). The consolidated financial statements are presented in Euro, which is the Company's functional and presentation currency.

Transactions in foreign currencies are recorded at the foreign exchange rate prevailing at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are translated at the foreign exchange rate prevailing at that date. Exchange differences arising on the settlement of monetary items or on reporting monetary items at rates different from those at which they were initially recorded during the period or in previous financial statements, are recognised in the consolidated income statement.

### 5.2.2.6. Intangible assets

#### RESEARCH AND DEVELOPMENT COSTS

Research and development costs are currently expensed as incurred. Development costs incurred are recognised as intangible assets if, and only if, all of the following conditions have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

Due to uncertainties inherent to the development and registration with health care authorities of the Group's Idylla™ solution and other clinical diagnostics platforms such as Idylla™-Enrich or Idylla™-Retrieve, and its tests, the Group considers that the conditions for capitalisation are not met until the regulatory procedures required by health care authorities have been finalised. Development costs incurred after the recognition criteria are met have not been material. As such, development expenditure not satisfying the above criteria and expenditure in the research phase of internal projects are recognised in the consolidated income statement as incurred.

#### PURCHASED INTANGIBLE ASSETS

Purchased intangible assets include patents and licenses, and purchased IT and software licences. Purchased intangible assets are capitalised based on the costs incurred to acquire and bring to use the specific asset.

Intangible assets are amortised in accordance with the expected pattern of consumption of future economic benefits derived from each asset. Practically, intangible assets are amortised on a straight line basis over their estimated useful lives as per the table below:

|               | <b>Estimated useful life</b> |
|---------------|------------------------------|
| Patents       | Patent life                  |
| Licenses      | 3 to 20 years                |
| ICT, software | 3 to 5 years                 |

Intangible assets are carried in the consolidated balance sheet at their initial cost less accumulated amortisation and impairment, if applicable.

### 5.2.2.7. Property, plant and equipment

Property, plant and equipment are initially recorded in the consolidated balance sheet at their acquisition cost, including the costs directly attributable to the acquisition and the installation of the asset.

Each item of property, plant and equipment is recorded at historical cost less accumulated depreciation and impairment, if applicable. A pro rata straight-line depreciation method is used to reflect the pattern in which the asset's future economic benefits are expected to be consumed. Practically the term over which property, plant and equipment is depreciated depends on the estimated useful life of each asset category, as per the table below.

|  | <b>Estimated useful life</b>                     |
|--|--|
| <b>ICT, laboratory and manufacturing equipment</b>                   | <b>3 to 7 years</b>                              |
| <b>Fittings and leasehold improvements</b>                           | <b>The shorter of rent duration and 10 years</b> |
| <b>Idylla™ systems for internal use and Idylla™ systems for rent</b> | <b>5 years</b>                                   |
| <b>Other</b>   | <b>10 years</b>                                  |

The Company records as manufacturing and other equipment under construction all the physical equipment, including custom-designed equipment and generic pieces of equipment, and related costs, such as certain specific engineering expenses, incurred for their design, build-up and installation and validation costs, until it is ready for its intended use. Manufacturing and other equipment under construction is carried at cost and is not depreciated until it is ready for its intended use.

Normal maintenance and repair costs of property, plant and equipment are expensed as incurred. Other subsequent expenses are capitalised, only when it is probable that future economic benefits associated with the items will flow to the Company and the cost of the item can be measured reliably, such as the replacement of an identified component of an asset.

An item of property, plant and equipment and any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the income statement when the asset is derecognised.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.

### 5.2.2.8. Impairment of tangible and intangible assets, other than goodwill

The Company assesses, at each reporting date, whether there is an indication that an asset may be impaired. If any indication exists, or when annual impairment testing for an asset is required, the Company estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's or cash-generating unit's (CGU) fair value less costs of disposal and its value in use.

The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. When the carrying amount of an asset or CGU exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

A previously recognised impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognised. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognised for the asset in prior years. Such reversal is recognised in the consolidated income statement.

#### 5.2.2.9. Inventory

Inventories are valued at the lower of cost and net realisable value. The cost of inventories is determined on a first in, first out (FIFO) basis.

Net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

#### 5.2.2.10. Financial instruments

Financial assets and financial liabilities are recognised when a Group entity becomes a party to the contractual provisions of the instruments.

Financial assets and financial liabilities are initially measured at fair value. Transactions costs that are directly attributable to the acquisition or issue of financial assets and liabilities (other than financial assets and financial liabilities at fair value through profit or loss) are added to or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition. Transactions costs directly attributable to the acquisition of financial assets or financial liabilities at fair value through profit or loss are recognised immediately in profit or loss.

#### FINANCIAL ASSETS

The Company has financial assets classified in the following categories: 'available for sale' (AFS) financial assets and 'loans and receivables'. The classification depends on the nature and the purpose of the financial assets and is determined at the time of initial recognition.

#### Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Loans and receivables include trade receivables, loans, cash and cash equivalents, and other receivables which are measured at amortised cost using the effective interest method, less any impairment.

Interest income is recognised by applying the effective interest rate, except for short-term receivables when the effect of discounting is immaterial.

#### Available for sale financial assets

AFS financial assets are non-derivatives that are either designated as AFS or are not classified as loans or receivable, held to maturity or financial assets at fair value through profit or loss. The Company accounts for its participation in MyCartis as an AFS financial asset as of 31 December 2015.

After initial measurement, AFS financial assets are subsequently measured at fair value with unrealised gains or losses recognised in other comprehensive income and credited in the AFS reserve until the investment is derecognised, at which time the cumulative gain or loss is recognised in other operating income, or the investment is determined to be impaired, when the cumulative loss is reclassified from the AFS reserve to the statement of profit or loss in finance costs.





Interest earned whilst holding AFS financial assets is reported as interest income using the effective interest rate method.

#### Regular Way trades

Purchases or sales of financial assets that require delivery of assets within a time frame established by regulation or convention in the market place (regular way trades) are recognised on the settlement date, i.e., the date that an asset is delivered by or to an entity.

#### Derecognition

A financial asset is primarily derecognised when the contractual rights to receive cash flows from the asset have expired or when the owner of the asset transferred its rights to receive cash flows and substantially all the risk and rewards of ownership of the financial asset to another party. If the Group neither transfers nor retains substantially all the risks and rewards of ownership and continues to control the transferred asset, the Group recognises its retained interest in the asset and an associated liability for amounts it may have to pay. If the Group retains substantially all the risks and rewards of ownership of a transferred financial asset, the Group continues to recognise the financial asset and also recognises a collateralised borrowing for the proceeds received.

#### Impairment of financial assets

The Group assesses, at each reporting date, whether there is objective evidence that a financial asset or a group of financial assets is impaired. An impairment exists if one or more events that has occurred since the initial recognition of the asset (an incurred 'loss event'), has a negative impact on the estimated future cash flows of the financial asset or the group of financial assets that can be reliably estimated.

The carrying amount of the asset is reduced through the use of an allowance account and the loss is recognised in the statement of profit or loss.

## FINANCIAL LIABILITIES

The Group only has financial liabilities classified as 'other financial liabilities' measured at amortised cost. The Group does not have financial liabilities at fair value through profit or loss or derivatives. The Group's financial liabilities include trade and other payables and loans and borrowings.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortised cost using the effective interest rate method. Gains and losses are recognised in profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included as finance costs in the consolidated income statement.

### Derecognition

The Group derecognises financial liabilities when, and only when, the Group's obligations are discharged, cancelled or they expire. The difference between the carrying amount of the financial liability derecognised and the consideration paid and payable is recognised in profit or loss.

## EQUITY INSTRUMENTS

Equity instruments issued by the Company are recorded at the fair value of the proceeds received, net of transactions costs.

### 5.2.2.11. Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks, other short-term bank deposits with a maturity of or less than 3 months, and which are subject to an insignificant risk of changes in value.

### 5.2.2.12. Income taxes

Income taxes include all taxes based upon the taxable profits of the Group including withholding taxes payable on transfer of income from group companies and tax adjustments from prior years and deferred income taxes.

#### Current income tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to calculate the amount are those that are enacted or substantively enacted, at the reporting date in the countries where the Group operates and generates taxable income.

#### Deferred income tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date. Deferred tax liabilities are recognised for all taxable temporary differences, except when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of

the transaction, affects neither the accounting profit nor taxable profit or loss.

Deferred tax assets are recognised for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilised, except when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

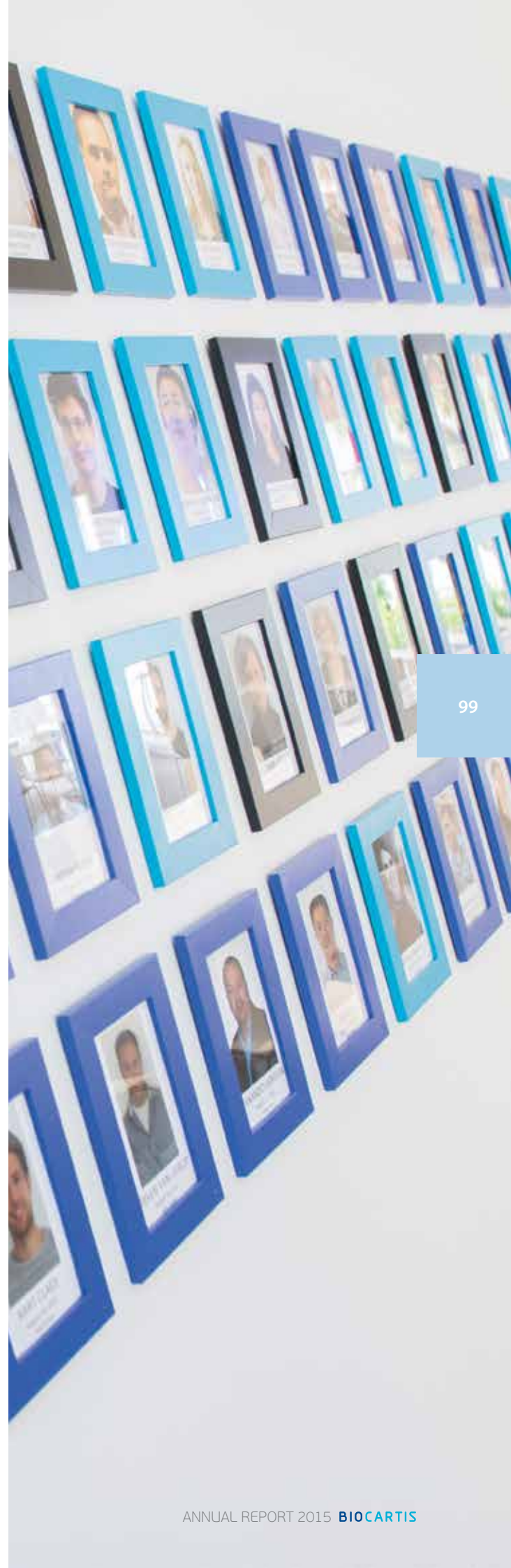
The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are re-assessed at each reporting date and are recognised to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority.

#### R&D Investment Tax Credits

Current IFRSs have no specific accounting principles with respect to the treatment of investment tax credits as these are scoped out of IAS 20 Government Grants and IAS 12 Income Taxes. As a result, the Company developed an accounting policy in accordance with IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors, whereby it opted to follow the analogy to IAS 12 Income Taxes. In following that analogy, there will be immediate recognition of an income tax credit and deferred tax asset when the Group satisfies the criteria to receive the credits. The recognition of the income tax credit is accounted for in the income statement under the line 'Income taxes'.



### 5.2.2.13. Employee benefits

#### SHORT-TERM EMPLOYEE BENEFITS

Short-term employee benefits include salaries and social security contributions, social taxes, paid vacation and bonuses. They are recognised as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period are shown as other current liabilities.

#### POST-EMPLOYMENT BENEFITS

Post-employment benefits include pensions and retirement benefits for employees working in Belgium and the Netherlands. They are covered by defined contribution plans.

##### Defined contribution plans

Under defined contribution plans, both the Group and its employees pay contributions based on salaries to organisations responsible for paying out pensions and social security benefits, in accordance with the laws and agreements applicable in each country. Contributions are recognised as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period are shown as other current liabilities.

Under the Belgian defined contribution pension plans, employers were by law of 28 April 2003 required to provide minimum guaranteed rates of return on employer contributions (3.25%) and employee contributions (3.75%). Following the law of 18 December 2015, these fixed rates were abandoned and a new variable minimum guaranteed rate of return is applicable for contributions paid since 1 January 2016. This percentage is annually calculated as 65% of the average 10 year OLO over a period of 24 months, with a minimum of 1.75% and a maximum of 3.75%. In view of the low OLO rates in recent years, the initial percentage is fixed at the minimum of 1.75%. Contributions paid until 31 December 2015 remain subject to the minimum guaranteed return of 3.25% on employer contributions and 3.75% on employee contributions. In view of the minimum guaranteed return, these defined contribution plans classify as defined benefit plans.

##### Defined benefit plans

Under defined benefit plans, which include regular or supplementary pension plans, contributions to these plans are normally paid into funds which are managed independently of the Group.

The Group's obligation towards the defined benefit plans and the annual cost recognised in the consolidated income statement is determined by an independent actuary using the 'projected unit credit method', taking into account actuarial assumptions such as discount rates, salary increases, employee turnover and mortality rates. The Group recognises actuarial gains and losses in full immediately during the year in which they arise as other comprehensive income.

Past service costs are recognised in profit or loss in the period of a plan amendment. Net interest is calculated by applying the discount rate to the net defined benefit liability or asset.

The retirement benefit obligation recognised in the consolidated balance sheet represents the present value of the defined benefit obligation reduced by the fair value of the plan assets. Any asset resulting from calculation is limited to the present value of the available funds and reductions in future contributions to the plan.

The post-employment benefits of the employees of Biocartis SA in Switzerland were considered as a defined benefit plan and have been included within the discontinued operations in 2014. The defined benefit plan has

been transferred to MyCartis NV, which was subsequently disposed of on 6 November 2014 and had no further impact in 2015.

The Belgian defined contribution plans are classified as defined contribution in view of the minimum guaranteed rate of return (refer to above).

#### SHARE-BASED COMPENSATION

The Group operates equity-settled share-based compensation plans. The fair value of the employee services received in exchange for the grant of stock options is determined at the grant date using an appropriate valuation model (Black-Scholes Merton model).

The total amount to be expensed over the vesting period, with a corresponding increase in the 'share-based payment reserve' within equity, is determined by reference to the fair value of the stock options granted, excluding the impact of any non-market vesting conditions (for example, profitability and sales growth targets). Non-market based vesting conditions are included in assumptions about the number of stock options that are expected to become exercisable. At each balance sheet date, the entity revises its estimates of the number of stock options that are expected to become exercisable. It recognises the impact of the revision of original estimates, if any, in the income statement, and a corresponding adjustment to equity over the remaining vesting period.

The proceeds received net of any directly attributable transaction costs are credited to share capital (par value) and share premium when the stock options are exercised.

#### 5.2.2.14. Provisions

The Group recognises provisions when it has a present obligation, legal or constructive, as a result of past events, when it is probable, defined as more likely than not, that an outflow of resources will be required to settle the obligation and when a reliable estimate of the amount can be made.

#### 5.2.2.15. Revenue recognition

The Group recognises revenue from the sale of the Idylla™ platform and related cartridges as well as from license fees, milestones and contingent payments earned on research and collaboration arrangements.

These transactions may involve multiple elements. The Group evaluates whether the elements under these arrangements have value to its collaboration partner or customer on a stand-alone basis.

If the Group determines that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition.

#### LICENSING, CONTRACTING AND COLLABORATION REVENUES

Upfront fees received by the Group in license and collaboration arrangements that include future obligations are recognised 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 fulfill its performance obligations, which may include technology transfer assistance, research and development activities, clinical, medical and regulatory activities, manufacturing and commercialisation activities.

Contingent consideration received upon the achievement of a substantive milestone is recognised in its entirety in the period in which the milestone is achieved, which is consistent with the substance of the Group's performance under the Group's various license and collaboration agreements. 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, relates solely to the Group's past performance, and is reasonable relative to all of the other deliverables and payments within the 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 recognise 100% of the contingent revenues when the contingency is achieved and collection is reasonably assured. Contingency and milestones payments, when recognised as revenue, are classified as contract revenues in the Group's Consolidated Income Statement.

Revenues and expenses from collaborations are recorded as contract revenues or research and development expenses in the period incurred.

#### PRODUCT SALES, REAGENT RENTAL CONTRACTS AND RENTAL CONTRACTS

##### Product sales

Revenues from the sale of goods are recognised when the Group has transferred to the buyer the significant risks and rewards of ownership of the goods, when the amount of revenues can be measured reliably, when it is probable that the economic benefits associated with the transaction will flow to the Group and when the costs incurred or to be incurred in respect of the transaction can be measured reliably.

Revenue from the sale of goods is measured at the fair value of the consideration received or receivable, net of returns and allowances, trade discounts and volume discounts.

### Reagent rental contracts

The Group also sells the console, instrument and cartridges under the form of an Idylla™ Reagent Rental Agreement whereby the Group delivers the console and instruments and the customer commits to purchase a minimum required volume (consumption) of cartridges over a defined period. The sales price of the console and instruments is included as an additional markup premium in the price of the cartridges and is as such paid over the period when the cartridges are purchased. When the minimum required consumption is not met, evaluated at each calendar year, the Group can increase the sales prices for the cartridges or can require the customer to pay an indemnity when the rental agreement is terminated early by the Group. In all events, the instrument and console price will be fully restituted by the customer.

If the Group determines that the significant risks and rewards for the Idylla™ systems are transferred upon delivery to the customer, the revenue for those Idylla™ systems is recognised at that time. Revenue for those Idylla™ systems is spread linearly over the term of the contract if the Group determines that the risks and rewards are not transferred upon delivery to the customer. The revenue of the cartridges (excluding markup) is recognised when the cartridges are delivered to the customer.

### Rental contracts

The Group also rents out Idylla™ systems, whereby the customer pays a regular rental fee for the temporary use of the Idylla™ system since there is no transfer of ownership. Under these type of rental contracts, the Idylla™ system revenue is considered as pure rental income and is recognised linearly over the term of the rental contract. Upon expiry of the rental contract, the rented out Idylla™ systems return to the Group.

#### 5.2.2.16. Grants

Government grants are not recognised until there is reasonable assurance that the Group will comply with the conditions attaching to them and that the grants will be received. Any outstanding receivables related to these grants are recorded as grants receivable.

#### R&D grants

On certain specific research and development projects, the costs incurred are partially reimbursed by IWT (Institute for the Promotion of Innovation by Science and Technology in Flanders), Hermes (a fund from the Agency for Entrepreneurship in Flanders), the European Commission or other institutional funds. These grants are recognised in profit or loss on a systematic basis over the periods in which the Group recognises as expenses the related costs which the grants are intended to compensate. They are presented as other operating income.

#### Investment grants

Grants from Hermes relating to investments in property, plant and equipment and intangible assets are deducted from the cost of the related asset. The grant is recognised in profit or loss over the life of a depreciable asset as a reduced depreciation expense.

#### 5.2.2.17. Leases

Leases are classified as financial leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. All other leases are classified as operating leases.

### The Group as lessee

Assets held under financial leases are initially recognized as assets of the Group at their fair value or, if lower, at the present value of the minimum lease payments, each determined at the inception of the lease. Initial direct costs incurred in connection with the lease are added to the amount recognized as an asset. The corresponding liability to the lessor is included in the consolidated balance sheet as a financial obligation. Lease payments are apportioned between financial charges and reduction of the lease obligation so as to achieve a constant rate of interest on the remaining balance of the liability. Financial charges are charged directly against income. If there is no reasonable certainty that the Group will obtain ownership by the end of the lease term, the asset shall be fully depreciated over the shorter of the lease term and its useful life. Payments made under operating leases are charged to the consolidated income statement on a straight-line basis over the period of the lease.

#### 5.2.2.18. Borrowing costs

Borrowing costs directly attributable to the acquisition, construction or production of an asset that necessarily takes a substantial period of time to get ready for its intended use or sale are capitalised as part of the cost of the asset. All other borrowing costs are expensed in the period in which they occur. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

### 5.2.3. Critical accounting estimates, assumptions and judgments

#### 5.2.3.1. Critical accounting estimates, assumptions and judgments

When preparing the consolidated financial statements, judgments, estimates and assumptions are made that affect the carrying value of certain assets, liabilities, revenues and expenses. These include the going concern assessment, the valuation of the share-based payment transactions, the valuation of employee benefits and actuarial assumptions underlying such calculations and the revenue recognition for multiple element arrangement, upfront fees and reagent rental contracts. These estimates and assumptions have been reviewed for each year and are reviewed on a regular basis, taking into consideration past experience and other factors deemed relevant under the then prevailing economic conditions. Changes in such conditions might accordingly result in different estimates in the Group's future consolidated financial statements.

#### CRITICAL JUDGMENTS

##### Going concern

The financial statements have been established on a going concern basis.

Based on management's judgment and taking into account available cash and cash equivalents per 31 December 2015, and as of the date of these financial statements, as well as current burn rate projections for 2016 and 2017 and funding initiatives as being decided by the board of directors, going concern is assured for at least 12 months from the date of these financial statements.

The board of directors supports management's efforts in securing additional financial means inter alia by signing non-dilutive cash-generating deals (including for example non-refundable upfront payments on licensing deals and grants).

The board of directors is confident that the Group's financial future will be safeguarded at least until the annual general meeting to be held in 2017. Should the Group not succeed in attracting additional funding in the future, it



may be unable to realise its assets and discharge its liabilities in the normal course of business.

#### Accounting for defined contribution plans in Belgium

The Belgian defined contribution plans classify as defined benefit plans in view of the guaranteed minimum rates of return. The Group analysed the impact of the application of the Projected Unit Credit Method on those plans and concluded that the application of that method would not have a material impact on the financial statements per 31 December 2015. As such no defined benefit obligation was recorded per 31 December 2015.

### CRITICAL ACCOUNTING ESTIMATES AND ASSUMPTIONS

#### Estimations of post-employment benefit obligations

The Group maintained until November 2014 a defined benefit pension plan in Switzerland. The related obligations recognised in the consolidated balance sheet represent the present value of the defined benefit obligations calculated annually by independent actuaries. These actuarial valuations include assumptions such as discount rates, return on assets, salary progression rates and mortality rates. These actuarial assumptions vary according to the local prevailing economic and social conditions. Details of the assumptions used are provided in note 5.2.25. The defined benefit pension plan was disposed of with the spin-off of the MyCartis business, which was subsequently disposed of on 6 November 2014.

#### Share-based payments

The Group has several equity-settled share based payment plans in place, valued using the Black-Scholes Merton option valuation model. Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which is dependent on the terms and conditions of the option plan. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them.

The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in Note 5.2.23.

#### Revenue recognition

For revenue recognition, the significant estimates relate to allocation of value to the separate elements in multiple-element arrangements. With respect to the allocation of value to the separate elements, the Company is using the stand-alone selling prices or management's best estimates of selling prices to estimate the fair value of the elements and account for them separately. Revenue is allocated to each deliverable based on the fair value of each individual element and is recognised when the revenue recognition criteria described above are met.

Upfront fees under collaboration or licensing agreements are recognised over the expected duration of the collaboration. Management estimates this period at the start of the collaboration and validates the remaining estimated collaboration term at each closing date.

#### 5.2.3.2. Segments

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

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

In addition, all non-current assets of the Group are located in the country of domicile per 31 December 2015.

## 5.2.4. Revenue

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

### 5.2.4.1. Collaboration revenues

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

| In EUR000                    | Years ended 31 December, |              |
|------------------------------|--------------------------|--------------|
|                              | 2015                     | 2014         |
| <b>Collaboration revenue</b> |                          |              |
| R&D services                 | 662                      | 228          |
| Upfront license revenues     | 5,025                    | 1,946        |
| Milestone revenues           | 4,000                    | 1,000        |
|                              | <b>9,686</b>             | <b>3,174</b> |
| <b>Product sales revenue</b> |                          |              |
| Idylla™ System Sales         | 2,299                    | 3,718        |
| Cartridge Sales              | 1,294                    | 1,542        |
|                              | <b>3,593</b>             | <b>5,260</b> |
| <b>Service revenue</b>       |                          |              |
| Service revenue              | 54                       | 44           |
|                              | <b>54</b>                | <b>44</b>    |
| <b>Total</b>                 | <b>13,334</b>            | <b>8,478</b> |

### Janssen Pharmaceutica

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

### Abbott Molecular

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

No revenue was recognised under this agreement in the years presented.



#### Amgen Inc.

Biocartis Group and Amgen Inc. have entered into a collaboration agreement to evaluate Idylla™ RAS testing as a tool for rapid decentralised testing in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain, and Turkey.

No revenue was recognised under this agreement in the years presented. Upfront payments for EUR 0.6m have been recorded in deferred income.

#### Merck KGaA (Merck)

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

No revenue was recognised under this agreement in the years presented.

#### Potential upfront and milestone revenues

In aggregate the potential upfront and milestone revenues that can be earned by the Group over the remaining term of these collaboration agreements amounts to EUR 5m (2014: EUR 6m).

#### 5.2.4.2. Product sales

Product sales relate to Idylla™ system sales (instruments and consoles) and the test sales (cartridges) to customers and collaboration partners. The total product sales can be categorised in commercial sales and research and development sales based upon the nature of the revenues (i.e. commercial versus research & development) as well as labeling of sold products (IVD products versus research use only products).

|                                | Years ended 31 December, |              |
|--------------------------------|--------------------------|--------------|
|                                | 2015                     | 2014         |
| Commercial revenue             | 2,550                    | 1,985        |
| Research & Development revenue | 1,044                    | 3,275        |
| <b>Total</b>                   | <b>3,593</b>             | <b>5,260</b> |

### 5.2.4.3. Revenues by region and major customers

| In EUR000                                    | Years ended 31 December, |              |
|--|--------------------------|--------------|
|  | 2015                     | 2014         |
| <b>Country of domicile</b>                   | <b>731</b>               | <b>27</b>    |
| Belgium                                      | 731                      | 27           |
| <b>Total all foreign countries, of which</b> | <b>12,603</b>            | <b>8,451</b> |
| United states of America                     | 9,890                    | 8,412        |
| Rest of the world                            | 2,713                    | 39           |
| <b>Total</b>                                 | <b>13,334</b>            | <b>8,478</b> |

Revenues in the above table are split up according to the location of the group or parent company of the client.

The Group has recognised revenues from one customer with individual revenue representing at least 10% of the total revenues. This customer accounts for EUR 9.9m of the revenues in 2015 (2014: EUR 8.4m).

### 5.2.5. Other operating income

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

| In EUR000                        | Years ended 31 December, |              |
|----------------------------------|--------------------------|--------------|
|                                  | 2015                     | 2014         |
| R&D project support (IWT grants) | 1,614                    | 1,482        |
| Other project grants             | 0                        | 407          |
| Other income                     | 3                        | 0            |
| <b>Total</b>                     | <b>1,617</b>             | <b>1,889</b> |

## 5.2.6. Cost of Goods Sold

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

| In EUR000                                   | Years ended 31 December, |               |
|---|--------------------------|---------------|
|   | 2015                     | 2014          |
| Staff costs                                 | -916                     | -1,423        |
| Material, lab consumables & small equipment | -1,104                   | -1,939        |
| Depreciation and amortisation               | -499                     | -618          |
| Royalty expense                             | -80                      | -202          |
| Other                                       | -43                      | -69           |
| <b>Total</b>                                | <b>-2,642</b>            | <b>-4,251</b> |

## 5.2.7. Research and Development expenses

| In EUR000                                    | Years ended 31 December, |                |
|--|--------------------------|----------------|
|  | 2015                     | 2014           |
| Staff costs                                  | -16,826                  | -12,634        |
| Subcontracting                               | -6,205                   | -4,031         |
| Laboratory expenses                          | -2,197                   | -1,385         |
| Platform and cartridge prototype costs       | -2,335                   | -350           |
| Consultancy                                  | -1,409                   | -968           |
| Quality and regulatory                       | -16                      | -95            |
| Intellectual property                        | -923                     | -782           |
| Facilities, office & other                   | -2,073                   | -1,625         |
| ICT  | -903                     | -454           |
| Travel, training & conferences               | -759                     | -426           |
| Depreciation and amortisation                | -4,443                   | -3,336         |
| Capitalised Idylla™ systems for internal use | 1,250                    | 1,072          |
| Capitalised Idylla™ systems for rent         | 285                      | 0              |
| <b>Total</b>                                 | <b>-36,554</b>           | <b>-25,014</b> |

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

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

In total 31 Idylla™ consoles and 82 Idylla™ instruments – both used for R&D purposes - were internally capitalised in 2015.

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

### 5.2.8. Marketing and Distribution expenses

| In EUR000                      | Years ended 31 December, |               |
|--------------------------------|--------------------------|---------------|
|                                | 2015                     | 2014          |
| Staff costs                    | -3,566                   | -2,000        |
| Subcontracting                 | -2,344                   | -302          |
| Sales and promotional expenses | -918                     | -117          |
| Business development           | -276                     | -54           |
| Consultancy                    | -228                     | -49           |
| Facilities, office & other     | -263                     | -120          |
| Travel, training & conferences | -1,079                   | -428          |
| Depreciation and amortisation  | -73                      | -25           |
| <b>Total</b>                   | <b>-8,747</b>            | <b>-3,095</b> |

Subcontracting include external sales force support from Janssen Pharmaceutica NV (JPNV), and external market research. Sales and promotional expenses include branding, advertisement, campaigns and other promotional activities related to the Group's products.

### 5.2.9. General and Administrative expenses

| In EUR000                              | Years ended 31 December, |               |
|--|--------------------------|---------------|
|  | 2015                     | 2014          |
| Staff costs                            | -2,809                   | -2,918        |
| External advice                        | -1,330                   | -1,601        |
| Facilities, office & other             | -1,287                   | -986          |
| Human resources                        | -965                     | -369          |
| Travel, training & conferences         | -266                     | -849          |
| Depreciation and amortisation expenses | -6                       | -457          |
| <b>Total</b>                           | <b>-6,662</b>            | <b>-7,180</b> |

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

## 5.2.10. Personnel expenses

| In EUR000                                  | Years ended 31 December, |                |
|--|--------------------------|----------------|
|  | 2015                     | 2014           |
| Short term employee benefits               | -23,687                  | -18,695        |
| Post-employee defined benefit expense      | 0                        | -4             |
| Post-employee defined contribution expense | -111                     | -112           |
| Termination benefits                       | -139                     | -20            |
| Share based compensation                   | -143                     | -143           |
|  | <b>-24,117</b>           | <b>-18,975</b> |

The headcount can be presented as follows:

|                                      | As of 31 December, |            |
|--------------------------------------|--------------------|------------|
|                                      | 2015               | 2014       |
| Operations staff                     | 89                 | 65         |
| Research and development staff       | 123                | 85         |
| Marketing and distribution staff     | 32                 | 20         |
| General and administrative staff     | 34                 | 24         |
| <b>Total headcount</b>               | <b>278</b>         | <b>194</b> |
| <b>Average full time equivalents</b> | <b>270</b>         | <b>189</b> |

## 5.2.11. Financial income and expense

| In EUR000                            | Years ended 31 December, |             |
|--------------------------------------|--------------------------|-------------|
|                                      | 2015                     | 2014        |
| Interest income                      | 107                      | 60          |
| Other financial income               | 0                        | 0           |
| <b>Total</b>                         | <b>107</b>               | <b>60</b>   |
| Interest expense                     | -775                     | -923        |
| Other financial expense              | -44                      | -9          |
| <b>Total</b>                         | <b>-819</b>              | <b>-933</b> |
| Foreign exchange gains/(losses), net | -78                      | -88         |
| <b>Total</b>                         | <b>-78</b>               | <b>-88</b>  |
| <b>Financial result, net</b>         | <b>-790</b>              | <b>-961</b> |

## 5.2.12. Discontinued operations

On 11 November 2014, the Group finalized the disposal of its Evaluation business (i.e. referred to as the MyCartis spin-out) for a total price of EUR 30m resulting in a gain on disposal of EUR 26.6m. Prior to 11 November 2014, the disposal was initiated by means of the following steps:

- On 1 July 2014, the Group contributed the Evaluation branch of activity into the share capital of MyCartis NV, previously known as Pronota NV, a Belgian biomarker discovery company. Following this contribution in kind, the Group held 80% of the shares of MyCartis NV. The results of MyCartis NV contribute to the Group's results as of that date.
- On 26 August 2014, Biocartis SA decreased its share capital for an amount of EUR 30.5m (CHF 37.0m), of which EUR 30.0m (CHF 36.4m) was paid out in kind in the form of all the shares held by Biocartis SA in MyCartis NV, and of which the remaining EUR 0.5m (CHF 0.6m) was an adjustment to the carrying value of the capital reduction liability towards shareholders, which was accounted for as an equity transaction. The completion of this capital decrease took place at 11 November 2014. As of that date, MyCartis NV is no longer consolidated in the Group's financial results.

| In EUR000  | Years ended 31 December |               |
|--|-------------------------|---------------|
|  | 2015                    | 2014          |
| Collaboration revenue                                      | 0                       | 134           |
| Product sales  | 0                       | 0             |
| Grants and other income                                    | 0                       | 0             |
| <b>Total revenues</b>                                      | <b>0</b>                | <b>134</b>    |
| <b>Cost of Goods Sold</b>                                  | <b>0</b>                | <b>0</b>      |
| Research and development expenses                          | 0                       | -5,651        |
| Marketing and distribution expenses                        | 0                       | -531          |
| General and administrative expenses                        | 0                       | -1,097        |
| <b>Total operating expenses</b>                            | <b>0</b>                | <b>-7,278</b> |
| <b>Operating loss for the period</b>                       | <b>0</b>                | <b>-7,144</b> |
| Financial income   | 0                       | 0             |
| Financial expense  | 0                       | 0             |
| Foreign exchange gains/(losses), net                       | 0                       | -8            |
| <b>Financial result, net</b>                               | <b>0</b>                | <b>-8</b>     |
| <b>Loss before taxes</b>                                   | <b>0</b>                | <b>-7,153</b> |
| Taxes  | 0                       | 0             |
| <b>Loss after taxes</b>                                    | <b>0</b>                | <b>-7,153</b> |
| Gain on disposal   | 0                       | 26,624        |
| Taxes on gain on disposal                                  | 0                       | 0             |
| <b>Net loss for the year from discontinuing operations</b> | <b>0</b>                | <b>19,472</b> |
| attributable to the shareholders                           | 0                       | 20,070        |
| attributable to non-controlling interest                   | 0                       | -598          |



The derecognised assets and liabilities at divestment date (November 2014) are presented below:

|                                |                     |
|--------------------------------|---------------------|
| <b>Non-current assets</b>      |                     |
| Goodwill                       | 298                 |
| Intangible assets              | 215                 |
| Property plant and equipment   | 427                 |
|                                | <u>940</u>          |
| <b>Current assets</b>          |                     |
| Other receivables              | 163                 |
| Other current assets           | 98                  |
| Cash and cash equivalents      | 5,138               |
|                                | <u>5,665</u>        |
| <b>Total assets</b>            | <b><u>6,605</u></b> |
| <b>Non-current liabilities</b> |                     |
| Financial debt                 | 120                 |
| Retirement benefit obligation  | 375                 |
|                                | <u>495</u>          |
| <b>Current liabilities</b>     |                     |
| Trade payables                 | 1,459               |
| Deferred income                | 124                 |
| Other current liabilities      | 306                 |
|                                | <u>1,889</u>        |
| <b>Total liabilities</b>       | <b><u>2,384</u></b> |
| <b>Net assets derecognised</b> | <b><u>4,221</u></b> |

The gain on disposal is calculated as follows:

|                          |               |
|--------------------------|---------------|
| Sales price              | 30,000        |
| Net assets derecognised  | -4,221        |
| Non-controlling interest | 845           |
|                          | <u>26,624</u> |

As part of the business acquisition (step 1) whereby the Group acquired a 80% stake in MyCartis NV on 1 July 2014, the carrying value of the acquired assets and assumed liabilities approximate their fair value and as such no fair value adjustments have been made. The assets acquired and liabilities assumed consisted primarily of cash for an amount of EUR 7.5m and resulted in a non-controlling interest measured at fair value of EUR 1.5m in 2014.

The contribution of the Evaluation branch in MyCartis NV resulted in a gain on dilution of EUR 6m which has been recognised directly in accumulated deficit in 2014. The total non-controlling interest at the time of the business combinations amounted to EUR 1.4m which is the non-controlling interest at fair value of the acquired business of EUR 1.5m less the non-controlling interest of the net assets of the Evaluation branch transferred of EUR -0.1m in 2014. The results of Evaluation are presented in the line 'income (loss) from discontinued operations' as shown on the tables.

The cash flow statement of the discontinued operations until divestment is as follows:

| <u>in EUR000</u>                    | <u>Years ended 31 December</u> |               |
|-------------------------------------|--------------------------------|---------------|
|                                     | <u>2015</u>                    | <u>2014</u>   |
| Cash flow from operating activities | 0                              | -7,017        |
| Cash flow from investing activities | 0                              | -181          |
| Cash flow from financing activities | 0                              | 0             |
|                                     | <u>0</u>                       | <u>-7,198</u> |

The basic and diluted earnings per share (EPS) from the discontinued operations are detailed as follows. The stock options plans were anti-dilutive in 2014 as the adjusted exercise price (considering the fair value of the services to be rendered for the unvested options) was higher than the market value of the common shares.

| <u>In EUR000</u>                 | <u>Years ended 31 December</u> |             |
|----------------------------------|--------------------------------|-------------|
|                                  | <u>2015</u>                    | <u>2014</u> |
| EPS from discontinued operations | 0.00                           | 0.79        |

### 5.2.13. Earnings per share

The Company has stock option plans that may be settled in common shares of the Company which are anti-dilutive considering the loss of the year. As such, the basic and diluted earnings per share are equal.

In 2014, the preference F shares were treated as common shares for purposes of the earnings per share considering that the preference shares were convertible to common shares at the option of the holder and conversion was mandatory at the date of the initial public offering that took place on 27 April 2015. Since that date, all shares belong to the same category and thus there are no longer preference shares. Also, the only additional right compared to ordinary shares was preferred liquidation proceeds (at the time of liquidation or certain sales of shares of the Company).

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

|   | <u>Years ended 31 December</u> |                     |
|---|--------------------------------|---------------------|
|   | <u>2015</u>                    | <u>2014</u>         |
| Profit/loss for the period attributable to the owners of the Company (in EUR000)          | -39,797                        | -9,118              |
| Weighted average number of ordinary shares for basic loss per share (in number of shares) | 37,061,213                     | 25,522,088          |
| <b>basic loss per share (EUR)</b>   | <u><u>-1.07</u></u>            | <u><u>-0.36</u></u> |

## 5.2.14. Intangible assets

The Group's intangible assets comprise acquired patents, licenses and software. The carrying amounts for the periods presented can be analysed as follows:

| In EUR000                            | Patents<br>and<br>licenses | ICT<br>software | Total        |
|--------------------------------------|----------------------------|-----------------|--------------|
| <b>Year ended 31 December 2014</b>   |                            |                 |              |
| Opening net carrying value           | 9,356                      | 629             | 9,985        |
| Additions                            | 701                        | 139             | 839          |
| Disposals                            | -239                       | -52             | -291         |
| Disposal depreciations               | 44                         | 37              | 80           |
| Amortisation expense                 | -638                       | -323            | -961         |
| <b>Closing net carrying value</b>    | <b>9,223</b>               | <b>429</b>      | <b>9,652</b> |
| <b>As at 31 December 2014</b>        |                            |                 |              |
| Cost                                 | 12,025                     | 1,121           | 13,146       |
| Accumulated amortisation             | -2,802                     | -692            | -3,494       |
| <b>Net carrying value</b>            | <b>9,223</b>               | <b>429</b>      | <b>9,652</b> |
| <b>Period ended 31 December 2015</b> |                            |                 |              |
| Opening net carrying value           | 9,223                      | 429             | 9,652        |
| Additions                            | 184                        | 187             | 371          |
| Disposals                            | 0                          | 0               | 0            |
| Disposal depreciations               | 0                          | 0               | 0            |
| Amortisation expense                 | -745                       | -291            | -1,036       |
| <b>Closing net carrying value</b>    | <b>8,662</b>               | <b>326</b>      | <b>8,987</b> |
| <b>As at 31 December 2015</b>        |                            |                 |              |
| Cost                                 | 12,209                     | 1,309           | 13,517       |
| Accumulated amortisation             | -3,547                     | -983            | -4,530       |
| <b>Net carrying value</b>            | <b>8,662</b>               | <b>326</b>      | <b>8,987</b> |

Patents and licenses primarily include a number of technology licenses acquired by the Group from Philips in 2010 for EUR 10.0m relating to the Group's flagship diagnostic platform 'Idylla™'. The carrying amount per 31 December 2015 is EUR 7.0m (2014: EUR 7.5m). The remaining useful life is 13 years. In 2011, the Group acquired a license from the same partner for access to the 'Idylla™-Enrich' technology for EUR 0.5m. The technology scope of the licenses from Philips consists of intellectual property rights, invention disclosures, technical and biological data, drawings and know-how. Simultaneously with this agreement, Philips and the Group have entered into asset transfer agreements, for the purpose of transferring the assets relating to the 'Idylla™' and 'Idylla™-Enrich' technologies to the Group.

Amortisation expense on intangible assets is shown in the income statement under research and development expenses.

The Group has not recorded any impairment related to its intangible assets

## 5.2.15. Property, plant and equipment

The Group's property, plant and equipment comprise ICT equipment, laboratory equipment, manufacturing equipment, Idylla™ systems for internal use, furniture and fixtures, leasehold improvements, other property and equipment, equipment under construction, assets held under lease and Idylla™ systems for rent. The carrying amounts can be analysed as follows:

|                                      | ICT equipment | Laboratory equipment | Manufacturing equipment | Systems for internal use | Furniture and fixtures | Leasehold improvements | Other property and equipment | Equipment under construction | Assets held under Lease | Systems for rent | Total         |
|--------------------------------------|---------------|----------------------|-------------------------|--------------------------|------------------------|------------------------|------------------------------|------------------------------|-------------------------|------------------|---------------|
| <b>In EUR000</b>                     |               |                      |                         |                          |                        |                        |                              |                              |                         |                  |               |
| <b>Year ended 31 December 2014</b>   |               |                      |                         |                          |                        |                        |                              |                              |                         |                  |               |
|                                      | <b>562</b>    | <b>686</b>           | <b>2,174</b>            | <b>805</b>               | <b>385</b>             | <b>870</b>             | <b>4</b>                     | <b>20</b>                    | <b>5,694</b>            |                  | <b>11,199</b> |
| Opening net carrying value           |               |                      |                         |                          |                        |                        |                              |                              |                         |                  |               |
| Additions                            | 174           | 296                  | 177                     | 1,072                    | 119                    | 90                     | 0                            | 0                            | 0                       |                  | 1,927         |
| Disposals                            | -159          | -285                 | -19                     |                          | -228                   | -150                   | 0                            | 0                            | 0                       |                  | -841          |
| Disposal depreciation                | 119           | 183                  | 19                      |                          | 71                     | 69                     | 0                            | 0                            | 0                       |                  | 461           |
| Depreciation charge of the period    | -207          | -257                 | -1,034                  | -237                     | -55                    | -309                   | -2                           | 0                            | -1,455                  |                  | -3,556        |
| Impairment losses                    | -12           | 0                    | -10                     |                          | -15                    | 0                      | 0                            | 0                            | 0                       |                  | -37           |
| <b>Closing net carrying value</b>    | <b>477</b>    | <b>623</b>           | <b>1,307</b>            | <b>1,640</b>             | <b>276</b>             | <b>570</b>             | <b>2</b>                     | <b>20</b>                    | <b>4,239</b>            |                  | <b>9,154</b>  |
| <b>As at 31 December 2014</b>        |               |                      |                         |                          |                        |                        |                              |                              |                         |                  |               |
| Cost                                 | 1,036         | 1,126                | 4,815                   | 1,919                    | 419                    | 1,187                  | 10                           | 20                           | 7,118                   |                  | 17,652        |
| Accumulated depreciation             | -560          | -503                 | -3,509                  | -279                     | -142                   | -618                   | -8                           | 0                            | -2,879                  |                  | -8,498        |
| <b>Net carrying value</b>            | <b>477</b>    | <b>623</b>           | <b>1,307</b>            | <b>1,640</b>             | <b>276</b>             | <b>570</b>             | <b>2</b>                     | <b>20</b>                    | <b>4,239</b>            |                  | <b>9,154</b>  |
| <b>Period ended 31 December 2015</b> |               |                      |                         |                          |                        |                        |                              |                              |                         |                  |               |
|                                      | <b>477</b>    | <b>623</b>           | <b>1,307</b>            | <b>1,640</b>             | <b>276</b>             | <b>570</b>             | <b>2</b>                     | <b>20</b>                    | <b>4,239</b>            |                  | <b>9,154</b>  |
| Opening net carrying value           |               |                      |                         |                          |                        |                        |                              |                              |                         |                  |               |
| Additions                            | 194           | 311                  | 4,807                   | 1,323                    | 126                    | 896                    | 0                            | 80                           | 1,216                   | 285              | 9,240         |
| Disposals                            | 0             | 0                    | -18                     | -205                     | 0                      | 0                      | 0                            | 0                            | 0                       | 0                | -223          |
| Disposal depreciation                | 0             | 0                    | 0                       | 58                       | 0                      | 0                      | 0                            | 0                            | 0                       | 0                | 58            |
| Depreciation charge of the period    | -204          | -302                 | -1,158                  | -502                     | -52                    | -310                   | -1                           | 0                            | -1,456                  | 0                | -3,984        |
| Transfers gross book value           | 0             | 0                    | 0                       | 0                        | 0                      | 0                      | 0                            | 0                            | 0                       | 0                | 0             |
| Transfers depreciations              | 0             | 0                    | 0                       | 0                        | 0                      | 0                      | 0                            | 0                            | 0                       | 0                | 0             |
| <b>Closing net carrying value</b>    | <b>467</b>    | <b>633</b>           | <b>4,939</b>            | <b>2,315</b>             | <b>351</b>             | <b>1,156</b>           | <b>1</b>                     | <b>101</b>                   | <b>3,998</b>            | <b>285</b>       | <b>14,245</b> |
| <b>As at 31 December 2015</b>        |               |                      |                         |                          |                        |                        |                              |                              |                         |                  |               |
| Cost                                 | 1,231         | 1,437                | 9,605                   | 3,038                    | 545                    | 2,083                  | 10                           | 101                          | 8,334                   | 285              | 26,669        |
| Accumulated depreciation             | -764          | -805                 | -4,666                  | -723                     | -194                   | -928                   | -9                           | 0                            | -4,336                  | 0                | -12,424       |
| <b>Net carrying value</b>            | <b>467</b>    | <b>633</b>           | <b>4,939</b>            | <b>2,315</b>             | <b>351</b>             | <b>1,156</b>           | <b>1</b>                     | <b>101</b>                   | <b>3,998</b>            | <b>285</b>       | <b>14,245</b> |

Assets held under lease relate to the Idylla™ semi-automated cartridge manufacturing line which was refinanced on 8 March 2013 via a EUR 7.9m sale and lease back. The net carrying value is EUR 2.8m as per 31 December 2015 (2014: EUR 4.2m). In 2015, the purchase option at the end of the lease period was decreased from EUR 0.2m to EUR 0.1m and the leasing period was extended (note 5.2.24). The additions of EUR 1.2m in 2015 concern the upgrade of the current cartridge production line that is planned to be completed in 2016. The total financial lease line granted is EUR 4.4m, of which EUR 1.2m was drawn per 31 December 2015. The purchase option amounts 1% of the invested amount.

The manufacturing equipment is related to the Idylla™ cartridge production line, the Idylla™ instrument and console production and the Idylla™-Enrich pilot. The additions on manufacturing equipment in 2015 for an amount of EUR 4.8m mainly relate to advances paid for the second Idylla™ cartridge production line that will be built in Mechelen (Belgium).

The total of Idylla™ systems for internal use consisted of 50 Idylla™ consoles (2014: 24) and 191 Idylla™ instruments (2014: 120) per 31 December 2015.

Idylla™ systems for rent concern 22 Idylla™ instruments (2014: 0) and 16 Idylla™ consoles (2014: 0) that are rented to third parties.

### 5.2.16. Financial participation

On 15 January 2015, the Group acquired a financial participation of 13.5% (per 31 December 2015: 9.53 %) in MyCartis NV through a contribution in kind for an amount of EUR 5.1m through the exercise of the share put option held by Debiopharm Diagnostics SA. The fair value at initial recognition did not differ from the transaction cost. The participation is accounted for as an available-for-sale financial asset. The fair value of the participation per 31 December 2015 does not differ from the carrying amount. As such no fair value adjustments and no impairments are recorded per 31 December 2015.

| <u>In EUR000</u>           | <u>As of 31 December,</u> |             |
|----------------------------|---------------------------|-------------|
|                            | <u>2015</u>               | <u>2014</u> |
| Initial recognition amount | 5,052                     | 0           |
| <b>Total</b>               | <b>5,052</b>              | <b>0</b>    |

### 5.2.17. Deferred tax assets

Deferred taxes relate to the investment tax credit on research and development and amount to EUR 2.0m per 31 December 2015 (2014: EUR 0.9m).

| <u>In EUR000</u>                    | <u>As of 31 December,</u> |             |
|-------------------------------------|---------------------------|-------------|
|                                     | <u>2015</u>               | <u>2014</u> |
| Tax credit research and development | 1,986                     | 947         |
| <b>Total</b>                        | <b>1,986</b>              | <b>947</b>  |

### 5.2.18. Inventory

The inventory can be analysed as follows:

| In EUR000                       | As of 31 December, |              |
|---------------------------------|--------------------|--------------|
|                                 | 2015               | 2014         |
| <b>Inventory</b>                |                    |              |
| Raw materials                   | 2,379              | 1,958        |
| Semi-finished products          | 190                | 107          |
| Finished products               | 3,268              | 1,518        |
| <b>Total</b>                    | <b>5,837</b>       | <b>3,583</b> |
| Amount recognised as an expense | -2,642             | -4,251       |

The production of Idylla™ systems was fully outsourced to a contract manufacturing organisation in 2015. Idylla™ instrument and console inventory materials were sold to this contract manufacturer for an amount of EUR 2.2m in 2015, resulting in a net loss of EUR 0.07m on this transaction.

### 5.2.19. Trade and other receivables

Trade and other receivables can be analyzed as follows:

| In EUR000                          | As of 31 December, |               |
|------------------------------------|--------------------|---------------|
|                                    | 2015               | 2014          |
| Trade receivables                  | 5,852              | 15,793        |
| Allowance for doubtful receivables | 0                  | 0             |
| <b>Total</b>                       | <b>5,852</b>       | <b>15,793</b> |
|                                    |                    |               |
|                                    | As of 31 December, |               |
|                                    | 2015               | 2014          |
| VAT receivables                    | 1,050              | 116           |
| Other receivables                  | 13                 | 32            |
| <b>Total</b>                       | <b>1,063</b>       | <b>148</b>    |

Trade receivables have decreased from EUR 15.8m per 31 December 2014 to EUR 5.9m per 31 December 2015. The decrease results from the payment of JPNV receivables in 2015.

At the reporting dates, the Group has no trade receivables that were past due but not impaired. No trade receivables were impaired at these dates.

The trade receivables from JPNV and the Idylla™ system contract manufacturing organisation account for more than 10% of the total trade receivable balance. The credit concentration risk is limited in view of the creditworthiness

of these partners. Reference is made to note 0 for further detail. The receivable from the contract manufacturing organisation relates to the sale of inventory parts (note 5.2.18). The payment is contingent upon the ordering of 225 Idylla™ systems. This order placement was done in December 2015.

### 5.2.20. Other current assets

Other current assets can be analysed as follows:

| In EUR000            | As of 31 December, |              |
|----------------------|--------------------|--------------|
|                      | 2015               | 2014         |
| Accrued grant income | 570                | 2,168        |
| Other accrued income | 80                 | 0            |
| Deferred charges     | 609                | 533          |
| <b>Total</b>         | <b>1,258</b>       | <b>2,700</b> |

119

Other current assets include accrued income mainly related to Flemish government grants from IWT for R&D projects totaling EUR 0.6m (2014: EUR 0.4m) and from the Hermes fund for strategic investments and training support totaling EUR 0.0m (2014: EUR 1.7m). The Group evaluates continuously if it fulfills the specific conditions as per specific grant agreements to justify that none of the grants receivables are to be impaired.

### 5.2.21. Cash and cash equivalents

The cash and cash equivalents can be analysed as follows:

| In EUR000   | As of 31 December, |               |
|---|--------------------|---------------|
|   | 2015               | 2014          |
| <b>Cash and cash equivalents</b>                              |                    |               |
| Cash at bank and on hand                                      | 102,587            | 9,419         |
| <b>Total cash and cash equivalents</b>                        | <b>102,587</b>     | <b>9,419</b>  |
| Total restricted cash   | 1,500              | 1,500         |
| <b>Total cash and cash equivalents for cash flow purposes</b> | <b>104,087</b>     | <b>10,919</b> |

The restricted cash relates to a deposit on a debt service reserve account as a security for the lease of the Idylla™ cartridge manufacturing line.

## 5.2.22. Share capital

### Issued share capital

As of 25 November 2014, Biocartis Group NV became the parent company and reporting entity of the Group. Previous to that date, Biocartis SA was the parent company and reporting entity.

The table below summarises the share capital and the outstanding shares of Biocartis Group NV as at 31 December 2014 and 31 December 2015 and of Biocartis SA as at 31 December 2013. The shares are fully paid, registered shares.

The number of shares issued and outstanding and the share capital is:

|   | Biocartis SA                                   |                           | Biocartis Group NV                             |                        |
|---|--|---------------------------|--|------------------------|
|   | Number of common shares issued and outstanding | Share capital in '000 CHF | Number of common shares issued and outstanding | Share capital in '000€ |
| <b>At 31 December 2013</b>  | <b>24,690,864</b>                              | <b>1,235</b>              |  |                        |
| Capital increase by conversion reserves   |  | 37,036                    |  |                        |
| Capital decrease on 26 August 2014, in effect on 6 November 2014                        |  | -37,036                   |  |                        |
| Share issue - Round F.1 at 29 August 2014   | 2,645,868                                      | 132                       |  |                        |
| <i>Change in reporting entity</i>   |  |                           |  |                        |
| Incorporation Biocartis Group NV at 24 November 2014 by contribution in kind            | -18,812  |                           | 16,992   | 153                    |
| Contribution in kind at 25 November   | -24,672,052                                    |                           | 24,673,872                                     | 222,115                |
| <b>At 31 December 2014</b>  | <b>0</b>                                       | <b>1,367</b>              | <b>24,690,864</b>                              | <b>222,268</b>         |
| Share issue - tranche 2 of round F on 15 January 2015                                   |  |                           | 2,519,855                                      | 20,488                 |
| Share issue - contribution in kind of the participation in Myc artis on 15 January 2015 |  |                           | 591,774  | 4,812                  |
| Capital increase by incorporation of share premium on 15 January 2015                   |  |                           |  | 8                      |
| Capital decrease by conversion into share premium on 13 April 2015                      |  |                           |  | -247,272               |
| Conversion preferred F shares into common shares on 28 April 2015                       |  |                           | 5,165,723                                      |                        |
| Share issue - Initial Public Offering on 28 April 2015                                  |  |                           | 8,695,652                                      | 87                     |
| Share issue - exercise of over - allotment warrant on 19 May 2015                       |  |                           | 1,304,347                                      | 13                     |
| Share issue - exercise of stock options on 3 June 2015                                  |  |                           | 21,000   | 0                      |
| Share issue - exercise of stock options on 6 October 2015                               |  |                           | 38,500   | 0                      |
| Share issue - exercise of stock options on 23 December 2015                             |  |                           | 36,328   | 0                      |
| <b>At 31 December 2015</b>  |  | <b>1,367</b>              | <b>40,544,188</b>                              | <b>405</b>             |



The following capital transactions took place at Biocartis Group NV from 1 January 2015 until 31 December 2015:

- On 15 January 2015, Biocartis Group NV raised EUR 21.5m fully paid by an increase in share capital by EUR 20.5m and an increase in share premium by EUR 1.0m. This concerns the second tranche of the series F round.
- On 15 January 2015, Biocartis Group NV raised EUR 5.1m through a contribution in kind of 2,253,262,501 shares in MyCartis NV following the execution of a put option held by Debiopharm Diagnostics SA. The share capital and share premium were increased by respectively EUR 4.8m and EUR 0.2m.
- On 15 January 2015, the share capital of Biocartis Group NV was raised by EUR 0.008m by way of conversion of share premium into share capital.
- On 13 April 2015, the share capital of Biocartis Group NV was decreased by EUR 247.3m by conversion into share premium.
- On 24 April 2015, Biocartis Group NV raised EUR 100.0m following an Initial Public Offering, fully paid by an increase in share capital of EUR 0.1m and an increase in share premium by EUR 99.9m.
- On 19 May 2015, Biocartis Group NV raised EUR 15.0m following the execution of the IPO over-allotment warrant. The amount was fully paid by an increase in share capital by EUR 0.013m and by an increase in share premium by EUR 15.0m.
- On 3 June 2015, Biocartis Group raised EUR 0.2m following the execution of 21,000 stock options. The amount is fully paid by an increase in share capital by EUR 0.00021m and an increase in share premium by EUR 0.2m.
- On 6 October 2015, Biocartis Group raised EUR 0.3m following the execution of 38,500 stock options. The amount is fully paid by an increase in share capital by EUR 0.00039m and an increase in share premium by EUR 0.3m.
- On 23 December 2015, Biocartis Group raised EUR 0.3m following the execution of 36,328 stock options. The amount is fully paid by an increase in share capital by EUR 0.00036m and an increase in share premium by EUR 0.3m.

#### IPO expenses

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

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

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

#### Option to acquire shares in the Company

On 15 August 2011, at the occasion of the Idylla™-Enrich technology acquisition, Philips, a shareholder of the Company, has been granted two conversion options, of which one remains outstanding per 31 December 2015. This option foresees that the Company can, at its sole discretion, grant Philips the right to convert all or part of the future payments that Biocartis is required to make under this agreement (including milestone, royalties and other

revenue sharing payments) into common shares of the Company. This right is limited to a maximum of 10% of the then outstanding capital of the Company on a fully diluted post-money basis. This option ends on 31 December 2018. However, the Company is also contractually able to replace future royalty and revenue sharing payments by a lump sum payment to Philips, reducing the above conversion option.

On 25 August 2014 Biocartis SA granted a put option right to Debiopharm Diagnostics SA, a shareholder of the Company, with respect to the 2,253,262,501 shares that Debiopharm Diagnostics SA held in MyCartis NV. This option right allowed Debiopharm Diagnostics SA to contribute, subject to the terms and conditions of a put option agreement and applicable law, their full share in MyCartis NV into the capital of the Company in exchange for 591,774 common shares of the Company. This put option right was exercised prior to 31 December 2014 and the resulting contribution in kind took place on 15 January 2015.

#### Voting rights

Each share gives the holders thereof the right to one vote. The shares are indivisible in respect of the Company and the Company only recognizes one owner per share as regards the exercise of the voting rights.

#### Dividends

The Company has not declared or paid any dividends on its shares. Currently, the board of directors expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future.

#### 5.2.23. Share based compensation

The table below provides an overview of the movement in stock options since 1 January 2014:

|  | SOP<br>2008   | SOP<br>2013    | SOP<br>2015   | SOP<br>WHC    | Total          |
|--|---------------|----------------|---------------|---------------|----------------|
| <b>Total outstanding at 31 December 2013</b> | <b>94,332</b> | <b>680,340</b> |               |               | <b>774,672</b> |
| Options granted                              | +             | 40,000         |               |               | 40,000         |
| Options exercised                            | -             |                |               |               |                |
| Options forfeited                            | -             |                |               |               |                |
| Options cancelled                            | -             |                |               |               |                |
| <b>Total outstanding at 31 December 2014</b> | <b>94,362</b> | <b>720,340</b> |               |               | <b>814,702</b> |
| Options granted                              | +             | 30,000         | 72,500        | 100,000       | 202,500        |
| Options exercised                            | -             | 26,660         | 95,828        |               | 122,488        |
| Options forfeited                            | -             |                |               | 33,000        | 33,000         |
| Options cancelled                            | -             |                |               |               |                |
| <b>Total outstanding at 31 December 2015</b> | <b>67,702</b> | <b>654,512</b> | <b>72,500</b> | <b>67,000</b> | <b>861,714</b> |

#### ESOP 2008

The 2008 Plan is a non-dilutive stock option plan, implying that no new shares are issued upon the exercise of the respective stock options. The Company has signed shadow agreements with certain founders (shareholders) whereby, upon exercise of the stock options under the plan, these founders will transfer common shares held by them to the option holder.

In total 26,660 options were exercised in 2015 at CHF 4.14 exercise price and a weighted average share price of EUR 13.43 at the moment of the exercise of the options. A total of 67,702 options are still outstanding per 31 December 2015. The weighted average remaining contractual life is 3.8 years.

The key terms of the SOP 2008 Plan are as follows:

- Options are granted for free
- Exercise price: CHF 4.14
- Option term: 10 years after the dates of the individual grants, expiry dates range between 2019 and 2020
- Vesting: time based vesting over 4 years (on a monthly basis; that is 1/48 per month)

The financial impact of the options granted under this plan is not material. The fair value of the options estimated by the Black-Scholes Merton model was EUR 0.1 per option.

### ESOP 2013

The 2013 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options. A maximum of 1,000,000 shares can be issued to employees, consultants and management of the Group, of which 720,340 options were granted per 31 December 2014.

In the course of 2015, a number of 30,000 stock options have been additionally granted and 95,828 options were exercised at an exercise price of EUR 8.1309 with a weighted average share price of EUR 12.74 at the moment of the exercise of the options.

A total of 654,512 options are still outstanding per 31 December 2015 of which 624,512 options have an exercise price of EUR 8.1309 and 30,000 options have an exercise price of EUR 13.28. The weighted average remaining contractual life is 4.8 years.

The key terms of the SOP 2013 Plan are:

- Options are granted for free
- Exercise price: the board of directors shall determine the exercise price when the stock options are granted to a selected participant.
- Granted stock options only become exercisable after vesting and can only be exercised during the full remaining lifetime of the stock options and then only during the following periods:
  - (i) as of 16 March until 31 March,
  - (ii) as of 16 September until 30 September,
  - (iii) and as of 1 December until 15 December.
- Option term: 10 years after the creation of the plan (expiry is in 2023) but upon grant of the option contractually reduced to 7 years.
- Vesting: time based vesting over 4 years (on a monthly basis; that is 1/48 per month), subject to acceleration in case of a change of a control event.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumptions:

|  | Grants<br>2013 | Grants<br>July 2014 | Grants<br>November<br>2014 | Grants<br>August<br>2015 |
|--|----------------|---------------------|----------------------------|--------------------------|
| Number of warrants granted                     | 680,340        | 20,000              | 20,000                     | 30,000                   |
| Number of warrants not vested<br>at 31/12/2015 | 50,833         | 12,500              | 14,167                     | 25,833                   |
| Exercise price                                 | EUR 9.35       | EUR 9.35            | EUR 8.13                   | EUR 13.28                |
| Expected dividend yield                        | 0              | 0                   | 0                          | 0                        |
| Expected stock price volatility                | 25%            | 30%                 | 30%                        | 31%                      |
| Risk-free interest rate                        | 1%             | 0%                  | 0%                         | 0%                       |
| Expected duration                              | 3.5 years      | 2.8 years           | 2.6 years                  | 2.3 years                |
| Forfeiture rate                                | 0%             | 0%                  | 0%                         | 0%                       |
| Fair value                                     | EUR 1.78       | EUR 1.87            | EUR 1.56                   | EUR 2.70                 |

The weighted average risk-free interest rates used are based on government bond rates at the date of grant with a term equal to the expected life of the options. The stock price volatility is determined by reference to the Nasdaq Biotech Index (NBI).

#### ESOP 2015

On 15 January 2015, an option plan was established, pursuant to which 217,934 options were issued. This plan was cancelled by the general shareholders' meeting of the Company on 13 April 2015 and replaced on the same date by a new stock option plan (the '2015 Plan'), enabling the Company to grant a maximum of 262,934 stock options (each stock option having the form of a warrant) to selected staff members (consisting of employees, consultants and members of the management) and directors. The 2015 Plan is a dilutive option plan, implying that new shares are issued upon the exercise of the respective stock options.

In total 72,500 options were granted in 2015 at EUR 13.28 exercise price. No options were exercised so 72,500 options are outstanding per 31 December 2015. The weighted average remaining contractual life is 6.59 years.

The key features of the stock options under the 2015 Plan are as follows:

- Options are granted for free.
- Exercise price: The board of directors shall determine the exercise price at the time of the grant of the stock options, based upon the stock exchange price of the underlying shares at the time of the grant or an average price calculated over a previous period.
- Option term: the stock options have a term of 10 years when they were created, but this term will be contractually reduced to seven years.
- Vesting: time based vesting over 4 years (on a monthly basis; that is 1/48 per month) subject to acceleration in case of a change of control event.

The fair value of each option is estimated on the date of grant using the Black & Scholes model with the following assumptions:

|   | <b>Grants<br/>2015</b> |
|---|------------------------|
| Number of warrants granted                  | 72,500                 |
| Number of warrants not vested at 31/12/2015 | 63,698                 |
| Exercise price                              | EUR 13.28              |
| Expected dividend yield                     | 0                      |
| Expected stock price volatility             | 31%                    |
| Risk-free interest rate                     | 0%                     |
| Expected duration                           | 3.4 years              |
| Forfeiture rate                             | 0%                     |
| Fair value                                  | EUR 3.29               |

The weighted average risk-free interest rates used are based on government bond rates at the date of grant with a term equal to the expected life of the options. The stock price volatility is determined by reference to the Nasdaq Biotech Index (NBI).

#### WHC Warrants

In execution of a decision of the board of directors of Biocartis SA of 24 April 2014, 100,000 options on shares of the Company were granted by the Company to Whitemarsh Capital LLC, a commercial partner of the Company that assists in brokering agreements for the Company with US governmental institutions for the payment of its products. On 25 November 2014, the option grant was rolled up in order to relate to the Company and the Company's shares instead of shares in Biocartis SA. The options, called 'WHC Warrants', were formally granted by an award letter on 14 April 2015. In the first half of 2015, 33,000 options were forfeited. None of the remaining 67,000 options have been vested to this date and it is uncertain if this will occur in the near future. No share-based compensation was recorded as per 31 December 2015.

#### Accounting for share-based payment

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

| <u>In EUR000</u>         | <u>Years ended 31 December,</u> |             |
|--------------------------|---------------------------------|-------------|
|                          | <u>2015</u>                     | <u>2014</u> |
| share based compensation | 179                             | 143         |
| <b>Total</b>             | <b>179</b>                      | <b>143</b>  |

### 5.2.24. Financial Debt

The financial debt can be analysed as follows:

| In EUR000                | As of 31 December, |              |
|--------------------------|--------------------|--------------|
|                          | 2015               | 2014         |
| PMV                      | 0                  | 6,707        |
| Lease company            | 2,120              | 1,821        |
| Bank                     | 542                | 0            |
| <b>Total non-current</b> | <b>2,662</b>       | <b>8,528</b> |
| PMV                      | 7,176              |              |
| Senter Novem             | 0                  | 3,895        |
| Lease company            | 918                | 1,161        |
| Bank                     | 58                 | 0            |
| <b>Total current</b>     | <b>8,152</b>       | <b>5,057</b> |

In 2010, The Group was granted a loan facility for a total amount of EUR 5.0m by PMV (Participatie Maatschappij Vlaanderen), a shareholder of the Company, bearing an interest rate of 7% and with a maturity date at 31 December 2016. The interest on the loan is capitalised until the maturity date and accrued in the consolidated balance sheet at the year-end.

In 2011, the Group also obtained an innovation loan of EUR 5.0m from the Dutch government institution Senter Novem, conditional upon certain spending commitments and activities in the Netherlands. The loan was fully repaid in 2015.

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 1.5m.

In 2015 Biocartis NV obtained two new financing facilities for the modifications to the current cartridge production line in Mechelen. The first new facility entails an investment credit for an amount of EUR 0.6m, provided by a bank. This facility has a payment term of 5 years and an interest rate of 1.93%. The second one entails a leasing facility for EUR 4.4m, provided by a lease company, of which EUR 1.2m was drawn per 31 December 2015. The interest applicable for this leasing facility equals the 5 year Interest Rate Swap (IRS) plus a margin of 1.57% and will be fixed when the entire investment package is drawn. The leasing includes a purchase option of 1% of the financed amount. The terms of the loans are summarized in the table below:

| Loan          | Year | Nominal amount (in EUR000) | Secured (s) Non secured (ns) | Interest rate | Maturity date |
|---------------|------|----------------------------|------------------------------|---------------|---------------|
| PMV           | 2010 | 5,000                      | Ns                           | 7.00%         | 31/12/2016    |
| Senter Novem  | 2011 | 2,250                      | S                            | 6.20%         | 1/10/2014     |
| Senter Novem  | 2011 | 2,750                      | S                            | 6.20%         | 1/10/2015     |
| Lease company | 2013 | 7,910                      | S                            | 3.35%         | 1/06/2021     |
| Lease company | 2015 | 1,216                      | S                            | IRS+1.57%     | 1/06/2021     |
| Bank          | 2015 | 600                        | S                            | 1.93%         | 1/06/2021     |

A reconciliation between the total of future minimum lease payments of the finance leases at the end of the reporting period and their present value is described in the table below:

| In EUR000              | As of 31 December,     |   |                        |   |
|------------------------|------------------------|---|------------------------|---|
|                        | 2015                   |   | 2014                   |   |
|                        | Minimum lease payments | Present value of minimum lease payments | Minimum lease payments | Present value of minimum lease payments |
| <b>Financial lease</b> |                        |   |                        |   |
| < 1 year               | 975                    | 918                                     | 1,240                  | 1,161                                   |
| >1 and < 5 years       | 1,972                  | 1,893                                   | 1,888                  | 1,821                                   |
| > 5 years              | 229                    | 227                                     |                        |   |
| <b>Total</b>           | <b>3,177</b>           | <b>3,038</b>                            | <b>3,128</b>           | <b>2,983</b>                            |
| less interests         | -138                   |   | -145                   |   |
| Present value          | <b>3,038</b>           | <b>3,038</b>                            | <b>2,983</b>           | <b>2,983</b>                            |

The minimum lease payments for the new leasing of EUR 1.2m in 2015 were calculated at an interest rate of 1.92%, consisting of the Interest Rate Swap of 31 December 2015 of 0.35% plus a margin of 1.57%.

The net carrying value of the related leased assets amounts to EUR 4.0m at 31 December 2015 (2014: EUR 4.2m).

## 5.2.25. Retirements benefit plans

### 5.2.25.1. Defined contribution plans

The post-employment benefits of the employees of Biocartis NV are defined contribution plans with minimum guaranteed rates of return (refer to 5.2.2.13.). As such they classify as defined benefit plans. The Group analysed the impact of the application of the Projected Unit Credit Method on those plans and concluded that the application of that method would not have a material impact on the financial statements per 31 December 2015. As such no defined benefit obligation was recorded per 31 December 2015.

The Group funds the plan by paying a fixed percentage of the monthly salary of the employee to the external insurance company in addition to an employee contribution. The total expense recognised in the consolidated income statement for contributions made under these defined contribution plans amount to EUR 0.5m in 2015 (2014: EUR 0.4m).

The expected 2016 employer contributions amount to approximately EUR 0.7m.

The average age of the 179 plan participants equals 40 years at 31 December 2015.

### 5.2.25.2. Defined benefit plan

The post-employment benefits of the employees of Biocartis SA in Switzerland were provided via a defined benefit plan. The post-employment benefits were all related to the MyCartis business which was disposed of on 11

November 2014 and Biocartis SA has no further obligations under this plan as of 2015. The full disclosures for the year 2014 are available in the consolidated financial statements for the years ended 31 December 2014, 2013 and 2012.

### 5.2.26. Other current liabilities

Other current liabilities include:

| In EUR000                              | As of 31 December, |              |
|--|--------------------|--------------|
|  | 2015               | 2014         |
| Provision vacation pay                 | 1,884              | 1,407        |
| Other social debt                      | 15                 | 8            |
| VAT payable                            | 0                  | 1,791        |
| Other                                  | 88                 | 87           |
| <b>Total other current liabilities</b> | <b>1,986</b>       | <b>3,293</b> |

### 5.2.27. Deferred income

| In EUR000      | As of 31 December, |              |
|----------------|--------------------|--------------|
|                | 2015               | 2014         |
| Grants         | 47                 | 75           |
| Partner income | 5,107              | 9,559        |
| <b>Total</b>   | <b>5,154</b>       | <b>9,634</b> |
| current        | 3,812              | 5,100        |
| non-current    | 1,342              | 4,534        |

Deferred partner income includes upfront payments from Amgen Inc. and upfront payments received from JPNV in relation to the strategic licensing, development and commercialisation collaborations. This amount will be recognised as collaboration revenue in the following 2 years with a majority in 2016.

|                                | Deferred partner income |
|--------------------------------|-------------------------|
| <b>As per 31 December 2013</b> | <b>2,270</b>            |
| Invoiced                       | 7,860                   |
| Recognised in profit or loss   | -571                    |
| <b>As per 31 December 2014</b> | <b>9,559</b>            |
| Invoiced                       | 574                     |
| Recognised in profit or loss   | -5,025                  |
| <b>As per 31 December 2015</b> | <b>5,107</b>            |



## 5.2.28. Accrued Expenses

Accrued expenses primarily include accruals for rental charges.

## 5.2.29. Taxes

### 5.2.29.1. Composition of tax expense

| In EUR000                          | Years ended 31 December, |             |
|------------------------------------|--------------------------|-------------|
|                                    | 2015                     | 2014        |
| Current tax                        | 391                      | 0           |
| Deferred tax                       | -1,039                   | -947        |
| <b>Income tax expense (profit)</b> | <b>-648</b>              | <b>-947</b> |

129

### 5.2.29.2. Tax reconciliation

Tax expenses for the year can be reconciled to the accounting loss as follows:

| In EUR000  | Years ended 31 December, |                |
|--|--------------------------|----------------|
|  | 2015                     | 2014           |
| <b>Loss before taxes</b>   | <b>-40,445</b>           | <b>-10,662</b> |
| Income tax credit calculated at 33,99%   | -13,747                  | -3,624         |
| Effect of different tax rates  | 24                       | -3,345         |
| Effect of income that is exempt from taxation  | -6,684                   | -2,284         |
| Effect of expenses that are non-deductible in determining tax profit                     | 284                      | 8,002          |
| Effect of unused tax losses and tax offsets not recognised as deferred tax assets        | 20,124                   | 10,094         |
| Effect of previously unrecognised and unused tax losses                                  |                          | -8,844         |
| Effect of tax credit for research and development  | -1,039                   | -947           |
| Effect of capital tax 2015 in Biocartis SA   | 104                      |                |
|  | <b>-935</b>              | <b>-947</b>    |
| Adjustments recognised in the current year in relation to the current tax of prior years | 287                      |                |
| <b>Income tax expense (profit) recognised in loss for the period</b>                     | <b>-648</b>              | <b>-947</b>    |

### 5.2.29.3. Unrecognised deferred tax assets

Due to the uncertainty surrounding the Group's ability to realise taxable profits in the near future, the Group has not recognised any deferred tax assets on tax loss carry forwards and temporary differences.

The Group has tax losses available for carry forward of EUR 133.8m (2014: EUR 86.8m). The tax losses related to Biocartis SA amount to EUR 39.2m in 2015 (2014: EUR 51.2m) with the following expiration years. Each annual tax loss expires seven years after the fiscal period it has been realised.

| Tax losses<br>In EUR000 | Expiry year |
|-------------------------|-------------|
| 8,541                   | 2019        |
| 34,290                  | 2020        |
| <b>42,831</b>           |             |

The tax losses of Biocartis NV for EUR 84.7m per 31 December 2015 (2014: EUR 34.5m) in Belgium will not expire as they can be carried forward indefinitely.

### 5.2.29.4. Recognised deferred tax assets

The Group has R&D tax credit carry-forwards in Belgium for a total amount of EUR 2.0m (2014: EUR 0.9m) for which a deferred tax asset of EUR 2.0m (2014: EUR 0.9m) has been recognised as the recognition criteria have been met as from 2014.

## 5.2.30. Financial risk management

### 5.2.30.1. Capital risk management

Capital comprises equity attributable to shareholders, borrowings and cash and cash equivalents. The Group's policy is to maintain a strong capital base in order to maintain investor and creditor confidence and to sustain the future development of the business. The Group's objectives when managing capital are to maintain sufficient liquidity to meet its working capital requirements, fund capital investment and purchases and to safeguard its ability to continue operating as a going concern.

The Group monitors capital regularly to ensure that the statutory capital requirements are met and may propose capital increases to the shareholders' meeting to ensure the necessary capital remains intact.

### 5.2.30.2. Financial risk factors

The Group's activities expose it to a variety of financial risks such as market risk, credit risk, and liquidity risk. The Group's finance department identifies and evaluates the financial risks in close co-operation with the operating units.

### 5.2.30.3. Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The Group's activities expose it primarily to changes in foreign currency exchange rates and interest rates.

## FOREIGN EXCHANGE RISK

The Group is exposed to foreign currency risks primarily through its operating activities. Certain purchase transactions and certain sales transactions of the Group are undertaken in Swiss Franc ('CHF'), Australian Dollar ('AUD'), British Pound ('GBP') and US Dollar ('USD'). The Group did not enter into any currency hedging arrangements in order to cover its exposure. The Group is managing its foreign currency risk by matching foreign currency cash inflows with foreign cash outflows. Therefore the sensitivity to certain potential changes in, especially the CHF, AUD, GBP and USD is limited. Exchange rate exposure towards the foreign currencies can furthermore be managed through the use of forward exchange contracts, based upon management's judgment. The Group has not applied hedge accounting in 2015 and 2014.

Financial assets include current bank accounts and petty cash. Financial liabilities include trade payables and accruals in foreign currency.

| In EUR000           | As of 31 December |      |
|---------------------|-------------------|------|
|                     | 2015              | 2014 |
| <b>Liabilities</b>  |                   |      |
| CHF - Switzerland   | 248               | 1    |
| USD - United States | 193               | 78   |
| GBP - Great Britain | 117               | 0    |
| <b>Assets</b>       |                   |      |
| CHF - Switzerland   | 88                | 152  |
| USD - United States | 624               | 4    |
| GBP - Great Britain | 58                | 0    |

The Group performed a sensitivity analysis for the two most significant currencies (USD, GBP). The impact of an increase or decrease in value by 10% of these currencies is not material.

## INTEREST RATE RISK

The interest rate risk is limited as the Group has only long-term borrowings with a fixed interest rate. Changes in interest rates will not increase/decrease profit or loss or other comprehensive income.

## OTHER MARKET RISK

The Group is not exposed to equity price risk or commodity price risk as it does not invest in these classes of investments.

## CREDIT RISK

Credit risk arises from cash and cash equivalents, short-term bank deposits, as well as credit exposure to collaboration partners. Credit risk refers to the risks that counterparty will default on its contractual obligations resulting in financial loss to the Group.

The Group has a limited number of collaboration partners and therefore has a significant concentration of

credit risk. However, it has policies in place to ensure that credit exposure is kept to a minimum and significant concentrations of credit exposure are only granted for short periods of time to high credit quality collaboration partners. Credit exposure with regard to R&D partnering activities is concentrated with a limited number of creditworthy partners.

The following shows the trade and other receivables towards customers representing more than 10% of total trade and other receivable balances:

| In EUR000                         | As of 31 December |               |
|-----------------------------------|-------------------|---------------|
|                                   | 2015              | 2014          |
| <b>carrying value</b>             |                   |               |
| JPNV                              | 1,486             | 15,723        |
| Plexus Corp.                      | 2,152             |               |
| Other trade and other receivables | 3,276             | 217           |
|                                   | <b>6,914</b>      | <b>15,941</b> |

None of the above receivables are impaired or overdue.

None of the financial assets reported above have been pledged as collateral, and no financial assets have been received as collateral. The only financial asset pledged is the EUR 1.5m guarantee for the lease, reported under cash and cash equivalents.

Cash and cash equivalent and short-term deposits are invested with highly reputable banks and financial institutions.

The maximum credit risk to which the Group is theoretically exposed as at the balance sheet date, is the carrying amount of the financial assets.

#### LIQUIDITY RISK

The Group's main sources of cash inflows are obtained through capital increases, loans, grants and collaboration agreements. Cash is invested in low risk investments such as short-term bank deposits. Ultimate responsibility for liquidity risk management rests with the Board of Directors, which has built, what it considers to be an appropriate risk management framework for the management of the Group's short, medium and long-term funding and liquidity requirements. The Group mainly makes use of liquid investments in current (Euro and foreign currency) accounts, short term deposit accounts and fiduciary deposits. Instruments used possess high grade credit ratings, capital reimbursement guarantees and limited time horizons up to a maximum of 12 months.

The Group maintains two credit lines with one financial institution of EUR 1.1m (2014: EUR 0.5m) mainly being used for investments and bank guarantees. As per 31 December 2015, the credit lines were used for EUR 1.1m (2014: EUR 0.5m).

The ability of the Group to maintain adequate cash reserves to sustain its activities in the medium term is highly dependent on the Group's ability to raise further funds from collaboration agreements, product sales, obtaining grants as well as the sale of new shares. As a consequence, the Group can potentially be exposed to significant liquidity risk in the medium term.

Analysis of contractual maturities of financial liabilities at 31 December is as follows (amounts in EUR000):

| In EUR000          | As of 31 December, |                |   |                |                |   |
|--------------------|--------------------|----------------|---|----------------|----------------|---|
|                    | 2015               |                |   | 2014           |                |   |
|                    | Trade payables     | financial debt | other current liabilities and accrued expense | Trade payables | financial debt | other current liabilities and accrued expense |
| Less than 1 month  | 13,927             | 99             | 1,986   | 4,265          |                | 3,293   |
| 1-3 months         |                    | 126            |   |                | 287            |   |
| 3 months to 1 year |                    | 7,927          |   |                | 4,770          |   |
| 1-5 years          |                    | 2,377          | 632   |                | 8,528          | 711   |
| 5+ years           |                    | 285            | 948   |                |                | 1,244   |
| <b>Total</b>       | <b>13,927</b>      | <b>10,815</b>  | <b>3,566</b>                                  | <b>4,265</b>   | <b>13,585</b>  | <b>5,248</b>                                  |

### 5.2.31. 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 31 December 2015 and 2014.
- The fair value of the participation in MyCartis is not significantly different than its carrying value on 31 December 2015 and is based upon the valuation used in the latest capital increase in MyCartis of 7 December 2015. 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; and

**Level 3:** techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data.

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

| In EUR000   | Carrying Value |             | Fair Value     |           |
|---|----------------|-------------|----------------|-----------|
|   | 2015           | 2014        | 2015           | 2014      |
| <b>Available for sale financial assets</b>                    |                |             |                |           |
| Participating interest  | 5,052          |             | 5,052          |           |
| <b>Total available for sale financial assets</b>              | <b>5,052</b>   |             | <b>5,052</b>   |           |
| <b>Loans and receivables measured at amortised cost</b>       |                |             |                |           |
| Trade and other receivables (current)                         | 6,914          | 15,9        | 6,914          | 15        |
| Other long term receivables                                   | 11             | 1           | 11             |           |
| Other current assets  | 1,258          | 2,7         | 1,258          | 2         |
| <b>Total loans and other receivables</b>                      | <b>8,183</b>   | <b>18,7</b> | <b>8,183</b>   | <b>18</b> |
| <b>Cash &amp; cash equivalents</b>                            |                |             |                |           |
| cash & cash equivalents                                       | 104,087        | 10,9        | 104,087        | 10        |
| <b>Total cash &amp; cash equivalents</b>                      | <b>104,087</b> | <b>10,9</b> | <b>104,087</b> | <b>10</b> |
| <b>Financial liabilities measured at amortised cost</b>       |                |             |                |           |
| Loans & Borrowings  | 10,815         | 13,5        | 11,171         | 14        |
| Trade payables  | 13,927         | 4,2         | 13,927         | 4         |
| Other liabilities and accrued charges                         | 3,566          | 5,2         | 3,566          | 5         |
| <b>Total financial liabilities measured at amortised cost</b> | <b>28,308</b>  | <b>23,0</b> | <b>28,664</b>  | <b>23</b> |

## 5.2.32. Contingencies

### Legal claims

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

### Potential claw back of government grants received

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

### Royalties

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

### Phillips option

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

## 5.2.33. Commitments

### 5.2.33.1. Capital commitments

Commitments related to capital expenditures at the balance sheet date are as follows:

| In EUR000                    | As of 31 December, |            |
|------------------------------|--------------------|------------|
|                              | 2015               | 2014       |
| ICT software                 | 31                 | 15         |
| ICT equipment                | 14                 | 18         |
| Laboratory equipment         | 443                | 20         |
| Manufacturing equipment      | 11,866             | 16         |
| Furniture and fixtures       | 40                 | 5          |
| Leasehold improvements       | 106                | 17         |
| Equipment under construction | 0                  | 20         |
| Assets held under Lease      | 3,184              | 0          |
| <b>Total</b>                 | <b>15,684</b>      | <b>111</b> |

Capital commitments relate to the upgrade of the current cartridge production line and the investment in the second cartridge production line. Both are 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 31 December 2015.

### 5.2.33.2. Operating commitments

The Group has a contractual commitment to buy a certain number of Idylla™ systems from the CMO (Contract Manufacturing Organisation), to whom the production of Idylla™ systems was outsourced in 2015. The remaining commitment per 31 December 2015 amounts to EUR 2.3m. It is expected that the commitment will be fulfilled in the first half of 2016.

### 5.2.33.3. Principal operating leases and contracts

The Group has entered into a number of operating leases in relation with its office and research and development and manufacturing facilities in Mechelen (Belgium), as well as in relation to employee cars for which the average lease term is 48 months.

The breakdown of the Group's committed future payments as per 31 December 2015 under its leasing contracts per nature and maturity is summarised in the table on the following page.

In line with the rental/lease agreements, a total amount of EUR 0.5m (2014: EUR 0.5m) in bank guarantees has been provided.

| <u>In EUR000</u>                       | As of 31 December     |              |                       |              |
|--|-----------------------|--------------|-----------------------|--------------|
|  | 2015                  |              | 2014                  |              |
|  | Rent/Lease facilities | Car Lease    | Rent/Lease facilities | Car Lease    |
| not later than 1 year                  | 1,297                 | 921          | 1,294                 | 498          |
| more than 1 year and less than 5 years | 5,811                 | 1,716        | 5,175                 | 703          |
| more than 5 years                      | 3,770                 | 0            | 4,483                 | 0            |
| <b>Total</b>                           | <b>10,878</b>         | <b>2,636</b> | <b>10,952</b>         | <b>1,201</b> |

| <u>In EUR000</u>                         | As of 31 December |              |
|--|-------------------|--------------|
|  | 2015              | 2014         |
| <b>Payments recognised as an expense</b> |                   |              |
| minimum lease payments                   | 2,112             | 1,867        |
| <b>Total</b>                             | <b>2,112</b>      | <b>1,867</b> |

### 5.2.34. Related-party transactions

Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes.

The nature of certain related party transactions (share options, revenue transactions) with shareholders has been disclosed in detail in the sections on Revenue (Note 5.2.4), Share Capital (Note 5.2.20) and Share Based Compensation (Note 5.2.21).

#### 5.2.34.1. Remuneration of key management

Remuneration of key management consists of the Directors and the members of the Executive Management Team.

| <u>In EUR000</u>   | As of 31 December |              |
|--|-------------------|--------------|
|  | 2015              | 2014         |
| Short-term employee benefits (salaries, social security bonuses and fringe benefits) | 1,834             | 1,202        |
| Post -employment benefits (Group insurance)  | 17                | 7            |
| Share based payment  | 122               | 67           |
| <b>Total</b>   | <b>1,973</b>      | <b>1,276</b> |



The post-employment benefits for the key management are part of the retirement benefit scheme to which all qualifying personnel are entitled. The contributions are paid as a percentage of the gross annual salary for the defined contribution schemes and provisionally calculated based on regulations following the defined benefit schemes in place. No loans, quasi-loans or other guarantees have been given to a member of the executive management.

Share-based payments are related to the stock options over the vesting period 2015 and 2014 under the ESOP 2013 and 2015 plan.

#### 5.2.34.2. Transactions with non-executive directors and shareholders

| In EUR000        | Sales of goods and services | Purchase of good and services | Interest cost | Trade receivables | Trade payables | Financial Debt |
|------------------|-----------------------------|-------------------------------|---------------|-------------------|----------------|----------------|
| 31 December 2015 |                             |                               | -469          |                   |                | 7,176          |
| 31 December 2014 | 8,412                       | -81                           | -439          | 15,723            |                | 6,707          |

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

- The interest cost and financial debt relate to the loan granted by PMV (see note 5.2.24).
- Sales of goods and services and trade receivables in 2014 concern the collaboration and product sales towards JPNV (or entities belonging to this group).

#### 5.2.34.3. Subsidiaries

Details of the Company's subsidiaries at 31 December 2015 are as follows:

| Name of subsidiary | Principal activity                      | Place of incorporation and operation  | interest and voting power held by the Group |         |
|--------------------|---|---|---|---------|
|                    |   |   | 2015  | 2014    |
| Biocartis SA       | Intermediate holding company            | Scientific Parc EPFL, PSE-C<br>1015 Lausanne<br>Switzerland                   | 100%  | 100%    |
| Biocartis NV       | Develop and market diagnostic platforms | Generaal De Wittelaan 11<br>B - 2800 Mechelen                                 | 99,99%*                                     | 99,99%* |
| Biocartis BV       | Develop and market diagnostic platforms | High Tech Campus 9<br>PO Box 775<br>NL - 5600 AT Eindhoven<br>The Netherlands | 100%**                                      | 100%**  |

\* All shares held by Biocartis SA, except for one share held by Biocartis BV.

\*\* All shares of Biocartis BV are held by Biocartis SA, a wholly owned subsidiary of Biocartis Group NV.

There are no significant restrictions on the ability to access or use assets, and settle liabilities of the Group, except for the debt service reserve account.

### 5.2.35. Events after the balance sheet date

There were no important events between 31 December 2015 and the approval date of this annual report.

### 5.2.36. Standards and interpretations published, but not yet applicable for the annual period beginning on 1 January 2015

- IFRS 9 Financial Instruments and subsequent amendments (applicable for annual periods beginning on or after 1 January 2018, but not yet endorsed in the EU)
- IFRS 15 Revenue from Contracts with Customers (applicable for annual periods beginning on or after 1 January 2018, but not yet endorsed in EU)
- IFRS 16 Leases (applicable for annual periods beginning on or after 1 January 2019, but not yet endorsed in EU)
- Improvements to IFRS (2010-2012) (applicable for annual periods beginning on or after 1 February 2015)
- Improvements to IFRS (2012-2014) (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IFRS 10, IFRS 12 and IAS 28 Investment Entities: Applying the Consolidation Exception (applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- Amendments to IAS 1 Presentation of Financial Statements – Disclosure Initiative (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IAS 7 Statement of Cash Flows – Disclosure Initiative (applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed in EU)
- Amendments to IAS 12 Income Taxes – Recognition of Deferred Tax Assets for Unrealised Losses (applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed in EU)
- Amendments to IAS 16 and IAS 38 Property, Plant and Equipment and Intangible Assets – Clarification of Acceptable Methods of Depreciation and Amortisation (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IAS 19 Employee Benefits - Employee Contributions (applicable for annual periods beginning on or after 1 February 2015)

The impact of the initial application of IFRS 16 is that generally all operating leases will have to be reflected in the statement of financial position. The management of the Group is still investigating the impact of the initial application of IFRS 15.



CHAPTER 6

# Statutory Annual Accounts

“

“TECHNOLOGY INCREASINGLY DRIVES COLLABORATIONS IN A RENEWED HEALTHCARE ECOSYSTEM, FOCUSED ON BETTER AND FASTER DIAGNOSTICS AND TREATMENTS FOR THE PATIENT.”

WERNER VERBIEST, GLOBAL HEAD OF JANSSEN DIAGNOSTICS, PART OF JANSSEN, PHARMACEUTICAL COMPANIES OF JOHNSON AND JOHNSON

## 6. Statutory Annual Accounts

### 6.1. Abbreviated statutory annual accounts

The Annual Accounts of Biocartis Group NV are presented in an abbreviated form. The annual report, the full annual accounts and the opinion of the statutory auditor are deposited at the National Bank of Belgium. On request a copy of these documents can be obtained.

There is also an electronic version of the full Statutory Annual Report which can be obtained via the internet from the Biocartis website ([www.biocartis.com](http://www.biocartis.com)).

The statutory financial statements as filed with the Belgian National Bank are based upon Belgian GAAP.

### 6.2. Activity Biocartis Group NV

Biocartis Group NV was incorporated on 24 November 2014 and became – after the contribution in kind of Biocartis SA and her subsidiaries - on 25 November 2014 the ultimate parent of the Biocartis group. The Biocartis group is active in developing innovative molecular diagnostic platforms providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. The Biocartis group is developing and marketing a rapidly expanding test menu on its Idylla™ platform addressing key unmet clinical needs in oncology and infectious diseases.

Biocartis Group NV is an active holding company: it maintains a portfolio of financial participations and is also actively involved in the management thereof by providing various legal, financial and other services.

The first accounting year of Biocartis Group NV was an extended accounting year starting from 24 November 2014 and ending on 31 December 2015; as such no comparison can be made with the period ended on 31 December 2014.

### 6.3. Income statement and balance sheet Biocartis Group NV

#### Income Statement

| in EUR000  | PERIOD ENDED 31 DECEMBER 2015 |
|--|-------------------------------|
| Revenues   | 1,709                         |
| Other operating income                               | 20                            |
| <b>Total operating income</b>                        | <b>1,730</b>                  |
| Services and other goods                             | -2,600                        |
| Salaries, social security contributions and pensions | -988                          |
| <b>Operating expenses</b>                            | <b>-3,588</b>                 |
| Financial income                                     | 450                           |
| Financial expenses                                   | -7,750                        |
| <b>Result before taxes</b>                           | <b>9,158</b>                  |
| Income taxes   | -18                           |
| <b>Net result</b>                                    | <b>-9,175</b>                 |

## Balance Sheet

| in EUR000  | PERIOD ENDED 31 DECEMBER 2015 |
|--|-------------------------------|
| Financial fixed assets                               | 227,320                       |
| <b>Non-current assets</b>                            | <b>227,320</b>                |
| Other receivables                                    | 54,747                        |
| Cash and cash equivalents                            | 80,904                        |
| Deferred charges                                     | 66                            |
| <b>Current assets</b>                                | <b>135,717</b>                |
| <b>Total assets</b>                                  | <b>363,036</b>                |
| Legal share capital                                  | 405                           |
| Share premium  | 364,206                       |
| Accumulated deficit                                  | -9,175                        |
| <b>Total equity</b>                                  | <b>355,436</b>                |
| Financial debt                                       | 7,176                         |
| Trade payables                                       | 320                           |
| Salaries, social security contributions and pensions | 104                           |
| <b>Total liabilities</b>                             | <b>7,600</b>                  |
| <b>Total equity and liabilities</b>                  | <b>363,036</b>                |

## 6.4. Discussion of statutory accounts

### Income statement

Total operating income in 2015 amounted to EUR 1.7m and consists mainly of expense recharges to the Biocartis Group NV subsidiaries. Operating expenses recorded in the period under review amounted to EUR 3.6m and consist of salaries, social security contributions and pensions expenses for EUR 1.0m and of expenses for services and other goods of EUR 2.6m. Services and other goods mainly consist of recurring general and administrative expenses.

Financial income amounted to EUR 0.5m and consisted of interest income on the financial advances to the Biocartis group subsidiaries and on the cash and equivalents held by Biocartis Group NV. On the other hand, financial expenses amounted to EUR 7.8m and relate to the non-recurring expenses made in relation of the IPO of Biocartis Group NV in April 2015 and interest charges on the PMV loan.

The net result after taxes for the period ended 31 December 2015 amounts to EUR 9.2m.

### Balance sheet

#### Assets

The financial fixed assets consist of shares in the Biocartis Group NV subsidiaries for EUR 222.3m and a financial participation in a third party company MyCartis NV for EUR 5.1m.

Other receivables amounted to EUR 54.7m and mainly relate to receivables on the Biocartis Group NV subsidiaries, mainly related to financial advances. The management of Biocartis Group NV believes that the intercompany receivables are realisable on the short term. Cash and equivalents amounted to EUR 80.9m per 31 December 2015. Deferred charges relate to prepaid expenses.

### Equity

Total equity per 31 December 2015 amounted to EUR 355.4m and the legal share capital and share premium amount to respectively EUR 0.4m and EUR 364.2m.

Following movements in equity were recorded during the reporting period:

- Incorporation by contribution in kind on 24 November 2014 of EUR 152,955
- Capital increase by contribution in kind on 25 November 2014 of EUR 222,114,578
- Capital increase on 15 January 2015 for an amount of EUR 20,488,256. The share premium account was increased with EUR 1,024,539
- Capital increase by conversion of share premium on 15 January 2015 amounting to EUR 8,281.
- Capital increase by contribution in kind on 1 January 2015 for an amount of EUR 4,811,553. The share premium account was increased with EUR 240,605
- Capital decrease by conversion into share premium of 13 April 2015 for an amount of EUR 247,271,140 to reduce the par value per share to EUR 0.01
- Capital increase following the IPO of 28 April 2015 amounting to EUR 86,957. The share premium account was increased with EUR 99,913,041
- Capital increase following the execution of the over-allotment warrant of 19 May 2015 for an amount of EUR 13,043. The share premium account was increased with EUR 14,986,947
- Capital increase following the execution of stock options of 3 June 2015 for an amount of EUR 210. The share premium account was increased with EUR 170,539
- Capital increase following the execution of stock options of 6 October 2015 for an amount of EUR 385. The share premium account was increased with EUR 312,655
- Capital increase following the execution of stock options of 23 December 2015 for an amount of EUR 363. The share premium account was increased with EUR 295,016

### Financial debt

As per 31 December 2015, financial debt comprised of a loan from Participatie Maatschappij Vlaanderen (PMV) of EUR 7.2m consisting of EUR 5m nominal amount and EUR 2.2m accrued interests. This loan is fully repayable in 2016.

### Other liabilities

As per 31 December 2015, trade payables amounted to EUR 0.3m and payables for salaries, social security contributions and pensions to EUR 0.1m.

### Total assets and liabilities

Total assets and on the other hand, total liabilities amounted per 31 December 2015 to EUR 363.0m. contributions and pensions to EUR 0.1m.

## 6.5. Appropriation of results

The statutory accounts of the Company reported a net loss of EUR -9.2m for the year 2015. The board of directors proposes to carry forward the statutory net loss of EUR -9.2m of 2015 to the following financial year.

## 6.6. Going concern valuation rules

The going concern valuation rules were used both for the statutory annual accounts and for the consolidated annual accounts of the Company and this notwithstanding the existence of losses carried forward. Pursuant to article 96 6° of the Code of Companies the board of directors motivates the use of going concern valuation rules as follows:

The financial plan and investment budgets of the company accounted for these losses and in line therewith the Company attracted financing. In January 2015, Biocartis Group NV raised 21.5 million euro and furthermore the Company raised EUR 115 million in the context of its IPO in April 2015, both through the issuance of new shares. Taken into account the strong cash position of the Company at the end of 2015 as well as the expectations for 2016, the board of directors is of the opinion that the losses carried forward do not endanger the going concern of the Company, at least until the annual general meeting of the Company in 2017, and thus that the application of the valuation rules going concern is justified.



CHAPTER 7

# Statutory Auditor's Report

STATUTORY AUDITOR'S REPORT TO THE SHAREHOLDERS' MEETING  
ON THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED  
31 DECEMBER 2015



# Biocartis Group NV

*Free translation - the original text of this report is in Dutch.*

## To the shareholders

As required by law, we report to you in the context of our appointment as the company's statutory auditor. This report includes our report on the consolidated financial statements together with our report on other legal and regulatory requirements. These consolidated financial statements comprise the consolidated balance sheet at 31 December 2015, the consolidated income statement, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated cash flow statement for the year then ended, as well as the summary of significant accounting policies and other explanatory notes.

## Report on the consolidated financial statements – Unqualified opinion

We have audited the consolidated financial statements of Biocartis Group NV (the company) and its subsidiaries (jointly 'the group'), prepared in accordance with International Financial Reporting Standards as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium. The consolidated balance sheet shows total assets of 148,378 (000) EUR and the consolidated income statement shows a consolidated loss (group share) for the year then ended of 39,797 (000) EUR.

### Board of directors' responsibility for the preparation of the consolidated financial statements

The board of directors is responsible for the preparation and fair presentation of consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium, and for such internal control as the board of directors determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

### Statutory auditor's responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing (ISA). Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the statutory auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the statutory auditor

considers internal control relevant to the group's preparation and fair presentation of consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the group's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the board of directors, as well as evaluating the overall presentation of the consolidated financial statements. We have obtained from the group's officials and the board of directors the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Unqualified opinion

In our opinion, the consolidated financial statements of Biocartis Group NV give a true and fair view of the group's net equity and financial position as of 31 December 2015, and of its results and its cash flows for the year then ended, in accordance with International Financial Reporting Standards as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

## Report on other legal and regulatory requirements

The board of directors is responsible for the preparation and the content of the directors' report on the consolidated financial statements.

As part of our mandate and in accordance with the Belgian standard complementary to the International Standards on Auditing applicable in Belgium, our responsibility is to verify, in all material respects, compliance with certain legal and regulatory requirements. On this basis, we make the following additional statement, which does not modify the scope of our opinion on the consolidated financial statements:

- The directors' report on the consolidated financial statements includes the information required by law, is consistent with the consolidated financial statements and is free from material inconsistencies with the information that we became aware of during the performance of our mandate.

Diegem, 8 April 2016

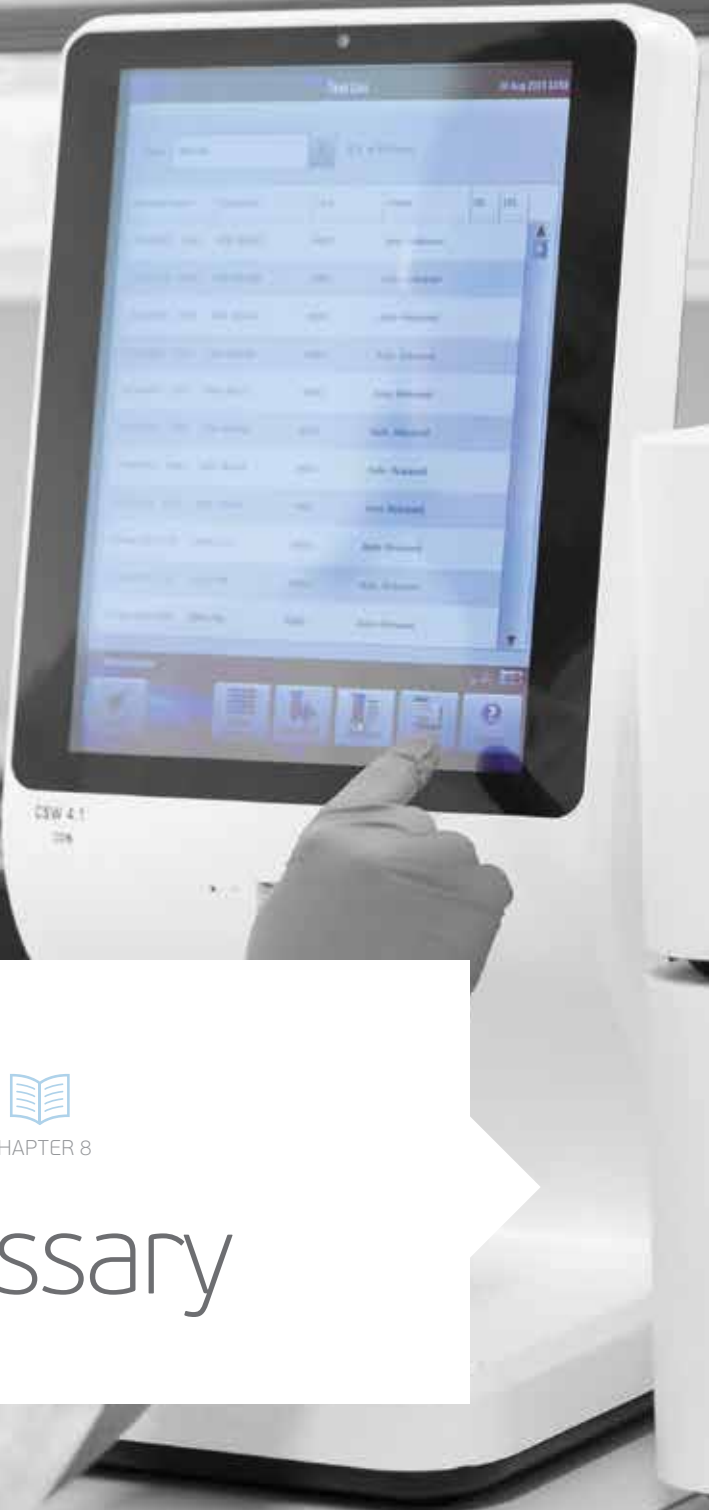
### The statutory auditor



**DELOITTE Bedrijfsrevisoren / Reviseurs d'Entreprises**

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

Represented by Gert Vanhees



CHAPTER 8

# Glossary

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

---

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

---

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

---

**cfDNA** This is cell free plasma DNA.

---

**Companion Diagnostics (CDx)** CDx is a bio-analytical method designed to assess: (i) whether or not a patient will respond favourably to a specific medical treatment; (ii) what the optimal dose is for a patient; and (iii) whether the patient can expect certain side effects from a medical treatment. Any prescription of a drug with a CDx is based on the outcome of the CDx. CDx tests are also used in the drug development process.

---

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

---

**Epidermal growth factor receptor (EGFR)** EGFR is a protein found on the surface of certain cells which can cause them to divide. It is found in abnormally high levels on the surface of many types of cancer cells.

---

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

**Formalin fixed, paraffin embedded (FFPE)**

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

**US Food and Drug Administration (FDA)**

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

**Immunoassay**

Immunoassays are assays that measure biomarkers through antigen-antibody interaction technologies. In most cases such assays are used to measure biomarkers of the immune system itself, e.g. HCV or HIV antibodies produced by the bodies, which are detected by means of HCV or HIV antigens.

**Influenza**

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

**In vitro diagnostics or In vitro diagnosis (IVD)**

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

**Kirsten rat sarcoma-2 virus oncogene (KRAS)**

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

**Metastatic Colorectal Cancer (mCRC)**

Colorectal Cancer (CRC) is the second most common cancer worldwide, with an estimated incidence of more than 1.36 million new cases annually. According to the International Agency for Research on Cancer, an estimated 694,000 deaths from CRC occur worldwide every year, accounting for 8.5% of all cancer deaths and making it the fourth most common cause of death from cancer.

|   |   |
|---|---|
| Molecular diagnostics (MDx)                     | MDx is a form of diagnostic testing used to detect specific sequences in DNA or RNA that may or may not be associated with disease. Clinical applications of MDx include infectious disease testing, oncology, pharmacogenomics and genetic disease screening.  |
| Micro satellite instability (MSI)               | MSI is a genetic hyper-mutability condition resulting from MMR that is functioning abnormally.  |
| Multiplexing                                    | The simultaneous detection of more than one analyte or biomarker from a single sample.  |
| Neuroblastoma RAS viral (v-ras) oncogene (NRAS) | NRAS is a protein that is encoded, in humans, by the NRAS gene. Like other members of the Ras family, the NRAS protein is a GTPase (a large family of hydrolase enzymes that can bind and hydrolyse guanosine triphosphate), and is an early player in many signal transduction pathways. The protein product of the normal NRAS gene performs an essential function in normal tissue signaling, and the mutation of a NRAS gene is associated with the development of many cancers.  |
| Polymerase chain reaction (PCR)                 | The specific and exponential amplification of DNA sequences by consecutive thermal cycling steps. Real-time PCR is a form of PCR whereby the amplified sequences are made visible by means of fluorescent labelling in real time, i.e., as they become 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.

---

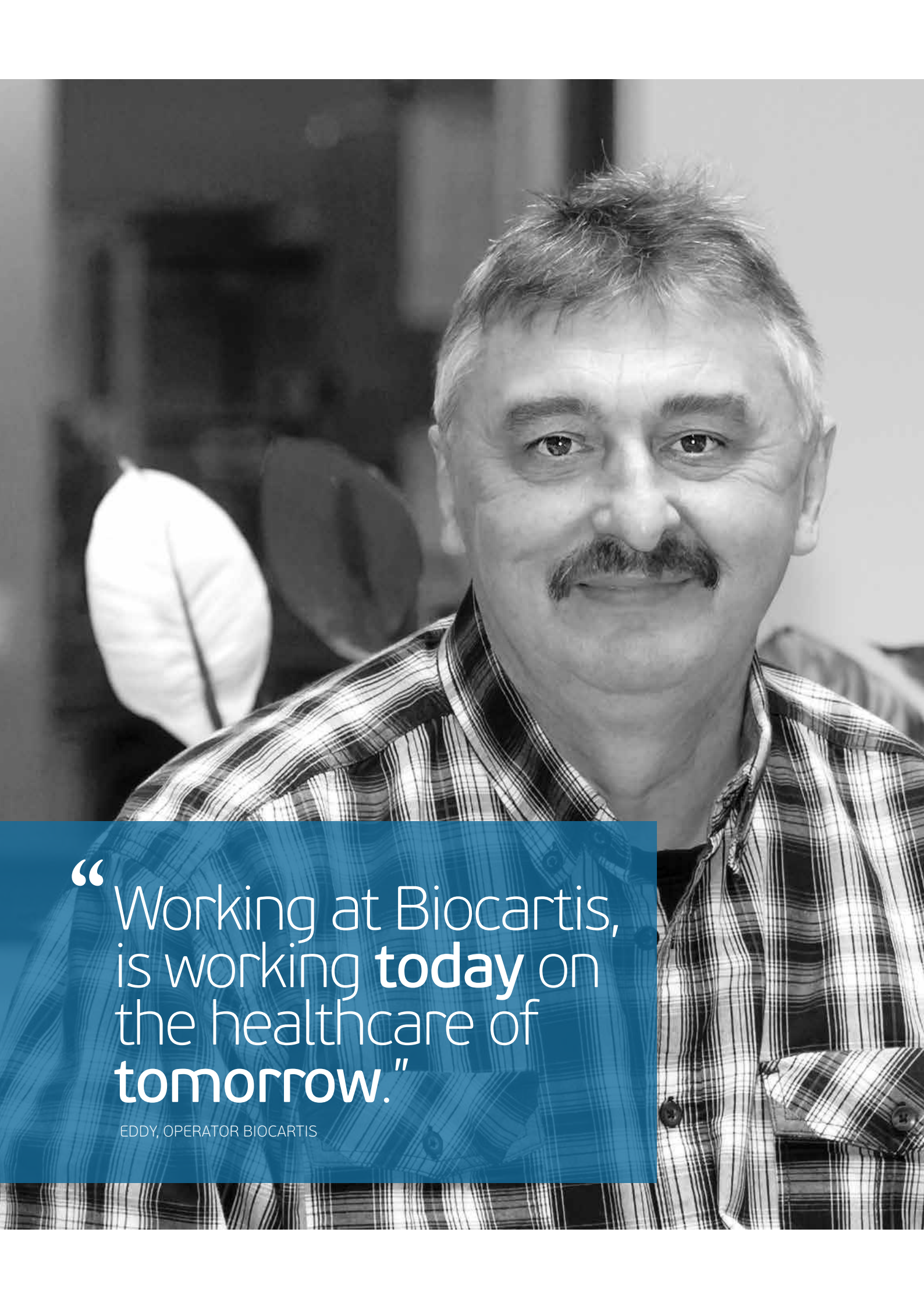
**Ribonucleic acid (RNA)**

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.



“Working at Biocartis,  
is working **today** on  
the healthcare of  
**tomorrow.**”

EDDY, OPERATOR BIOCARTIS

**Biocartis NV**

Generaal De Wittelaan 11 B3 2800 Mechelen Belgium  
+32 15 632 600 info@biocartis.com www.biocartis.com

design: www.mediaclan.it

