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The document and the offer when made are only addressed to and directed at persons in member states of the European Economic Area (“**EEA**”) other than Belgium who are “qualified investors” within the meaning of article 2(1)(e) of the Prospectus Directive (Directive 2003/71/EC and amendments thereto, including Directive 2010/73/EU, to the extent implemented in the relevant Member State of the European Economic Area) (the “**European Prospectus Directive**”) and any implementing measure in each relevant Member State of the EEA (“**Qualified Investors**”). In addition, in the United Kingdom (“**UK**”), this document is being distributed only to, and is directed only at, Qualified Investors (i) who have professional experience in matters relating to investments falling within article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the “**Order**”) and Qualified Investors falling within article 49(2)(a) to (d) of the Order, and (ii) to whom it may otherwise lawfully be communicated (all such persons together being referred to as “**Relevant Persons**”). This document must not be acted on or relied on (i) in the UK, by persons who are not Relevant Persons, and (ii) in any member state of the EEA other than Belgium and the UK, by persons who are not Qualified Investors. Any investment or investment activity to which this document relates is available only to (i) in the UK, Relevant Persons, and (ii) in any member state of the EEA other than Belgium and the UK, Qualified Investors, and will be engaged in only with such persons.

THE SECURITIES REFERENCED IN THIS DOCUMENT MAY ONLY BE DISTRIBUTED IN “OFFSHORE TRANSACTIONS” AS DEFINED IN, AND IN ACCORDANCE WITH, REGULATION S UNDER THE US SECURITIES ACT OF 1933, AS AMENDED (THE “**US SECURITIES ACT**”) OR WITHIN THE UNITED STATES TO QUALIFIED INSTITUTIONAL BUYERS (“**QIBs**”) AS DEFINED IN AND IN ACCORDANCE WITH RULE 144A UNDER THE US SECURITIES ACT (“**RULE 144A**”). ANY FORWARDING, REDISTRIBUTION OR REPRODUCTION OF THIS DOCUMENT IN WHOLE OR IN PART IS UNAUTHORISED. FAILURE TO COMPLY WITH THIS NOTICE MAY RESULT IN A VIOLATION OF THE US SECURITIES ACT OR THE APPLICABLE LAWS OF OTHER JURISDICTIONS.

NOTHING IN THIS ELECTRONIC TRANSMISSION CONSTITUTES AN OFFER OF SECURITIES FOR SALE IN THE UNITED STATES OR ANY OTHER JURISDICTION WHERE IT IS UNLAWFUL TO DO SO. THE SECURITIES HAVE NOT BEEN AND WILL NOT BE REGISTERED UNDER THE US SECURITIES ACT OR WITH ANY SECURITIES REGULATORY AUTHORITY OF ANY STATE OR OTHER JURISDICTION OF THE UNITED STATES AND MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED IN THE UNITED STATES EXCEPT (1) IN ACCORDANCE WITH RULE 144A TO A PERSON THAT THE HOLDER AND ANY PERSON ACTING ON ITS BEHALF REASONABLY BELIEVES IS A QIB OR (2) IN AN OFFSHORE TRANSACTION IN ACCORDANCE WITH RULE 903 OR RULE 904 OF REGULATION S UNDER THE US SECURITIES ACT, IN EACH CASE IN ACCORDANCE WITH ANY APPLICABLE SECURITIES LAWS OF ANY STATE OF THE UNITED STATES OR PURSUANT TO AN EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE US SECURITIES ACT AND APPLICABLE STATE OR LOCAL SECURITIES LAWS.

**Confirmation of your representation:** By accepting electronic delivery of this document, you are deemed to have represented to the Issuer and the Underwriters that (i) you are acting on behalf of, or you are either (a) an institutional investor outside the United States (as defined in Regulation S under the US Securities Act), or (b) in the United States and a QIB that is acquiring securities for your own account or for the account of another QIB; (ii) if you are in the United Kingdom, you are a Relevant Person; (iii) if you are in any member state of the EEA other than Belgium or the United Kingdom, you are a Qualified Investor; (iv) the securities acquired by you in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, any person in circumstances which may give rise to an offer of any securities to the public other than their offer or resale in Belgium or in any

member state of the EEA which has implemented the European Prospectus Directive to Qualified Investors (as defined in the European Prospectus Directive); and (v) if you are outside the United States, United Kingdom and EEA (and the electronic mail addresses that you gave the Issuer and to which this document has been delivered are not located in such jurisdictions) you are a person into whose possession this document may lawfully be delivered in accordance with the laws of the jurisdiction in which you are located.

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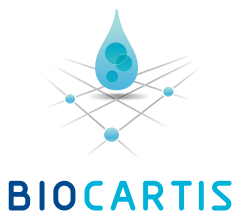
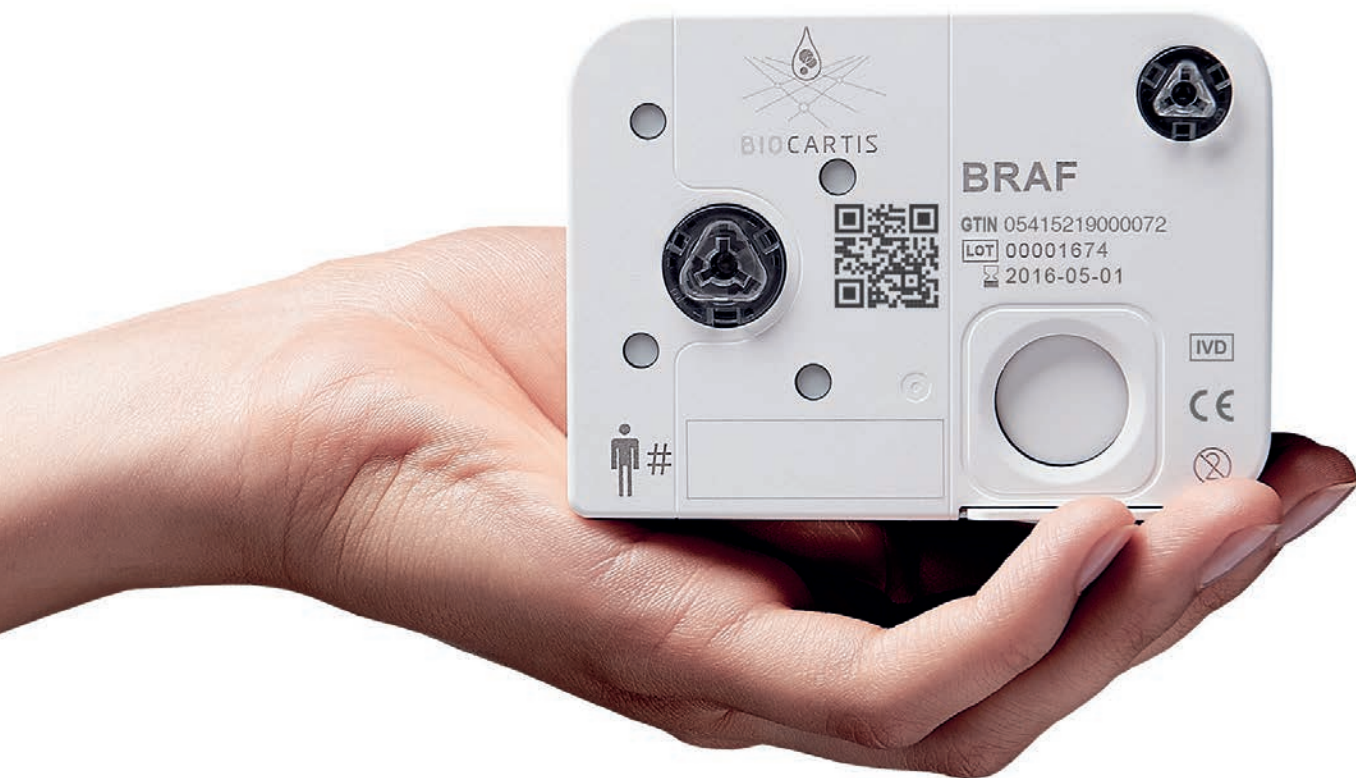
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The Underwriters are acting exclusively for the Issuer and no one else in connection with the offer. They will not regard any other person (whether or not a recipient of this document) as their respective client in relation to the offer and will not be responsible to anyone other than the Issuer for providing the protections afforded to their respective clients nor for giving advice in relation to the offer or any transaction or arrangement referred to herein.

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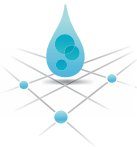
# IPO PROSPECTUS

April 14<sup>th</sup> 2015



Biocartis Group NV  
Generaal De Wittelaan 11 B3  
2800 Mechelen - Belgium

[www.biocartis.com](http://www.biocartis.com)



## BIOCARTIS

### Biocartis Group NV

#### PRICE RANGE: €10.00 TO €11.50 PER OFFERED SHARE

This prospectus (the "**Prospectus**") relates to the initial offering (the "**Offering**") by Biocartis Group NV (the "**Issuer**"), a limited liability company organised under the laws of Belgium, of up to 8,695,652 new shares (the "**New Shares**"), with no nominal value, of the Issuer, within a price range between €10.00 and €11.50 per new share (the "**Price Range**"). The Offer Price (as defined below) may be set within the Price Range or below the lower end of the Price Range, but will not exceed the higher end of the Price Range. In the event the Offer Price is set below the lower end of the Price Range, this will be published in a supplement to the Prospectus and in that event investors will have the right to withdraw their orders made prior to the publication of the supplement.

KBC Securities NV/SA, as stabilisation manager (the "**Stabilisation Manager**"), acting on behalf of the Underwriters (as defined herein), is expected to be granted a warrant to purchase additional new shares in a number equal to up to 15% of the number of New Shares subscribed for in the Offering at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering (the "**Over-allotment Option**"), and the additional new shares issued pursuant to the Over-allotment Option and the New Shares collectively being referred to as the "**Offered Shares**"). The Over-allotment Option will be exercisable for a period of 35 days following the Listing Date (as defined below). The Stabilisation Manager, acting on behalf of the Underwriters, may engage in transactions that stabilise, maintain or otherwise affect the price of the shares of the Issuer during a period of 30 days following the Listing Date. These activities may support the market price of the shares at a level higher than that which might otherwise prevail.

The Offering consists of: (i) an initial public offering to retail and institutional investors in Belgium (the "**Belgian Offering**"); (ii) a private placement in the United States to persons who are reasonably believed to be "qualified institutional buyers" ("**QIBs**") as defined in Rule 144A ("**Rule 144A**") under the US Securities Act of 1933, as amended (the "**US Securities Act**"), in reliance on Rule 144A; and (iii) private placements to certain qualified and/or institutional investors under applicable laws of the relevant jurisdiction in the rest of the world (those qualified and/or institutional investors together with the QIBs are collectively being referred to as the "**Institutional Investors**"). The Offering outside the United States will be made in compliance with Regulation S under the US Securities Act ("**Regulation S**"). Private placements may take place in member states of the European Economic Area ("**EEA**") pursuant to an exemption under the Directive 2003/71/EC of the European Parliament and of the Council of the European Union (as amended, including by Directive 2010/73/EU, the "**European Prospectus Directive**") as implemented in the relevant EEA member state.

Certain existing shareholders of the Issuer have committed to subscribe for an aggregate amount of €21,512,800.00 in the Offering at the Offer Price subject to the closing of the Offering (the "**Participating Shareholders**").

The shares have not been and will not be registered under the US Securities Act or the applicable securities laws of any state or other jurisdiction of the United States and may not be offered, sold, pledged or transferred within the United States, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act. Prospective purchasers are hereby notified that sellers of the shares may be relying on the exemption from the provisions of Section 5 of the US Securities Act provided by Rule 144A. For a description of certain restrictions on transfer of the shares, see "**Transfer restrictions**".

This Prospectus does not constitute, and neither the Issuer nor the Global Coordinator and the other Underwriters are making, an offer to sell the Offered Shares or soliciting an offer to purchase any of the Offered Shares to any person in any jurisdiction where such an offer or solicitation is not permitted. The Offered Shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other Offering related documents may be distributed or sent to any person or into any jurisdiction, except in circumstances that will result in the compliance with all applicable laws and regulations. Persons into whose possession this Prospectus may come are required to inform themselves about, and to observe all, such restrictions. Neither the Issuer nor the Global Coordinator and the other Underwriters accept any responsibility for any violation by any person, whether or not it is a prospective purchaser of Offered Shares, of any such restriction.

**An investment in the Offered Shares involves substantial risks and uncertainties, and in particular the risk that Biocartis has incurred operating losses, negative operating cashflow and an accumulated deficit since inception and may never become profitable, risks regarding the market acceptance of Biocartis's Idylla™ platform and its menu of assays (the Idylla™ BRAF Mutation Test is the only assay that is commercialised today), risks in the development of a menu of assays and risks in relation to its (currently limited) commercialisation infrastructure. Prospective investors should read the entire Prospectus, and, in particular, should see elements D.1 and D.3 of the "Summary" beginning on page 1 and "Risk factors" beginning on page 21 for a discussion of certain factors that should be considered in connection with an investment in the Offered Shares. All of these factors should be considered before investing in the Offered Shares. Prospective investors must be able to bear the economic risk of an investment in the Offered Shares and should be able to sustain a partial or total loss of their investment.**

The offering period (the "**Offering Period**") will begin on 15 April 2015 and is expected to end no later than 4:00 pm (CEST) on 29 April 2015, subject to early closing or extension, provided that the Offering Period will in any event be open for at least six business days from the availability of this Prospectus. Any early closing or extension of the Offering Period will be announced in the Belgian financial press, and the dates for each of pricing and allocation, publication of the Offer Price and results of the Offering, conditional trading and closing of the Offering will in such case be adjusted accordingly.

The price per Offered Share (the "**Offer Price**") will be determined during the Offering Period through a book-building process in which only Institutional Investors may participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time. See "**The Offering—Offer Price**" for further information.

The Offer Price, the number of Offered Shares placed in the Offering and the allocation of Offered Shares to Retail Investors (as defined herein) is expected to be made public on or about 30 April 2015 and in any event no later than the first or second business day after the end of the Offering Period. The Offer Price will be a single price in euro, exclusive of the Belgian tax on stock exchange transactions, and of costs, if any, charged by financial intermediaries for the submission of applications.

Prior to the Offering, there has been no public market for the shares. An application has been made to list all of the Issuer's existing shares as well as newly issued Offered Shares on the regulated market of Euronext Brussels under the symbol "BCART". Trading of the shares on the regulated market of Euronext Brussels is expected to commence, on an "if-and-when-issued and/or delivered" basis, on or about 4 May 2015 (the "**Listing Date**"), provided that this may be accelerated in case of early closing.

Delivery of the Offered Shares is expected to take place in book-entry form against payment therefore in immediately available funds on or about 5 May 2015, provided that this may be accelerated in case of early closing (the "**Closing Date**"), to investors' securities accounts via Euroclear Belgium, the Belgian central securities depository. See "**The Offering**".

This document constitutes an offer and listing prospectus for purposes of article 3 the European Prospectus Directive and has been prepared in accordance with article 20 of the Belgian Act of 16 June 2006 on the public offering of securities and the admission of securities to trading on a regulated market, as amended (the "**Belgian Prospectus Act**"). The English version of this Prospectus was approved by the Belgian Financial Services and Markets Authority (the "**FSMA**") on 14 April 2015.

Global Coordinator

KBC Securities

Joint Bookrunners

Kempen & Co

KBC Securities

Petercam

PROSPECTUS DATED 14 APRIL 2015

## IMPORTANT INFORMATION

In accordance with article 61, §1 and §2 of the Belgian Prospectus Act, the Issuer, represented by its board of directors, assumes responsibility for the information contained in this Prospectus. Having taken all reasonable care to ensure that such is the case, the Issuer, represented by its board of directors, declares that, to the best of its knowledge, the information contained in this Prospectus is in accordance with the facts and contains no omission likely to affect its import.

None of KBC Securities NV/SA, Kempen & Co N.V. or Petercam NV/SA (the “**Underwriters**”), nor any of their respective directors, officers, or employees, makes any representation or warranty, express or implied, as to, or assumes any responsibility for, the accuracy or completeness or verification of the information in this Prospectus, and nothing in this Prospectus is, or shall be relied upon as, a promise or representation by the Underwriters or any of their respective directors, officers, or employees whether as to the past or the future. Accordingly, the Underwriters disclaim, to the fullest extent permitted by applicable law, any and all liability, whether arising in tort, contract or otherwise, in respect of this Prospectus or any such statement.

This Prospectus is intended to provide information to potential investors in the context of and for the sole purpose of evaluating a possible investment in the Offered Shares. It contains selected and summarised information, does not express any commitment or acknowledgement or waiver, and does not create any right, express or implied, towards anyone other than a potential investor. Investors must assess, with their own advisers if necessary, whether the Offered Shares are a suitable investment for them, considering their personal income and financial situation. In case of any doubt about the risk involved in investing in the Offered Shares, investors should abstain from so investing.

In making an investment decision, investors must rely on their own assessment, examination, analysis and enquiry of the Issuer, the terms of the Offering and the contents of this Prospectus, including the merits and risks involved. Any purchase of shares should be based on the assessments that an investor may deem necessary, including the legal basis and consequences of the Offering, and including possible tax consequences that may apply, before deciding whether or not to invest in the shares. In addition to their own assessment of the Issuer and the terms of the Offering, investors should rely only on the information contained in this Prospectus, including the risk factors described herein, and any notices that the Issuer publishes under applicable law or the relevant rules of Euronext Brussels.

The summaries and descriptions of legal provisions, accounting principles or comparisons of such principles, legal company forms or contractual relationships reported in the Prospectus may under no circumstances be interpreted as a basis for credit or other evaluation, or as investment, legal or tax advice for prospective investors. Prospective investors are urged to consult their own financial adviser, accountant or other advisers concerning the legal, tax, economic, financial and other aspects associated with the trading or investment in the shares.

Investors must also acknowledge that they have not relied on the Underwriters or any person affiliated with the Underwriters in connection with any investigation of the information contained in this Prospectus or their investment decision; and they have relied only on the information contained in this Prospectus, and that no person has been authorised to give any information or to make any representation concerning the Issuer or its subsidiaries or the shares (other than as contained in this Prospectus) and, if given or made, any such other information or representation should not be relied upon as having been authorised by the Issuer or the Underwriters.

None of the Issuer or the Underwriters, or any of their respective representatives, is making any representation to any offeree or purchaser of the shares regarding the legality of an investment in the shares by such offeree or purchaser under the laws applicable to such offeree or purchaser. Each investor should consult with his or her own advisers as to the legal, tax, business, financial and related aspects of a purchase of the shares.

No person has been authorised to give any information or to make any representation in connection with the Offering other than those contained in this Prospectus, and, if given or

made, such information or representation must not be relied upon as having been authorised. Without prejudice to the Issuer's obligation to publish supplements to the Prospectus when legally required (as described below), neither the delivery of this Prospectus nor any sale made at any time after the date hereof shall, under any circumstances, create any implication that there has been no change in Biocartis's affairs since the date hereof or that the information set forth in this Prospectus is correct as of any time since its date.

The Underwriters are acting exclusively for the Issuer and no one else in connection with the Offering. They will not regard any other person (whether or not a recipient of this document) as their respective clients in relation to the Offering and will not be responsible to anyone other than the Issuer for providing the protections afforded to their respective clients nor for giving advice in relation to the Offering or any transaction or arrangement referred to herein.

The FSMA approved the English version of this Prospectus on 14 April 2015 in accordance with article 23 of the Belgian Prospectus Act. The FSMA's approval does not imply any opinion by the FSMA on the suitability and the quality of the Offering or on the status of the Issuer.

This Prospectus has been prepared in English and translated into Dutch. The Issuer is responsible for the consistency between the Dutch and English versions of the Prospectus. In the case of discrepancies between the different versions of this Prospectus, the English version will prevail.

The information in this Prospectus is as of the date printed on the front cover, unless expressly stated otherwise. The delivery of this Prospectus at any time does not imply that there has been no change in Biocartis's business or affairs since the date hereof or that the information contained herein is correct as of any time subsequent to the date hereof. In accordance with article 34 of the Belgian Prospectus Act, in the event of a significant new factor or material mistake or inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the Offered Shares during the period from the date of approval of the Prospectus to the Listing Date, a supplement to this Prospectus shall be published. Any supplement is subject to approval by the FSMA, in the same manner as this Prospectus and must be made public in the same manner as this Prospectus.

If a supplement to the Prospectus is published, investors will have the right to withdraw their orders made prior to the publication of the supplement provided that the new factor, mistake or inaccuracy referred to in the previous paragraph arose before the end of the Offering Period and the delivery of the Offered Shares. Such withdrawal must be done within the time period set forth in the supplement (which shall not be shorter than two business days after publication of the supplement).

The distribution of this Prospectus and the Offering may, in certain jurisdictions, be restricted by law, and this Prospectus may not be used for the purpose of, or in connection with, any offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorised or to any person to whom it is unlawful to make such offer or solicitation. This Prospectus does not constitute an offer to sell, or an invitation of an offer to purchase, any shares in any jurisdiction in which such offer or invitation would be unlawful. The Issuer and the Underwriters require persons into whose possession this Prospectus comes to inform themselves of and observe all such restrictions. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction. None of the Issuer or the Underwriters accepts any legal responsibility for any violation by any person, whether or not a prospective purchaser of shares, of any such restrictions. The Issuer and the Underwriters reserve the right in their own absolute discretion to reject any offer to purchase shares that the Issuer, the Underwriters or their respective agents believe may give rise to a breach or violation of any laws, rules or regulations.

## **STABILISATION**

In connection with the Offering, KBC Securities NV/SA will act as Stabilisation Manager on behalf of the Underwriters and may engage in transactions that stabilise, maintain or otherwise affect the price of the shares or any options, warrants or rights with respect to, or other interest

in, the shares or other securities of the Issuer for up to 30 days from the Listing Date (the “**Stabilisation Period**”). These activities may support the market price of the shares at a level higher than that which might otherwise prevail. Stabilisation will not be executed above the Offer Price. Such transactions may be effected on the regulated market of Euronext Brussels, in the over-the-counter markets or otherwise. The Stabilisation Manager and its agents are not required to engage in any of these activities and, as such, there is no assurance that these activities will be undertaken; if undertaken, the Stabilisation Manager or its agents may discontinue any of these activities at any time and they must terminate at the end of the 30-day period mentioned above.

Within five business days of the end of the Stabilisation Period, the following information will be made public in accordance with article 5, §2 of the Belgian Royal Decree of 17 May 2007 on primary markets practices: (i) whether or not stabilisation was undertaken; (ii) the date at which stabilisation started; (iii) the date on which stabilisation last occurred; (iv) the price range within which stabilisation was carried out, for each of the dates on which stabilisation transactions were carried out; and (v) the final size of the Offering, including the result of the stabilisation and the exercise of the Over-allotment Option, if any.

### **NOTICE TO PROSPECTIVE INVESTORS IN THE UNITED STATES**

The shares have not been and will not be registered under the US Securities Act and are being offered and sold: (i) outside the United States in compliance with Regulation S, and (ii) in the United States only to persons who are reasonably believed to be QIBs in reliance on Rule 144A. Prospective investors are hereby notified that sellers of the shares may be relying on the exemption from the registration requirements of Section 5 of the US Securities Act provided by Rule 144A. For certain restrictions on transfer of the shares, see “*Transfer restrictions*”.

The shares have not been recommended by any US federal or state securities commission or regulatory authority. Furthermore, the foregoing authorities have not confirmed the accuracy or determined the adequacy of this Prospectus. Any representation to the contrary is a criminal offense in the United States.

In the United States, this Prospectus is being furnished on a confidential basis solely for the purpose of enabling a prospective investor to consider purchasing the particular securities described herein. The information contained in this Prospectus has been provided by the Issuer and other sources identified herein. Distribution of this Prospectus to any person other than the offeree specified by the Underwriters or their representatives, and those persons, if any, retained to advise such offeree with respect thereto, is unauthorised, and any disclosure of its contents, without the Issuer’s prior written consent, is prohibited. Any reproduction or distribution of this Prospectus in the United States, in whole or in part, and any disclosure of its contents to any other person is prohibited. This Prospectus is personal to each offeree and does not constitute an offer to any other person or to the public generally to subscribe for, or otherwise acquire, the shares.

### **NOTICE TO NEW HAMPSHIRE RESIDENTS**

**NEITHER THE FACT THAT A REGISTRATION STATEMENT OR AN APPLICATION FOR A LICENCE HAS BEEN FILED UNDER CHAPTER 421-B OF THE NEW HAMPSHIRE REVISED STATUTES (“RSA 421-B”) WITH THE STATE OF NEW HAMPSHIRE NOR THE FACT THAT A SECURITY IS EFFECTIVELY REGISTERED OR A PERSON IS LICENSED IN THE STATE OF NEW HAMPSHIRE CONSTITUTES A FINDING BY THE SECRETARY OF STATE OF THE STATE OF NEW HAMPSHIRE THAT ANY DOCUMENT FILED UNDER RSA 421-B IS TRUE, COMPLETE AND NOT MISLEADING. NEITHER ANY SUCH FACT NOR THE FACT THAT AN EXEMPTION OR EXCEPTION IS AVAILABLE FOR A SECURITY OR A TRANSACTION MEANS THE SECRETARY OF THE STATE OF NEW HAMPSHIRE HAS PASSED IN ANY WAY UPON THE MERITS OR QUALIFICATIONS OF, OR RECOMMENDED OR GIVEN APPROVAL TO, ANY PERSON, SECURITY, OR TRANSACTION. IT IS UNLAWFUL TO MAKE, OR CAUSE TO BE MADE, TO ANY PROSPECTIVE PURCHASER, CUSTOMER OR CLIENT ANY REPRESENTATION INCONSISTENT WITH THE PROVISIONS OF THIS PARAGRAPH.**

## NOTICE TO INVESTORS IN THE EUROPEAN ECONOMIC AREA

An offer to the public of any shares may not be made in any Member State of the European Economic Area (“EEA”) other than an offer to the public of Offered Shares in Belgium unless the Prospectus has been (i) approved by the competent authority in such Member State or passported and (ii) published in accordance with the European Prospectus Directive as implemented in such Member State. This Prospectus has been prepared on the basis that all offers of shares other than the offers contemplated in Belgium, will be made pursuant to an exemption under the European Prospectus Directive, as implemented in Member States of the EEA, from the requirement to produce a prospectus for offers of shares. Accordingly, any person making or intending to make any offer within the EEA of shares which are the subject of the placement contemplated in this Prospectus should only do so in circumstances in which no obligation arises for the Issuer or any of the Underwriters to produce a prospectus for such offer. The Offering is solely conducted by the Issuer, and neither the Issuer nor the Underwriters have authorised, nor do the Issuer or the Underwriters authorise, the making of any offer of shares through any financial intermediary.

The shares have not been, and will not be, offered to the public in any Member State of the European Economic Area, except for Belgium. Notwithstanding the foregoing, an offering of the shares may be made in a Member State of the European Economic Area that has implemented the European Prospectus Directive (a “**Relevant Member State**”):

- to any legal entity that is a qualified investor as defined in the European Prospectus Directive;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the European Prospectus Directive) subject to obtaining the prior consent of the Global Coordinator for any such offer; or
- in any other circumstances falling within article 3(2) of the European Prospectus Directive, if applicable;

provided that no such offer of shares shall result in a requirement for the publication by the Issuer or any Underwriter of a prospectus pursuant to article 3 of the European Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the Offering and the shares so as to enable an investor to decide to purchase or subscribe to shares, as that definition may be varied in that Relevant Member State by any measure implementing the European Prospectus Directive in that Relevant Member State, the expression “European Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the Directive 2010/73/EU), and includes any relevant implementing measure in the Relevant Member State.

## NOTICE TO INVESTORS IN THE UNITED KINGDOM

Offers of Offered Shares pursuant to the Offering are only being made to persons in the United Kingdom who are “qualified investors” or otherwise in circumstances which do not require publication by the Issuer of a prospectus pursuant to section 85(1) of the U.K. Financial Services and Markets Act 2000.

Any investment or investment activity to which the Prospectus relates is available only to, and will be engaged in only with, persons who (i) are investment professionals falling within article 19(5) or (ii) fall within article 49(2)(a) to (d) (“high net worth companies, unincorporated associations, etc.”) of the U.K. Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or other persons to whom such investment or investment activity may lawfully be made available (together, “**Relevant Persons**”). Persons in the United Kingdom who are not Relevant Persons should not take any action on the basis of the Prospectus and should not act or rely on it.



## AVAILABILITY OF THIS PROSPECTUS

This Prospectus is available to prospective investors in Belgium in English and Dutch. The Prospectus will be made available to prospective investors at no cost at the Issuer's registered office, located at Generaal De Wittelaan 11 bus B, 2800 Mechelen, Belgium and can be obtained by prospective investors in Belgium on request from the KBC Telecenter at +32 (0)3 283 29 70 or Petercam NV/SA at +32 (0)2 229 64 46.

Subject to selling and transfer restrictions, the Prospectus is available to prospective investors in English and Dutch on the following websites: [www.biocartis.com](http://www.biocartis.com), [www.kbc.belbiocartis.be](http://www.kbc.belbiocartis.be), [www.kbcsecurities.be](http://www.kbcsecurities.be), [www.bolero.be](http://www.bolero.be) and [www.petercam.be](http://www.petercam.be).

The posting of the Prospectus or any summary thereof on the internet does not constitute an offer to sell or a solicitation of an offer to buy any of the shares to or from any person in any jurisdiction in which it is unlawful to make such offer or solicitation to such person. The electronic version may not be copied, made available or printed for distribution. Although certain references are made to the Issuer's website, information on the Issuer's website ([www.biocartis.com](http://www.biocartis.com)) (other than the Prospectus) or any other website does not form part of the Prospectus. This Prospectus is valid only if circulated in accordance with applicable law.

## AVAILABLE INFORMATION

The Issuer has filed its deed of incorporation and must file its restated articles of association and all other deeds and resolutions that are to be published in the Annexes to the Belgian Official Gazette (*Belgisch Staatsblad/Moniteur Belge*) with the clerk's office of the commercial court of Antwerp, division Mechelen, where they are available to the public. Biocartis Group NV is registered with the register of legal entities (Antwerp, division Mechelen) under enterprise number 0505.640.808. A copy of the Issuer's most recent articles of association will also be available on its website.

In accordance with Belgian law, the Issuer must prepare annual audited statutory and consolidated financial statements. The annual statutory and consolidated financial statements and the reports of the Issuer's board of directors and statutory auditor relating thereto must be filed with the Belgian National Bank, where they are available to the public. Furthermore, as a company with shares listed on the regulated market of Euronext Brussels, the Issuer will also publish an annual financial report (which includes its audited statutory and consolidated financial statements, the report of its board of directors and the report of the statutory auditor) and an annual announcement preceding the publication of the annual financial report, as well as a half-yearly financial report on the first six months of its financial year (which includes a condensed set of financial statements and an interim management report). Copies of these documents will be made available on the Issuer's website and on STORI, the Belgian central storage mechanism, which is operated by the FSMA and can be accessed via [www.fsma.be](http://www.fsma.be).

The Issuer will also have to disclose price sensitive information (inside information) and certain other information to the public. In accordance with the Belgian Royal Decree of 14 November 2007 on the obligations of issuers of financial instruments that are admitted to trading on a regulated market, such information and documentation will be made available through the Issuer's website, press releases, the communication channels of Euronext Brussels, or a combination of these, and on STORI.

The Issuer has agreed that, for so long as any of the shares are "restricted securities" within the meaning of Rule 144(a)(3) under the US Securities Act, the Issuer will, during any period in which it is neither subject to Section 13 or 15(d) of the US Securities Exchange Act of 1934 (the "US Exchange Act") nor exempt from reporting pursuant to Rule 12g3-2(b) under the US Exchange Act, provide to any holder or beneficial owner of such restricted securities or to any prospective purchaser of such restricted securities designated by such holder or beneficial owner, on the request of such holder, beneficial owner or prospective purchaser, the information required to be provided to such persons pursuant to Rule 144A(d)(4) under the US Securities Act. The Issuer is not currently subject to the periodic reporting requirements of the US Exchange Act.

## PRESENTATION OF FINANCIAL AND OTHER INFORMATION

### Financial statements

This Prospectus contains the audited consolidated financial information of the Issuer as of and for the years ended 31 December 2014, 2013 and 2012 (the “**Financial Statements**”). These Financial Statements were prepared in accordance with International Financial Reporting Standards, as adopted by the European Union (“**IFRS**”).

The Issuer was incorporated on 24 November 2014 to act as a new holding company for the business of Biocartis. All shares in Biocartis S.A., which served as a holding company for Biocartis’s operations and carried out its activities through various subsidiaries, have been contributed to the Issuer (in two consecutive stages, on 24 November 2014 and 25 November 2014, respectively) on a share-for-share basis for a total amount of €222 million. This contribution in kind is considered in the consolidated financial statements of the Issuer for the period ended 31 December 2014 to be a transaction between entities under common control and consequently does not fall within the scope of IFRS 3 ‘Business combinations’. In this context, the continuity of the book values method has been applied.

In view hereof, the consolidated Financial Statements include the Issuer and its subsidiaries and comprise Biocartis. Prior to the incorporation of the Issuer, the consolidation was performed at the level of Biocartis S.A. The consolidated financial statements of the Issuer have therefore been presented as if the Issuer has been in existence and control of the Group since 1 January 2012.

The aforementioned transaction between entities under common control did not have a significant impact at the consolidated group level of Biocartis. Therefore, the activities of the consolidated group are given for 12 months for 2014, with comparative information for 2013 and 2012, respectively.

The Issuer’s consolidated financial statements as of and for the years ended 31 December 2014, 2013 and 2012 have been audited by Deloitte Bedrijfsrevisoren BV ovve CVBA, with registered office at Berkenlaan 8B, 1831 Diegem, Belgium, represented by Gert Vanhees, auditor, who rendered an unqualified audit report on these financial statements with a matter of emphasis paragraph on going concern, which should be read in conjunction with the Issuer’s consolidated financial statements and the report of the board of directors relating to that period. Deloitte Bedrijfsrevisoren BV ovve CVBA was appointed at the extraordinary general shareholders’ meeting of the Issuer held on 24 November 2014 as the Issuer’s statutory auditor for the statutory term of three years. For further information on the Issuer’s statutory auditor, see “*Statutory auditor*”.

### Rounding

Certain monetary amounts and other figures included in this Prospectus have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

### Other Information

In this Prospectus, references to the “*Issuer*” are to Biocartis Group NV and references to “*Biocartis*,” “*we*,” “*us*” or “*our*” are to the Issuer together with Biocartis S.A. and its consolidated subsidiaries.

## PRESENTATION OF INDUSTRY, MARKET AND OTHER INFORMATION

This Prospectus includes market, economic and industry data, which were obtained by Biocartis from industry publications and surveys, industry reports prepared by consultants, internal surveys and customer feedback. These market data are primarily presented in the sections “*Industry*” and “*Business*”. The market, economic and industry data have primarily been derived and extrapolated from reports provided by MarketsandMarkets. For further information, see Annex B “*Sources*”.

The third party sources the Issuer has used generally state that the information they contain has been obtained from sources believed to be reliable. Some of these third party sources also state, however, that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on significant assumptions. As Biocartis does not have access to the facts and assumptions underlying such market data, or statistical information and economic indicators contained in these third party sources, Biocartis is unable to verify such information and, while Biocartis believes it to be reliable, Biocartis cannot guarantee its accuracy or completeness.

In addition, certain information in this Prospectus is not based on published data obtained from independent third parties or extrapolations therefrom, but rather is based upon Biocartis's best estimates, which are in turn based upon information obtained from trade and business organisations and associations, consultants and other contacts within the industries in which Biocartis competes, information published by Biocartis's competitors and Biocartis's own experience and knowledge of conditions and trends in the markets in which Biocartis operates.

Biocartis cannot assure you that any of the assumptions that Biocartis has made while compiling this data from third party sources are accurate or correctly reflect Biocartis's position in the industry and none of Biocartis's internal estimates have been verified by any independent sources. None of the Issuer or the Underwriters makes any representation or warranty as to the accuracy or completeness of this information. None of the Issuer or the Underwriters have independently verified this information and, while the Issuer believes it to be reliable, none of the Issuer or the Underwriters can guarantee its accuracy.

## **JURISDICTION AND SERVICE OF PROCESS IN THE UNITED STATES AND ENFORCEMENT OF FOREIGN JUDGMENTS IN BELGIUM**

The Issuer is a limited liability company incorporated under the laws of Belgium. All of the Issuer's directors and all members of its executive management team are non-residents of the United States. All of the Issuer's assets and of the assets of these individuals are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon these individuals or the Issuer or to enforce against them judgments obtained in the United States whether or not based on the civil liability provisions of the US securities laws or other laws of the United States or any state thereof.

Original actions or actions for the enforcement of judgments of US courts relating to the civil liability provisions of the federal or state securities laws of the United States are not directly enforceable in Belgium. The United States and Belgium currently do not have a multilateral or bilateral treaty providing for reciprocal recognition and enforcement of judgments, other than arbitral awards, in civil and commercial matters. In order for a final judgment for the payment of money rendered by US courts based on civil liability to produce any effect on Belgian soil, it is accordingly required that this judgment be recognised and be declared enforceable by a Belgian court pursuant to the relevant provisions of the 2004 Belgian Code of Private International Law (the "PIL Code"). Recognition or enforcement does not imply a review of the merits of the case and is irrespective of any reciprocity requirement. A US judgment will, however, not be recognised or declared enforceable in Belgium if it infringes upon one or more of the grounds for refusal which are exhaustively listed in article 25 of the PIL Code. In addition to recognition or enforcement, a judgment by a federal or state court in the United States against the Issuer may also serve as evidence in a similar action in a Belgian court if it meets the conditions required for the authenticity of judgments according to the law of the state where it was rendered.

In addition, with regard to enforcements by legal proceedings in Belgium (including the recognition of foreign court decisions in Belgium), a registration tax at the rate of 3% of the amount of the judgment is payable by the debtor, if the sum of money which the debtor is ordered to pay by a Belgian court, or by a foreign court judgment that is either (i) automatically enforceable and registered in Belgium, or (ii) rendered enforceable by a Belgian court, exceeds €12,500. The registration tax is payable by the debtor. The creditor is jointly liable up to a maximum of one-half of the amount the creditor recovers from the debtor. A stamp duty is payable for each original copy of an enforcement judgment rendered by a Belgian court, with a maximum of €1,250.

## FORWARD-LOOKING STATEMENTS

All statements in this Prospectus that do not relate to historical facts and events are "forward-looking statements". Forward-looking statements can be found under the captions "Summary", "Risk factors", "Operating and Financial review and prospects", "Industry", "Business" and in other sections of this Prospectus. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes," "estimates," "anticipates," "expects," "intends," "may," "will," "plans," "continue," "ongoing," "potential," "predict," "project," "target," "seek" or "should" or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. These forward-looking statements appear in a number of places throughout this Prospectus. Forward-looking statements include statements regarding Biocartis's intentions, beliefs or current expectations concerning, among other things, its results of operations, prospects, growth, strategies and dividend policy and the industry in which Biocartis operates. In particular, certain statements are made in this Prospectus regarding management's estimates of future growth.

By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance. You should not place undue reliance on these forward-looking statements. Any forward-looking statements are made only as of the date of this Prospectus and, without prejudice to the Issuer's obligations under applicable law in relation to disclosure and ongoing information, Biocartis does not intend, and does not assume any obligation, to update forward-looking statements set forth in this Prospectus.

Many factors may cause Biocartis's results of operations, financial condition, liquidity and the development of the industries in which Biocartis competes to differ materially from those expressed or implied by the forward-looking statements contained in this Prospectus.

These factors include:

- the commercial market acceptance of the Idylla™ platform and its menu of assays;
- delays in the development of a broad and clinically relevant menu of assays;
- Biocartis's ability in further growing its commercialisation infrastructure;
- the effect of disruptions in Biocartis's manufacturing or outsourcing ability;
- the effect of disruptions in supplies of components required for the Idylla™ platform;
- competition from superior, alternative or more widespread solutions and technology developers;
- changes in the payment, reimbursement and price control policies of governments and other parties;
- the effect of product recall or liability claims and/or any adverse publicity;
- changes in government regulations and legislation and healthcare policies, including with respect to reimbursements;
- the effect of claims asserting the infringement of or oppositions against intellectual property rights;
- the risks associated with infringements of, renewal or entering into licence agreements;
- failure to obtain and maintain adequate protection for the intellectual property Biocartis develops;
- restrictions on jointly developed intellectual property;
- failure to obtain sufficient additional funding;
- reliance on Biocartis's executive management and its ability to recruit, train, motivate and retain employees;
- increased labour costs;

- changes in tax rates, tax liabilities or tax rules;
- fluctuations in currency exchange rates;
- the effect of liability related to privacy or personal information Biocartis collects;
- breaches of security in Biocartis's products or computer systems;
- failure to realise benefits from and adverse impact of unanticipated costs associated with acquisitions;
- the risks associated with operating internationally;
- the incurrence of losses that are not insured;
- the effects of health, safety and environmental regulations; and
- the impairment of goodwill or other intangible assets.

These risks and others described under "*Risk factors*" are not exhaustive. Other sections of this Prospectus describe additional factors that could adversely affect Biocartis's results of operations, financial condition, liquidity and the development of the sectors in which Biocartis operates. New risks can emerge from time to time, and it is not possible for Biocartis to predict all such risks, nor can Biocartis assess the impact of all such risks on its business or the extent to which any risks, or combination of risks and other factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, you should not rely on forward-looking statements as a prediction of actual results.

## EXCHANGE RATES

In this Prospectus, unless otherwise indicated, all amounts are expressed in euro. The following tables set forth, for the periods and dates indicated, certain information regarding the daily reference exchange rates published by the European Central Bank (“**ECB Daily Reference Rate**”) for the euro and the US Dollar. On 13 April 2015, the ECB Daily Reference Rate was €1.0552 per US\$ 1. This rate may differ from the actual rates used in the preparation of the financial statements and other financial information appearing in this Prospectus. Inclusion of these exchange rates is not meant to suggest that the US Dollar amounts (as the case may be) actually represent such euro amounts or that such amounts could have been converted into euro at any particular rate, if any. The following tables have been set out solely for the purpose of convenience.

	US Dollars per one euro			
	Period End <sup>(1)</sup>	Average <sup>(2)</sup>	High	Low
<b>Year</b>				
2010 .....	1.3362	1.3257	1.4563	1.1942
2011 .....	1.2939	1.3920	1.4882	1.2889
2012 .....	1.3194	1.2848	1.3454	1.2089
2013 .....	1.3791	1.3281	1.3814	1.2768
2014 .....	1.2141	1.3285	1.3953	1.2141
<b>Month</b>				
January 2015 .....	1.1305	1.1621	1.2043	1.1198
February 2015 .....	1.1240	1.1350	1.1447	1.1240
March 2015 .....	1.0759	1.0838	1.1227	1.0557
April 2015 (through April 13) .....	1.0552	1.0741	1.0862	1.0552

**Notes:**

- (1) Represents the exchange rate on the last business day of the applicable period.
- (2) Represents the average of the ECB Daily Reference Rates on each business day of each month during the relevant one-year period and, with respect to monthly information, the average of the ECB Daily Reference Rates on each business day for the relevant period.

In this Prospectus, references to “**euro**”, “**EUR**” or “**€**” are references to the euro, the single currency of the participating member states in the Third Stage of European Economic and Monetary Union of the Treaty Establishing the European Community, as amended from time to time; references to “**US Dollar**” or “**US\$**” are references to the United States dollar, the lawful currency of the United States of America.

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## SUMMARY

Summaries are made up of disclosure requirements known as “Elements”. These elements are numbered in Sections A-E (A.1-E.7).

This summary contains all the Elements required to be included in a summary for this type of securities and issuer. Because some Elements are not required to be addressed, there may be gaps in the numbering sequence of the Elements.

Even though an Element may be required to be inserted in the summary because of the type of securities and issuer, it is possible that no relevant information can be given regarding the Element. In this case a short description of the Element is included in the summary with the mention of “not applicable”.

### Section A—Introduction and warnings

Element	Disclosure requirement
A.1	<p><b>Introduction and warning</b></p> <p>This summary must be read as an introduction to this prospectus (the “<b>Prospectus</b>”) and is provided to aid investors when considering whether to invest in the Offered Shares (as defined below), but is not a substitute for this Prospectus. Any decision to invest in the shares should be based on consideration of this Prospectus as a whole. Following the implementation of the relevant provisions of the Directive 2003/71/EC of the European Parliament and of the Council of the European Union (as amended, including by Directive 2010/73/EU) in each Member State of the European Economic Area, no civil liability will attach to the persons responsible for this summary in any such Member State solely on the basis of this summary, including any translation thereof, unless it is misleading, inaccurate or inconsistent when read together with the other parts of this Prospectus or it does not provide, when read together with the other parts of this Prospectus, key information in order to aid investors when considering whether to invest in the shares. Where a claim relating to this Prospectus is brought before a court in a Member State of the European Economic Area, the plaintiff may, under the national legislation of the Member State where the claim is brought, be required to bear the costs of translating this Prospectus before the legal proceedings are initiated.</p>
A.2	<p><b>Consent for use of the Prospectus for subsequent resale</b></p> <p>Not applicable. Biocartis Group NV (the “<b>Issuer</b>”) does not consent to the use of the Prospectus for the subsequent resale or final placement of securities by financial intermediaries.</p>

### Section B—Issuer

Element	Disclosure requirement
B.1	<p><b>The legal and commercial name of the Issuer</b></p> <p>The legal name of the Issuer is Biocartis Group NV. It carries out its business under the name of Biocartis.</p>
B.2	<p><b>Domicile and legal form of the Issuer</b></p> <p>The Issuer is a limited liability company organised in the form of a <i>naamloze vennootschap/société anonyme</i> under the laws of Belgium. Biocartis Group NV is registered with the legal entities register (Antwerp, division Mechelen) under number 0505.640.808. The Issuer’s registered office is located at Generaal De Wittelaan 11 bus B, 2800 Mechelen, Belgium.</p>

Element	Disclosure requirement
B.3	<p data-bbox="320 226 1396 286"><b>Current operations and principal activities of the Issuer and the principal markets in which it competes</b></p> <p data-bbox="320 309 1396 723">The Issuer (together with its subsidiaries consolidated in its consolidated IFRS financial statements at the relevant time, “<b>Biocartis</b>”), founded in 2007, is focused on the US\$5 billion (2013 estimate) molecular diagnostics (“<b>MDx</b>”) market. The MDx market is estimated to be one of the fastest growing segments of the approximately US\$53 billion (2013 estimate) in vitro diagnostic (“<b>IVD</b>”) market. Biocartis aims to become a global leading player in MDx by providing innovative, personalised healthcare solutions which allow instant global access to accurate, “first time right” molecular information. For this purpose, it has developed an innovative and proprietary CE-IVD marked MDx platform, the Idylla™ platform, that offers accurate, highly-reliable molecular information from a wide variety of biological sample types, enabling fast and effective diagnostics treatment selection and treatment progress monitoring. Biocartis is using its Idylla™ platform to develop and market a broad set of high value clinical assays, providing high quality reproducible results.</p> <p data-bbox="320 741 1396 1155">Biocartis’s market opportunity is driven by an increasing use of MDx in the management of cancer, infectious diseases, and other severe conditions and, in particular, the growing adoption of personalised medicine that requires advanced diagnostics tests to be carried out rapidly and cost effectively enabling key clinical decisions to be made on a timely basis. Currently, most clinical molecular testing involves a series of complex, labour intensive, time-consuming and relatively costly steps (each of which needs to be conducted in a specialised, dedicated laboratory environment), including the preparation of clinical samples, isolation of human or pathogenic genetic material (such as DNA) from the sample, amplification, detection and quantification of this genetic material, and result delivery and interpretation. Biocartis’s Idylla™ platform fully automates these otherwise complex and costly steps, enabling low to mid volume, high clinical value molecular testing to take place at the point-of-need.</p> <p data-bbox="320 1173 1396 1709">In terms of assay development, Biocartis’s predominant focus is oncology (the fastest growing MDx market segment and a disease area with significant unmet needs) with its BRAF Mutation Test (launched in September 2014), KRAS, NRAS, NRAS/BRAF and NRAS/BRAF/EGFR492 assays, MSI assay and liquid biopsy testing assays. Its second focus is infectious diseases (the largest MDx market segment and a disease area characterised by high prevalence), with its sepsis assay (along with Idylla™-Enrich, a dedicated pre-enrichment platform for bloodstream infections, intended to be used in conjunction with the sepsis assay), a respiratory tract panel assay (known as Influenza Virus—Respiratory Syncytial Virus), a Respiratory MP (mixed panel) assay, human immunodeficiency virus (“<b>HIV</b>”), hepatitis B (“<b>HBV</b>”) and hepatitis C virus (“<b>HCV</b>”) viral load assays and an Ebola assay. In addition to the unmet needs, size of market and expected growth in these markets, Biocartis is focusing on these areas because it believes the Idylla™ platform uniquely meets these areas’ needs. Biocartis intends to launch at least four to five new assays per year, complemented by additional assays developed in conjunction with its strategic partners, including Janssen Pharmaceutica NV, a Johnson &amp; Johnson company (“<b>J&amp;J</b>”) and Abbott Molecular, a division of Abbott Laboratories.</p> <p data-bbox="320 1727 1396 1980">The Idylla™ platform is a sample-to-result platform, and several other companies have brought such platforms to the market. 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).</p>

Element	Disclosure requirement
	<p>Management believes that the Idylla™ platform can be differentiated from other sample-to-result platforms because:</p> <ul style="list-style-type: none"> <li>• it believes the Idylla™ platform is the only sample-to-result platform able to process a wide diversity of sample types, including very complex samples such as formalin fixed, paraffin embedded (“FFPE”) and fresh (frozen) tissue, with a single instrument and without requiring any manual sample pre-treatment;</li> <li>• with respect to infectious diseases, the Idylla™ platform can make a difference by accelerating turn around times and improving ease of use and multiplexing of a range of disease causing agents in a syndromic panel without compromising diagnostic performance;</li> <li>• it is a versatile platform (because of its multiplex capacity and ability to detect different types of biomarkers (RNA and DNA) and to quantify biomarkers), which allows for the development of highly complex assays, while competitor portfolios are currently focused on less complex assays;</li> <li>• unlike a batch based system, up to eight independently operating Idylla™ instruments can be connected to a single console, meaning that each instrument can independently address different assays started at different times;</li> <li>• its technologies allow sensitive multiplexing to a level that management believes is unsurpassed in routine IVD settings; and</li> <li>• it has been designed for use in decentralised settings.</li> </ul> <p>In terms of assays, Biocartis’s key competitors are as follows: Roche cobas and Qiagen (for the BRAF Mutation Test and the KRAS and NRAS assays), Diacarta (for the NRAS/BRAF and NRAS/BRAF/EGFR492 assays), Promega (for the MSI assay), Sysmex Inostics’ digital PCR service (called “BEAMing”) (for liquid biopsy testing), T2 Biosystems with its T2Dx system (for Idylla™-Enrich and the sepsis assay), Focus Diagnostics and Hologic (Prodesse) (for Biocartis’s first respiratory panel assay, known as Influenza Virus—Respiratory Syncytial Virus), bioMérieux (BioFire FilmArray), Luminex (xMap) and Autogenomics (for the Respiratory MP (mixed panel) assay), Roche, Abbott, Novartis and Siemens (for the HIV, HBV, and HCV viral load assays) and Cepheid, BioFire Defense and Roche (for the Ebola assay).</p> <p>Biocartis’s key target customer groups are pathologists/oncologists and rapid response and microbiology laboratories. Biocartis is seeking to obtain, as fast as possible, critical mass in menu availability for each of its core customer groups: a compelling menu of oncology assays for pathologists/oncologists, followed by a menu of infectious disease assays for rapid response and microbiology laboratories. Therefore, Biocartis has opted from the start to team up with leading industry partners, e.g., J&amp;J and Abbott Molecular, to accelerate menu development and speed up commercial reach. In addition, Biocartis is now seeking to team up with external development parties to further expand menu development. Biocartis works regularly with external (academic) research institutions, facilitating access to novel and innovative biomarkers to further support the assay menu pipeline.</p> <p>Biocartis is moving fast to establish a global sales and distribution network for Biocartis’s products. Following the CE-marking of its Idylla™ platform and the Idylla™ BRAF Mutation Test, and their successful launch in 2014, Biocartis has built, and continues to expand, a direct sales presence in Western Europe. In parallel, Biocartis intends to first build a strong and dedicated distributor network in the key countries where the CE-mark is accepted. In other countries where additional regulatory requirements apply, Biocartis will opt for a direct sales model, a distributor model or a partnership model. In order to accelerate the generation of revenue and create traction in the market, in specific geographies, Biocartis plans to make certain of its assays available as research use only assays initially, prior to obtaining full regulatory approval.</p>

Element	Disclosure requirement
	<p>Biocartis's intellectual property rights form the basis of its products and technologies and are a critical factor for its success. 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. Biocartis's patent portfolio consists of 56 patent families, of which:</p> <ul style="list-style-type: none"> <li>• 30 are proprietary families comprising issued and pending patents worldwide whose patent life will expire between 2020 and 2034; and</li> <li>• 26 are in-licensed families.</li> </ul> <p>The value of the unique Idylla™ platform is protected by a group of 49 patent families (of which 26 are in-licensed families) and six invention disclosures, comprising issued patents and pending patent applications worldwide, covering the platform technology (basic system, fluidics, ultra-sonification, thermal control, downstream analysis and signal processing) and its associated biochemistry (assay design, reagent storage, sample intake, etc.). The Idylla™-Enrich platform is protected by a group of seven patent families (comprising issued patents and pending patent applications worldwide) owned by Biocartis, covering the hardware aspects of the platform, as well as the assay aspects of the sepsis assay.</p> <p>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.</p>
B.4a	<p><b>Significant recent trends affecting the Issuer and the industries in which it operates</b></p> <p>A number of key trends and drivers are expected to converge and lead to accelerated development of assays and diagnostic technologies, further expanding the MDx market over the next few years:</p> <ul style="list-style-type: none"> <li>• <b>Increased adoption of personalised medicine and growth of companion diagnostics:</b> Society is progressively experiencing a shift from the “one drug fits all” paradigm and “trial-and-error-practice” of medicine to a more precise molecular biomarker-assisted tailored treatment, personalised medicine.</li> </ul> <p>This shift has also resulted in a paradigm shift from diagnostics that traditionally helped to confirm/screen the presence of a disease, towards testing specific biomarkers that are able to predict the risk of developing a certain disease, its course and response to a specific drug treatment (companion diagnostics). For instance, today, cancer drugs are increasingly twinned with a diagnostic test that can determine whether a patient will respond to the drug based on the tumour's genetic characteristics.</p> <p>The rise of personalised medicine is expected to result in increased demand for diagnostic tests and/or companion diagnostics at throughput rates that correspond to smaller volumes of patient-specific or treatment-specific individual situations.</p> <ul style="list-style-type: none"> <li>• <b>Enhanced biomarker identification and molecular techniques:</b> Certain key scientific developments over the last decade have significantly accelerated biomarker discovery in clinical research, the elucidation 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.</li> <li>• <b>Decentralisation of molecular testing:</b> The trend towards personalised medicine has created a pull towards near-patient testing and away from testing by specialised molecular laboratories. This is expected to require the development of</li> </ul>

Element	Disclosure requirement
	<p>sample-to-result solutions that can be used in non-expert settings by healthcare workers with no special laboratory training. Such solutions should also allow for molecular testing in less developed areas of the world.</p> <ul style="list-style-type: none"> <li>• <b>Growing prevalence and management of chronic illness:</b> Chronic illnesses increase the importance of monitoring, for which diagnostic testing is crucial.</li> <li>• <b>Expected shift of healthcare spending from treatment to more pro-active diagnosis:</b> Faced with rising healthcare costs and budget constraints, a more intelligent approach towards patient care is required to optimise the use of healthcare resources. MDx provide physicians with more and better information, enhancing their 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.</li> </ul> <p>The global MDx market is expected to grow from approximately US\$5 billion in 2013 to approximately US\$8 billion in 2018, representing a compound annual growth rate ("CAGR") of 9.7%.</p>
B.5	<p><b>Description of the group and the Issuer's position within the group</b></p> <p>The group consists of the holding company, Biocartis Group NV, and three consolidated subsidiaries. In addition, Biocartis currently holds approximately 13% of the share capital in MyCartis NV.</p> <p>The following chart represents the structure of Biocartis as at the date of this Prospectus:</p> <div data-bbox="341 1070 1366 1397" data-label="Diagram"> <pre> graph TD     A["Biocartis Group NV (Belgium)"] --- B["Biocartis S.A. (Switzerland)"]     B --- C["Biocartis NV (Belgium)"]     B --- D["Biocartis B.V. (The Netherlands)"] </pre> </div>
B.6	<p><b>Relationship with major shareholders</b></p> <p>The Issuer has a relatively widely held shareholder base. For an overview of the Issuer's existing shareholders, see also Element E.6.</p> <p>Currently, the existing shareholders of the Issuer have entered into a shareholders' agreement (the "<b>Shareholders' Agreement</b>"), containing amongst others terms regarding the Issuer's business and governance, as well as pre-emptive rights and other transfer restrictions regarding the Issuer's shares. The Issuer is a party to this Shareholders' Agreement. The Shareholders' Agreement will be terminated effective as of the closing of the Offering. The Issuer is not aware of shareholders entering into a new shareholders' agreement following the closing of the Offering.</p> <p>The Issuer entered into several transactions with related parties, including its principal shareholders. The most significant transactions with related parties for the year ended 31 December 2014 and as of the date hereof are summarised below:</p> <ul style="list-style-type: none"> <li>• On 25 August 2014, Biocartis entered into an Investment Agreement with several of its shareholders, pursuant to which it raised commitments for €64.5 million pursuant to the F-round financing (with three equal tranches,</li> </ul>

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	<p>of which two tranches have been contributed and the third is, in relevant part, contingent on closing of the Offering or reaching a certain milestone).</p> <ul style="list-style-type: none"> <li>• Biocartis also entered into an amended and restated license and development agreement with Janssen Pharmaceutica NV, a Johnson &amp; Johnson company, while one of the Issuer's shareholders, Johnson &amp; Johnson Innovation – JJDC, Inc., is also a Johnson &amp; Johnson company. In addition, Biocartis recognised revenues from these entities amounting to €1.2 million, €3.7 million and €8.4 million in 2012, 2013 and 2014, respectively.</li> </ul> <p>Benaruca S.A., the investment company of the Issuer's chief executive officer, Dr. Pauwels, is a shareholder of the Issuer.</p>																																																																																																											
B.7	<p><b>Selected historical key financial information</b></p> <p>The financial data set forth below as of December 31, 2014, 2013 and 2012 and for the years then ended have been extracted without material adjustment from the audited consolidated financial information of the Issuer as of and for the period ended 31 December 2014, and the audited consolidated financial information of Biocartis S.A. as of and for the years ended 31 December 2013 and 2012 (the "Financial Statements"). The Financial Statements have been prepared in accordance with International Financial Reporting Standards, as adopted by the European Union ("IFRS"). Biocartis's functional and presentation currency is euro.</p> <p><b>Statement of comprehensive income</b></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2"></th> <th colspan="3" style="text-align: center;">Year ended 31 December</th> </tr> <tr> <th style="text-align: center;">2014</th> <th style="text-align: center;">2013</th> <th style="text-align: center;">2012</th> </tr> <tr> <th></th> <th colspan="3" style="text-align: center;"><i>(in €000)</i></th> </tr> </thead> <tbody> <tr> <td><b>Revenue</b></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Collaboration revenue .....</td> <td style="text-align: right;">3,218</td> <td style="text-align: right;">6,247</td> <td style="text-align: right;">2,102</td> </tr> <tr> <td>Product sales revenue .....</td> <td style="text-align: right;">5,260</td> <td style="text-align: right;">2,086</td> <td style="text-align: right;">1,449</td> </tr> <tr> <td></td> <td style="text-align: right;"><b>8,478</b></td> <td 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<b>Consolidated balance sheet data</b>			
	<b>As at 31 December</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
	<i>(in €000)</i>		
<b>Assets</b>			
<b>Non-current assets</b>			
Intangible assets .....	9,652	9,985	10,278
Property, plant and equipment .....	9,154	11,199	10,994
Participating interests .....	0	245	0
Other long term receivables .....	117	107	106
Deferred tax assets .....	947	0	0
	<b>19,870</b>	<b>21,536</b>	<b>21,378</b>
<b>Current assets</b>			
Inventory .....	3,583	1,116	183
Trade receivables .....	15,793	3,082	1,442
Other receivables .....	148	993	793
Other current assets .....	2,700	4,371	1,898
Cash and cash equivalents .....	10,919	29,047	40,494
	<b>33,142</b>	<b>38,609</b>	<b>44,810</b>
<b>Total assets</b> .....	<b>53,012</b>	<b>60,145</b>	<b>66,188</b>
<b>Equity and liabilities</b>			
<b>Capital and reserves</b>			
Legal share capital .....	222,268	926	795
Historical share capital adjustment .....	(221,232)	0	0
Share premium .....	166,592	175,946	146,394
Gains and losses on defined benefit plans .....	0	(309)	(379)
Share based payment reserve .....	1,166	1,023	0
Accumulated deficit .....	(148,513)	(145,631)	(110,010)
<b>Total equity attributable to the owners of the Issuer</b> .....	<b>20,280</b>	<b>31,955</b>	<b>36,800</b>
<b>Non-current liabilities</b>			
Financial debt .....	8,528	12,822	10,089
Deferred income .....	4,534	1,711	5,002
Retirement benefit obligation .....	0	267	490
Accrued charges .....	1,955	1,741	2,026
	<b>15,017</b>	<b>16,541</b>	<b>17,607</b>
<b>Current liabilities</b>			
Financial debt .....	5,057	3,373	1,250
Trade payables .....	4,265	5,847	8,454
Deferred income .....	5,100	772	1,320
Other current liabilities .....	3,293	1,657	757
	<b>17,714</b>	<b>11,649</b>	<b>11,781</b>
<b>Total equity and liabilities</b> .....	<b>53,012</b>	<b>60,145</b>	<b>66,188</b>



Element	Disclosure requirement		
<b>Cash flow statement data</b>			
	<b>As at 31 December</b>		
	<u>2014</u>	<u>2013</u>	<u>2012</u>
	<i>(in €000)</i>		
<b>Operating activities</b>			
Loss for the period .....	(9,715)	(35,620)	(44,431)
<b>Adjustments for</b>			
Depreciation and amortisation .....	4,437	3,557	2,622
Depreciation and amortisation included in discontinued operations .....	81	181	156
Impairments .....	37	0	0
Tax income in profit and loss .....	(947)	0	0
Financial result, net .....	897	1,065	600
Net movement in retirement benefit obligation .....	108	(153)	25
Gain on disposal MyCartis NV .....	(26,624)	0	0
Share based payment expense .....	143	1,023	0
<b>Changes in working capital</b>			
Net movements in inventories .....	(2,524)	(933)	(10)
Net movement in trade and other receivables and other current assets .....	(2,736)	(4,313)	818
Net movement in trade payables and other current liabilities .....	1,860	(1,992)	244
Net movement in deferred income .....	(746)	(3,839)	(1,286)
Interests paid .....	(155)	(155)	0
<b>Cash flow from operating activities .....</b>	<b>(35,884)</b>	<b>(41,179)</b>	<b>(41,262)</b>
<b>Investing activities</b>			
Interest received .....	60	100	102
Purchases of property, plant and equipment .....	(1,927)	(3,138)	(7,313)
Purchases of intangible assets .....	(840)	(512)	(350)
Acquisition shares in other companies .....	0	(245)	0
Disposal shares in other companies .....	245	0	0
Acquisition of a subsidiary .....	7,514	0	0
Proceeds from sale and rent back of property, plant and equipment .....	0	0	1,904
<b>Cash flow from investing activities .....</b>	<b>5,052</b>	<b>(3,795)</b>	<b>(5,657)</b>
<b>Financing activities</b>			
Proceeds from issue of common equity shares .....	0	29,682	53,117
Proceeds from issue of preference shares F .....	21,244	0	0
Proceeds from sale and lease back of property, plant and equipment .....	0	5,000	0
Disposal of MyCartis NV to capital owners of the parent .....	(5,138)	0	0
Repayment of borrowings .....	(3,378)	(894)	0
Bank charges .....	(1)	(18)	0
<b>Cash flow from financing activities .....</b>	<b>12,727</b>	<b>33,770</b>	<b>53,117</b>
<b>Net increase/(decrease) in cash and cash equivalents .....</b>	<b>(18,105)</b>	<b>(11,204)</b>	<b>6,198</b>
Cash and cash equivalents at the beginning of the period .....	29,047	40,494	34,357
Effects of exchange rate changes on the balance of cash held in foreign currencies .....	(23)	(243)	(61)
<b>Cash and cash equivalents at the end of the period .....</b>	<b>10,919</b>	<b>29,047</b>	<b>40,494</b>

Element	Disclosure requirement
	<p><b>Summary analysis of selected operating results</b></p> <p><b>Revenues and other operating income:</b> Biocartis's total income increased from €6.2 million in 2012 to €11.8 million in 2013. This increase was primarily attributable to a €4.1 million increase in collaboration revenues. In addition, Biocartis had a €0.6 million increase in product sales and a €0.9 million increase in grants and other income. Total revenue decreased from €11.8 million in 2013 to €10.4 million in 2014. Operating income decreased in 2014 due to a decrease in collaboration revenues and grants and other income, partially offset by growth in product sales in 2014.</p> <p><b>Collaboration revenues:</b> Biocartis's collaboration revenues have been derived from its research and development services, licence fees and milestone payments. Research and development services decreased from €815 thousand in 2012 to €226 thousand in 2013, then increased to €271 thousand in 2014. Licence fees changed from €1.3 million in 2012 to €4.0 million in 2013 to €1.9 million in 31 December 2014. Licence fees are primarily related to the recognition of deferred upfront payments received from partners. In addition, Biocartis received milestone payments of €2.0 million and €1.0 million which were recognised in 2013 and 2014, respectively.</p> <p><b>Product sales revenue:</b> Product sales revenue comprises sales of Idylla™ consoles and instruments as well as Idylla™ cartridges to customers and collaboration partners. Product sales revenue increased from €1.4 million in 2012 to €2.1 million in 2013 to €5.3 million in 2014. In 2012 and 2013 and prior to September 2014 sales related only to sales of cartridges, instruments and consoles to collaboration partners for research and development purposes. Biocartis received its first revenues from in vitro diagnostic sales in an amount of €2.0 million in 2014.</p> <p><b>Grants and other income:</b> Grants and other income changed from €2.6 million in 2012 to €3.5 million in 2013 to €1.9 million in 2014 due to corresponding changes in research and development project support, strategic investments and training support and other revenues.</p> <p><b>Costs of goods sold:</b> Costs of goods sold increased from €1.2 million in 2012 to €2.0 million in 2013 and again to €4.3 million in 2014, primarily as a result of increases in each of staff costs and materials as more systems were sold to collaboration partners (prior to commercial launch in September 2014) and to collaboration partners and customers following commercial launch.</p> <p><b>Research and development expenses:</b> Total research and development expenses decreased from €34.0 million in 2012 to €27.8 million in 2013 to €25.0 million in 2014 as the Idylla™ platform passed the design freeze and verification phases and moved into commercialisation in 2014.</p> <p><b>Marketing and distribution expenses:</b> Marketing and distribution expenses increased over the periods under review from €691 thousand in 2012 to €1.2 million in 2013 to €3.1 million in 2014. This growth is primarily linked with the commercial roll-out of the Idylla™ platform in September 2014, and particularly with the growth in staff costs in 2014 to €2.0 million (compared to €364 thousand in 2012 and €757 thousand in 2013) and €302 thousand in subcontracting expenses (previously nil). Biocartis expects to increase these costs to support the expanded commercial roll out of the Idylla™ platform.</p> <p><b>General and administrative expenses:</b> General and administrative expenses increased from €6.1 million in 2012 to €7.3 million in 2013 and €7.2 million in 2014 as a result of the growth in its overall activities and headcount. General and administrative headcount increased from 19 FTEs as of 31 December 2012 to 24 FTE's as of 31 December 2014.</p> <p><b>Operating loss:</b> As a result of the foregoing, the operating loss decreased from €35.8 million in 2012 to €26.4 million in 2013 and increased to €29.2 million in 2014.</p>

Element	Disclosure requirement
	<p><b>Financial result, net:</b> Financial result (net) arises principally from interest earned on cash invested and cash equivalent investments from deposit accounts at market rates as well as from interest payable on Biocartis's borrowings and from net foreign exchange gains/losses. The financial result remained relatively stable over the periods under review, slightly increasing from a net financial loss of €0.7 million in 2012 to a net financial loss of €1.1 million in 2013 and decreasing to a net financial loss of €1.0 million in 2014, which corresponds to higher interest expense on certain loans and foreign exchange losses. These fluctuations also reflect changes in the mix of financial instruments.</p> <p><b>Gain (loss) for the year after taxes from discontinued operations:</b> On 11 November 2014, Biocartis S.A. finalised the spin off of its former Evaluation™ business into a separate company called "MyCartis NV" in order to enable Biocartis to focus on the Idylla™ platform. Prior to November 2014, Biocartis has been developing a separate life sciences multiplex platform, called Evaluation™. The gain after taxes from discontinued operations amounted to €19.5 million in 2014. For further information on the spin off, see Note 3.12 to the Financial Statements.</p> <p><b>Loss for the year:</b> As a result of the foregoing, the loss incurred by Biocartis decreased from €44.4 million in 2012 to €35.6 million in 2013 to €9.7 million in 2014.</p> <p><b>Summary analysis of selected consolidated balance sheet data</b></p> <p><b>Total Equity:</b> Biocartis's total equity decreased from €36.8 million as at 31 December 2012 to €32.0 million as at 31 December 2013 to €20.3 as at 31 December 2014, which primarily related to an increase of accumulated deficit from €110.0 million as at 31 December 2012 to €145.6 million as at 31 December 2013 to €148.5 million as at 31 December 2014 partially offset by changes in share premium from €146.4 million as at 31 December 2012 to €175.9 million as at 31 December 2013 to €166.6 million as at 31 December 2014.</p> <p><b>Liabilities:</b> As at 31 December 2014, non-current liabilities included €8.5 million borrowings. This relates to the debt of €6.7 million of the subsidised loan from PMV (€5.0 million in principal amount plus accrued interest expenses), and to €1.8 million of the €7.9 million lease from KBC Lease Belgium NV. Biocartis's current liabilities relate primarily to trade payables from its outsourced research and development projects and indebtedness under loan agreements.</p> <p><b>Summary analysis of cash flow statement data</b></p> <p><b>Cash flow from operating activities</b> represented net cash outflows of €41.3 million, €41.2 million and €35.9 million in 2012, 2013 and 2014, respectively. Over the periods under review, Biocartis's loss for the period decreased though working capital increased due to the increase in inventory and trade and other receivables.</p> <p><b>Cash flow from investing activities</b> represented net cash outflows of €5.7 million and €3.8 million in 2012 and 2013, respectively, and net cash inflow of €5.1 million in 2014. The decrease in net cash outflow in 2013 compared to 2012 resulted from the decrease in purchases of property, plant and equipment from €7.3 million to €3.1 million partially offset by the decrease in proceeds from sale and rent back of property, plant and equipment from €1.9 million to nil. A reversal from net cash outflow in 2013 to net cash inflow in 2014 resulted from recognition of a gain from an acquisition of a subsidiary of €7.5 million and the decrease in purchases of property, plant and equipment from €3.1 million to €1.9 million.</p> <p><b>Cash flow from financing activities</b> represented net cash inflows of €53.1 million, €33.8 million and €12.7 million in 2012, 2013 and 2014, respectively. The net cash inflows resulted from the capital increases Biocartis did as part of its equity fund raisings of €53.1 million, €29.7 million and €21.2 million in 2012, 2013 and 2014, respectively, net of direct issuance costs. In 2013, Biocartis received a €5.0 million instalment under sale and lease back arrangement with KBC Lease Belgium NV. In 2014, Biocartis repaid borrowings of €3.4 million and recognised a loss of €5.1 million from the disposal of MyCartis NV.</p>

Element	Disclosure requirement
B.8	<p><b>Selected key pro forma financial information</b></p> <p>Not applicable. No pro forma information has been included in the Prospectus.</p>
B.9	<p><b>Profit forecast or estimate</b></p> <p>Not applicable. No profit forecast or estimate has been included in the Prospectus or otherwise published by the Issuer.</p>
B.10	<p><b>A description of the nature of any qualifications in the audit report on the historical financial information</b></p> <p>Not applicable.</p>
B.11	<p><b>Working capital</b></p> <p>On the date of this Prospectus, the Issuer is of the opinion that, taking into account its available cash and cash equivalents, it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months from the date of the Prospectus.</p> <p>However, the Issuer is of the opinion that the proceeds of the Offering (together with its available cash and cash equivalents) will (in the event the Offering is completed) provide the Issuer with sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months from the date of the Prospectus.</p> <p>In case the Issuer would not be able to attract additional funds (beyond its existing cash and cash equivalents and excluding any proceeds of the Offering or receipt of the committed F-round financing in the amount of €21.5 million), it expects to run out of working capital by 31 December 2015.</p> <p>The Issuer's 12 month working capital shortfall in the event the Issuer would not be able to attract any such additional funds is projected to be approximately € 20 million. In the event the Issuer would not be able to attract any additional funds pursuant to the Offering, the Issuer will rely on the third and final tranche of the committed F-round financing in the amount of € 21.5 million, providing the milestone to trigger this tranche will be met in the course of 2015, which the Issuer believes is likely. (In the event the Offering does proceed, the F-round investors have committed to subscribe for € 21.5 million in shares subject to the closing of the Offering.)</p>

### Section C—Shares

Element	Disclosure requirement
C.1	<p><b>Type and class of the securities being offered and admitted to trading</b></p> <p>All shares are ordinary shares of the Issuer, without nominal value.</p> <p>The shares can be in registered or dematerialised form. The following ISIN code has been assigned to the shares: BE0974281132</p>
C.2	<p><b>Currency of the shares</b></p> <p>The currency of the shares is euro.</p>
C.3	<p><b>Number of shares issued</b></p> <p>As of the date of this Prospectus, the Issuer's share capital amounts to €304,483.61, represented by 30,448,361 shares, each representing the same pro rata fraction of the Issuer's share capital. Assuming a full placement of the New Shares (as defined below) in the Offering, the Issuer will issue 8,695,652 New Shares. In case the Over-allotment Option (as defined below) is exercised in full, the Issuer will issue an</p>

Element	Disclosure requirement
	<p>additional 1,304,347 new shares. A portion of the issue price per share equal to the fractional value of the existing shares will be allocated to the Issuer's share capital. The portion of the issue price in excess of the fractional value of the existing shares will be booked as issue premium. As a result, the Issuer's share capital will amount to €391,440.13 in case of a full placement of the New Shares, and €404,483.60 in case also the Over-allotment Option is exercised in full. Each share shall represent the same pro rata fraction of the Issuer's share capital.</p> <p>In addition to the outstanding shares, the Issuer has a number of outstanding warrants in relation to an aggregate of 1,362,934 new shares to be issued, consisting of:</p> <ul style="list-style-type: none"> <li>• 1,000,000 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 1,000,000 new shares of the Issuer, and of which 720,340 stock options have been granted and 279,660 stock options can still be granted;</li> <li>• 262,934 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 262,934 new shares of the Issuer, which still need to be granted;</li> <li>• warrants, called "WHC Warrants", granted to Whitemarsh Capital LLC, a commercial partner of Biocartis, with each warrant exercisable into one share, in relation to 100,000 new shares.</li> </ul> <p>The 94,362 stock options that are still outstanding under the "2008 Plan" are options in relation to existing shares and do not have the form of a warrant. The 2008 Plan is therefore a non-dilutive plan. Furthermore, Koninklijke Philips N.V. ("Philips") entered into a conversion option agreement with the Issuer, allowing Philips to convert certain royalty and other payments due to it up to a maximum 10% of the then outstanding capital of the Issuer on a fully diluted post-money basis, but only if the Issuer 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 Issuer at its sole discretion.</p>
C.4	<p><b>Rights attached to the shares</b></p> <p>All of the shares will be of the same class and will have the same voting rights. All of the shares are profit sharing as from any distribution in respect of which the relevant record date or due date falls on or after the date of the issue of such shares, including any distribution in relation to the financial year that has started on 1 January 2015, as the case may be.</p>
C.5	<p><b>Restrictions on the free transferability of the shares</b></p> <p>All shares are freely transferable, subject to any transactional restrictions.</p>
C.6	<p><b>Applications for admission to trading on a regulated market and identity of all the regulated markets where the shares are or are to be traded</b></p> <p>An application has been made to list all shares in the Issuer on the regulated market of Euronext Brussels under the symbol "BCART". Trading of the shares on the regulated market of Euronext Brussels is expected to commence, on an "if-and-when-issued and/or delivered" basis, on or about 4 May 2015 (the "Listing Date").</p>
C.7	<p><b>Description of the dividend policy</b></p> <p>Biocartis has not declared or paid dividends on its shares. Currently, the board of directors of the Issuer expects to retain all earnings, if any, generated by the Issuer's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future.</p>

Element	Disclosure requirement
	<p>The Issuer's ability to distribute dividends is subject to the availability of sufficient distributable profits as defined under Belgian law on the basis of the Issuer's statutory unconsolidated financial statements instead of its consolidated financial statements.</p> <p>The amount of any dividends and the determination of whether to pay dividends in any year may be affected by a number of factors, including the Issuer's business prospects, cash requirements and financial performance, the condition of the market and the general economic climate and other factors, including tax and other regulatory considerations. As a consequence of these and other factors, there can be no assurance as to whether dividends or similar payments will be paid in the future or, if they are paid, their amount.</p>

#### Section D—Risks

Element	Disclosure requirement
D.1	<p><b>Risks relating to the Issuer's industry and business</b></p> <p>The Issuer is subject to the following material risks, in addition to other risks that are mentioned in the section "Risk Factors":</p> <ul style="list-style-type: none"> <li>• <b><i>Biocartis has incurred operating losses, negative operating cashflow and an accumulated deficit since inception and may never become profitable.</i></b> <p>Biocartis has incurred operating losses and negative operating cashflow in each period since it was founded in 2007. Net loss from continuing operations for the year ended 31 December 2014 was €29.2 million. As of 31 December 2014, Biocartis had an accumulated deficit of €148.5 million. These losses have resulted principally from costs incurred in the design, industrialisation and commercialisation of the Idylla™ platform, the development of assays, the establishment of manufacturing facilities that comply with the US Food and Drug Administration's ("FDA") standards, as well as from general and administrative costs associated with Biocartis's operations. Biocartis intends to continue to develop MDx assays, and to conduct regulatory activities and sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in Biocartis incurring further losses for at least the next few years. Biocartis only started to generate commercial revenue as of the commercial launch of the CE-IVD marked Idylla™ platform and its first oncology assay, the Idylla™ BRAF Mutation Test, in September 2014.</p> <p>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.</p> </li> <li>• <b><i>The commercial success of Biocartis will depend on commercial market acceptance of the Idylla™ platform and its menu of assays.</i></b> <p>Biocartis launched its Idylla™ platform and its first assay, the Idylla™ BRAF Mutation Test, for commercial sale in countries recognising CE-marked IVD devices in September 2014. This followed the registration of these products with the Belgian Federal Agency for Medicinal and Health Products (the "<b>Belgian Competent Authority</b>") as CE-marked IVDs for distribution in the European Union ("EU") on 29 August 2014. To date, these are the only products that have been commercialised by Biocartis, and 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.</p> </li> </ul>

Element	Disclosure requirement
	<ul style="list-style-type: none"> <li data-bbox="320 219 1396 376"> <p><b><i>Delays in the development of a broad and clinically relevant menu of assays may occur and may result in increased costs and/or jeopardise Biocartis's ability to obtain market acceptance and/or relevant regulatory approvals in line with its strategy. Biocartis cannot assure you that it will launch at least four to five new assays per year.</i></b></p> <p>To date, the Idylla™ platform has only been commercialised on a limited basis with a single assay, the Idylla™ BRAF Mutation Test, both of which were launched in September 2014, in the European Union and those countries recognising CE-marked IVD devices.</p> <p>The availability of a broad and clinically relevant menu of assays is an important decision factor to acquire and use a diagnostic platform, and management believes that offering a compelling, broad menu of assays in addition to the Idylla™ BRAF Mutation Test will be a key driver of demand for the Idylla™ platform. The continued development and commercialisation of additional assays is therefore a key part of Biocartis's strategy. In addition, Biocartis intends to seek regulatory approval for the Idylla™ platform and its menu of assays in a broad range of jurisdictions (including in the United States).</p> <p>Although Biocartis has a dedicated and experienced research and development team in place to efficiently develop assays, there can be no assurance that it will be able to launch at least four to five new assays per year.</p> </li> <li data-bbox="320 920 1396 1014"> <p><b><i>Biocartis has only limited experience in commercialising MDx platforms and assays and therefore may not be successful in further growing its commercialisation infrastructure.</i></b></p> <p>Biocartis has limited experience in deploying a commercialisation infrastructure in diagnostics markets and may not succeed in hiring additional key personnel, or making appropriate arrangements with distributors and other parties, to execute the commercial deployment of the Idylla™ platform and assays.</p> <p>Biocartis currently has a limited commercialisation infrastructure, which it intends to expand. To commercialise the Idylla™ platform and assays, Biocartis will need to expand its distribution chain in order to ensure timely delivery of its products to customers and will need to continue to build a maintenance and service organisation in order to ensure adequate installation and servicing of instruments and consoles. Biocartis will also need to coordinate commercialisation with its partners, distributors and other third parties outside of its control.</p> <p>In addition, relative to some of its competitors and partners, Biocartis is limited in size and resources. It may not be able to compete under favourable conditions when it comes to selling the Idylla™ platform in comparison with larger companies that are able to propose to customers several MDx platforms simultaneously, together with financing solutions which reduce customers' capital expenditure.</p> <p>If Biocartis fails in further growing its commercialisation infrastructure successfully, this will have a materially adverse effect on Biocartis's business, financial condition and results of operations.</p> <p>The Issuer is also subject to the following risks, in addition to other risks that are mentioned in the section "Risk Factors":</p> <ul style="list-style-type: none"> <li data-bbox="320 1850 1396 2036"> <p><b><i>The MDx industry is highly competitive and subject to rapid technological changes. If Biocartis's current or future competitors develop superior, alternative or more widespread solutions and technologies, or obtain regulatory clearance or approval before Biocartis does, or obtain greater intellectual property protection, Biocartis's competitive position and operations would be negatively impacted.</i></b></p> </li> </ul> </li> </ul>

Element	Disclosure requirement
	<ul style="list-style-type: none"> <li>• Biocartis faces uncertainties over the reimbursement for its products by third parties and may be subject to strict price controls. Biocartis’s potential customers are in part dependent on such reimbursement from third-party payors, and inadequate coverage of reimbursement may compromise Biocartis’s commercial success, which may adversely affect its future profitability.</li> <li>• 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.</li> <li>• 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.</li> <li>• The FDA and other regulatory agencies 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.</li> <li>• 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’s business could suffer.</li> <li>• Biocartis is dependent on (sub)licences for key technologies from third parties and may require additional licences. There can be no assurance that Biocartis will be able to comply with its obligations under the (sub)licences, or the (sub)licensors will be able to maintain and adequately protect their intellectual property rights.</li> <li>• 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.</li> <li>• Certain technologies and patents have been developed with collaboration partners, and Biocartis may face restrictions on this jointly developed intellectual property.</li> </ul>
D.3	<p><b>Risks relating to the shares and the Offering</b></p> <p>The shares and Offering are subject to the following material risks, in addition to other risks that are mentioned in the section “Risk Factors”:</p> <ul style="list-style-type: none"> <li>• The fact that no minimum amount is set for the Offering may affect the Issuer’s investment plans.</li> <li>• There has been no prior public market for the Issuer’s shares and there may not be an active market for the shares.</li> <li>• The market price of the shares may fluctuate widely in response to various factors.</li> <li>• Future sales of substantial amounts of the Issuer’s shares, or the perception that such sales could occur, could adversely affect the market value of the shares.</li> <li>• The Issuer has no fixed dividend policy.</li> <li>• Certain significant shareholders of the Issuer after the Offering may have different interests from the Issuer and may be able to control the Issuer, including the outcome of shareholder votes.</li> <li>• Any future capital increases by the Issuer could have a negative impact on the price of the shares.</li> </ul>



## Section E—The Offering

Element	Disclosure requirement
E.1	<p><b>Expenses and net proceeds of the Offering</b></p> <p>The aggregate of the administrative, legal and audit expenses as well as the other costs in connection with the Offering (including but not limited to legal publications, printing and translation of the Prospectus and Offering related documents) and the remuneration of the Belgian Financial Services and Markets Authority (the “<b>FSMA</b>”) and Euronext Brussels NV/SA, is expected to amount to approximately €2.3 million. Additionally, fees and commissions payable to the Underwriters (as defined below) by the Issuer are expected to be approximately €3.6 million assuming a full placement of the New Shares and that the Offer Price (as defined below) is at the midpoint of the Price Range (as defined below), or €4.2 million assuming a full placement of the Offered Shares (including the exercise in full of the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, in each case not including a size fee of 0.5% and a discretionary fee of up to 1% of the gross proceeds of the Offering.</p> <p>Assuming a full placement of the New Shares and that the Offer Price is at the midpoint of the Price Range, the gross proceeds from the issue of the New Shares are estimated to be approximately €93.5 million. Assuming a full placement of the Offered Shares (including the exercise in full of the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, the gross proceeds from the issue of the Offered Shares are estimated to be approximately €107.5 million.</p> <p>Based on the aforementioned assumptions, the Issuer estimates to receive net proceeds of approximately €87.6 million in case of a full placement of the New Shares and approximately €101.0 million in case of a full placement of the Offered Shares (including the exercise in full of the Over-allotment Option).</p>
E.2a	<p><b>Use of proceeds</b></p> <p>Of the net proceeds from the Offering that it will raise, the Issuer currently anticipates to use, in order of importance and based on the aforementioned assumptions:</p> <ul style="list-style-type: none"> <li>• approximately 50% to develop and launch new proprietary assays, including strengthening the research and development team to support this development. Biocartis intends to launch at least four to five assays per year, complemented by additional assays developed in conjunction with its partners, including J&amp;J and Abbott Molecular;</li> <li>• approximately 15% to expand its sales and marketing team;</li> <li>• approximately 15% for further system developments, including Idylla™-Enrich, Idylla™-Retrieve, and Idylla™ Connect and a solution for high volume testing; and</li> <li>• any remaining funds, approximately 20%, for general corporate purposes, such as working capital needs, general and administrative expenses, and the additional costs associated with being a public company.</li> </ul>
E.3	<p><b>Terms and conditions of the Offering</b></p> <p>The offering (the “<b>Offering</b>”) consists of: (i) an initial public offering to retail and institutional investors in Belgium; (ii) a private placement in the United States to persons who are reasonably believed to be “qualified institutional buyers” (“<b>QIBs</b>”) as defined in Rule 144A (“<b>Rule 144A</b>”) under the US Securities Act of 1933, as amended (the “<b>US Securities Act</b>”), in reliance on Rule 144A; and (iii) private placements to certain qualified and/or institutional investors under applicable laws of the relevant jurisdiction, in the rest of the world (those qualified and/or institutional investors together with the QIBs are collectively being referred to as the “<b>Institutional Investors</b>”). The Offering outside the United States will be made in compliance with Regulation S under the US Securities Act.</p>

Element	Disclosure requirement
	<p>The Offering is an offering of up to 8,695,652 new shares of the Issuer (the “<b>New Shares</b>”).</p> <p>KBC Securities NV/SA, as stabilisation manager (the “<b>Stabilisation Manager</b>”), on behalf of KBC Securities NV/SA, Kempen &amp; Co N.V. and Petercam NV/SA (the “<b>Underwriters</b>”), is expected to be granted by the Issuer a warrant to purchase additional new shares in an aggregate amount equal to up to 15% of the number of New Shares subscribed for in the Offering at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering (the “<b>Over-allotment Option</b>”, and the additional new shares issued pursuant to the Over-allotment Option and the New Shares collectively being referred to as the “<b>Offered Shares</b>”). The Over-allotment Option will be exercisable for a period of 35 days following the Listing Date.</p> <p>The closing date is expected to be 5 May 2015 (the “<b>Closing Date</b>”) unless the Offering Period is closed earlier. The Offer Price must be paid by investors upon submission of the subscription orders or, alternatively, by authorising their financial institutions to debit their bank accounts with such amount for value on the Closing Date.</p> <p>Certain existing shareholders of the Issuer have committed to subscribe for an aggregate amount of €21,512,800.00 in the Offering at the Offer Price subject to the closing of the Offering (the “<b>Participating Shareholders</b>”). The Participating Shareholders will be allocated all of the Offered Shares that he or she committed to subscribe for.</p> <p>The offering period (the “<b>Offering Period</b>”) will begin on 15 April 2015 and is expected to end no later than 4:00 pm (CEST) on 29 April 2015, subject to early closing or extension, provided that the Offering Period will in any event be open for at least six business days from the availability of this Prospectus. Any early closing or extension of the Offering Period will be announced in the Belgian financial press, and the dates for each of pricing and allocation, publication of the Offer Price and results of the Offering, conditional trading and closing of the Offering will in such case be adjusted accordingly. In the event the Offering Period is extended, this will be published in the Belgian financial press. Prospective investors can submit their subscription orders during the Offering Period. Taking into account the fact that the Offering Period may be closed early, investors are invited to submit their applications as promptly as possible.</p> <p>The price per Offered Share (the “<b>Offer Price</b>”) will be determined during the Offering Period through a book-building process in which only Institutional Investors may participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time. The Offer Price is expected to be between €10.00 and €11.50 per Offered Share (the “<b>Price Range</b>”). The Offer Price may be set within the Price Range or below the lower end of the Price Range but will not exceed the higher end of the Price Range. In the event the Offer Price is set below the lower end of the Price Range, this will be published in a supplement to the Prospectus and in that event investors will have the right to withdraw their orders made prior to the publication of the supplement. The Offer Price will apply to all investors, whether Retail Investors (i.e., an individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a “qualified investor” as defined in article 10, §1 of the Belgian Prospectus Act) or Institutional Investors.</p>

Element	Disclosure requirement
E.4	<p><b>Material interests to the Offering</b></p> <p>Assuming a full placement of the Offered Shares (including its exercise in full of the Over-allotment Option), the fees, and commissions payable to the Underwriters will be approximately €4.2 million. This does not include any incentive fees which may be paid at the discretion of the Issuer, nor size fees. The Issuer has also agreed to reimburse the Underwriters for certain expenses incurred by them in connection with the Offering.</p>
E.5	<p><b>Lock-up</b></p> <p>The current shareholders of the Issuer (excluding some minority shareholders holding in the aggregate 1.65% of the currently outstanding shares) and each of the executive managers have entered into a lock-up arrangement with the Global Coordinator in respect of (i) the shares and all other “<i>effecten met een aandelenkarakter</i>” 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 Issuer, an affiliate of the Issuer or in cooperation with the Issuer 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 Issuer (together “<b>Locked Financial Instruments</b>”) 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) sell, exchange, pledge, assign by way of security, grant any right “<i>in rem</i>”, 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.</p> <p>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 the Global Coordinator and (ii) any such transfer shall solely be effected through a coordinated sale.</p> <p>None of the restrictions for the shareholders and executive management members referred to above apply to (i) shares being lent to the Stabilisation Manager, (ii) transfers to legal successors or other transferees in case of death of a natural person or in case of liquidation, concursus, merger or de-merger (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), (iii) 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), (iv) acceptance of a public tender offer, (v) any transfer of shares subscribed for or acquired after the Offering (except if those shares are acquired pursuant to one of the other exemptions), (vi) any transfer of shares pursuant to the shadow option agreements entered into by the Issuer, Benaruca SA, Mr. Ferdinand Verdonck and Mr. Philippe Renaud dated 2 July 2009, as amended, in relation to the 2008 Plan, and (vii) any transfer of shares under a stock lending agreement to a financial institution for market making and liquidity providing purposes.</p>

Element	Disclosure requirement							
E.6	<b>Dilution resulting from the Offering</b>							
	<p>The following table presents the ownership of the shares immediately prior to the closing of the Offering; immediately after the closing of the Offering assuming a full placement of the New Shares; and immediately after the closing of the Offering assuming a full placement of the Offered Shares. An assumption has been made that the existing shareholders will not participate in the Offering in addition to pre-commitments by the Participating Shareholders. The natural persons holding less than 1% of the outstanding shares prior to the closing of the Offering have been presented under "other".</p>							
<b>Shareholder</b>	<b>Shares owned before the closing of the Offering</b>		<b>Shares owned assuming full placement of the New Shares</b>		<b>Shares owned assuming full placement of the Offered Shares</b>		<b>Shares owned on a fully diluted basis assuming full placement of the Offered Shares<sup>(6)</sup></b>	
	<i>(Number)</i>	<i>(%)</i>	<i>(Number)</i>	<i>(%)</i>	<i>(Number)</i>	<i>(%)</i>	<i>(Number)</i>	<i>(%)</i>
Johnson & Johnson Innovation – JJDC, Inc. <sup>(1)</sup> .....	4,948,098	16.25	6,188,408	15.81	6,188,408	15.30	6,188,408	13.46
Debiopharm								
Diagnostics S.A. ..	4,749,707	15.60	4,749,707	12.13	4,749,707	11.74	4,749,707	10.33
RMM S.A. <sup>(2)</sup> .....	3,989,058	13.10	3,989,058	10.19	3,989,058	9.86	3,989,058	8.67
Benaruca								
S.A. <sup>(1)(3)(4)</sup> .....	2,541,684	8.35	2,542,459	6.50	2,542,459	6.29	2,542,459	5.53
BIOSPV Limited <sup>(3)</sup> ...	539,834	1.77	539,834	1.38	539,834	1.33	539,834	1.17
Topbio1 LP .....	1,804,644	5.93	1,804,644	4.61	1,804,644	4.46	1,804,644	3.92
PMV-TINA								
Comm.VA <sup>(1)</sup> .....	1,768,398	5.81	1,845,917	4.72	1,845,917	4.56	1,845,917	4.01
Participatie- Maatschappij Vlaanderen NV ...	428,000	1.41	428,000	1.09	428,000	1.06	428,000	0.93
Coöperatieve AESCAP Venture I U.A. ....	1,440,850	4.73	1,440,850	3.68	1,440,850	3.56	1,440,850	3.13
Dham NV .....	1,283,990	4.22	1,283,990	3.28	1,283,990	3.17	1,283,990	2.79
Koninklijke Philips N.V. <sup>(5)</sup> .....	1,149,947	3.78	1,149,947	2.94	1,149,947	2.84	5,331,076	11.59
Hitachi Chemical Co. Ltd <sup>(1)</sup> .....	1,040,535	3.42	1,443,635	3.69	1,443,635	3.57	1,443,635	3.14
bioMérieux SA .....	963,000	3.16	963,000	2.46	963,000	2.38	963,000	2.09
Padoki civil law partnership <sup>(1)</sup> .....	953,790	3.13	1,017,719	2.60	1,017,719	2.52	1,017,719	2.21
Advent Private Equity Fund IV Limited								
Partnership .....	758,317	2.49	758,317	1.94	758,317	1.87	758,317	1.65
Lucien Verelst .....	387,415	1.27	387,415	0.99	387,415	0.96	387,415	0.84
Philippe Renaud <sup>(4)</sup> ..	379,004	1.24	379,004	0.97	379,004	0.94	379,004	0.82
The Wellcome Trust Limited .....	310,233	1.02	310,233	0.79	310,233	0.77	310,233	0.67
Other .....	1,011,857	3.32	1,227,410	3.14	1,227,410	3.03	2,590,344	5.63
Free float .....			6,694,466	17.10	7,998,813	19.78	7,998,813	17.39
<b>Total .....</b>	<b>30,448,361</b>	<b>100</b>	<b>39,144,013</b>	<b>100</b>	<b>40,448,360</b>	<b>100</b>	<b>45,992,423</b>	<b>100</b>
Total of Benaruca S.A. and BIOSPV Limited <sup>(3)</sup> .....	3,081,518	10.12	3,082,293	7.87	3,082,293	7.62	3,082,293	6.70
Total of PMV-TINA Comm.VA and Participatie- Maatschappij Vlaanderen NV ...	2,196,398	7.21	2,273,917	5.81	2,273,917	5.62	2,273,917	4.94

Element	Disclosure requirement
	<p>Notes:</p> <p>(1) This shareholder is one of the Participating Shareholders who committed to subscribe for new shares in the Offering. The Participating Shareholders are Johnson &amp; Johnson Innovation – JJDC, Inc., Benaruca S.A., Ferdinand Verdonck, Padoki civil law partnership, PMV-TINA Comm.VA, Petercam NV/SA as nominee on behalf of certain of its clients, Hilde Windels, Biover II BVBA, Hitachi Chemical Co. Ltd and Kokopilau civil law partnership. For the purpose of the overview, it is assumed that 2,001,186 new shares are issued to the Participating Shareholders at an Offer Price that is at the mid-point of the Price Range.</p> <p>(2) This shareholder is controlled by Rudi Mariën, a director of the Issuer.</p> <p>(3) This shareholder is controlled by Rudi Pauwels, a director of the Issuer.</p> <p>(4) This shareholder has entered into a shadow option agreement in relation to the 2008 Plan.</p> <p>(5) This shareholder has entered into a conversion option agreement with the Issuer.</p> <p>(6) Assuming the exercise of all outstanding warrants (entailing the issue of up to 1,362,934 new shares) and the exercise of the conversion option by Philips for the maximum number of shares covered (entailing the issue of up to a maximum of 4,181,129 in the event 41,811,294 shares are outstanding following the closing of the Offering and all outstanding warrants have been exercised, it being understood that the actual number of shares issuable will depend on a number of factors as explained in Element C.3) (see also Element B.6).</p>
E.7	<p><b>Estimated expenses charged to the investor by the Issuer</b></p> <p>Not applicable. No fees or expenses in connection with the Offering will be charged to investors by the Issuer.</p>

## RISK FACTORS

*The following risk factors may affect the future operating and financial performance of Biocartis and the value of an investment in Issuer's shares. Examples of past experience have been included where material in aiding the understanding of the risk. Investors should carefully consider the following risk factors, as well as the other information contained in this Prospectus, before making an investment decision. 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's business, financial condition and results of operations.*

### **Risks related to Biocartis's business**

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

Biocartis has incurred operating losses and negative operating cashflow in each period since it was founded in 2007. Net loss from continuing operations for the year ended 31 December 2014 was €29.2 million. As of 31 December 2014, Biocartis had an accumulated deficit of €148.5 million. These losses have resulted principally from costs incurred in the design, industrialisation and commercialisation of the Idylla™ platform, the development of assays, the establishment of manufacturing facilities that comply with the US Food and Drug Administration's ("FDA") standards, as well as from general and administrative costs associated with Biocartis's operations. Biocartis intends to continue to develop molecular diagnostic ("MDx") assays, and to conduct regulatory activities and sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in Biocartis incurring further losses for at least the next few years. Biocartis only started to generate commercial revenue as of the commercial launch of the CE-IVD marked Idylla™ platform and its first oncology assay, the Idylla™ BRAF Mutation Test, in September 2014.

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.

It is possible that Biocartis will experience fluctuating revenues, operating results and cash flows. In that case, as a result, period-to-period comparisons of financial results are not necessarily meaningful, and results of operations in prior periods should not be relied upon as an indication of future performance.

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

Biocartis launched its Idylla™ platform and its first assay, the Idylla™ BRAF Mutation Test, for commercial sale in countries recognising CE-marked in vitro diagnostic ("IVD") devices in September 2014. This followed the registration of these products with the Belgian Federal Agency for Medicinal and Health Products (the "**Belgian Competent Authority**") as CE-marked IVDs for distribution in the European Union ("EU") on 29 August 2014. To date, these are the only products that have been commercialised by Biocartis, and 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.

Many factors can influence market acceptance, including:

- speed and breadth of building an installed base of instruments and consoles, which will, in part, depend on the ability of Biocartis and its partners to commercialise the Idylla™ platform as part of their total offering to healthcare providers;
- the convenience and ease of use of the products compared to competing products;
- breadth and quality of Biocartis's menu of assays and the timing of their development and launch (for further information, see "*—Delays in the development of a broad and*

*clinically relevant menu of assays may occur and may result in increased costs and/or jeopardise Biocartis's ability to obtain market acceptance and/or relevant regulatory approvals in line with its strategy. Biocartis cannot assure you that it will launch at least four to five new assays per year");*

- accurate anticipation of patients', healthcare providers' and payors' needs and emerging technology trends;
- competition (for further information, see "*—The MDx industry is highly competitive and subject to rapid technological changes. If Biocartis's current or future competitors develop superior, alternative or more widespread solutions and technologies, or obtain regulatory clearance or approval before Biocartis does, or obtain greater intellectual property protection, Biocartis's competitive position and operations would be negatively impacted*");
- unavailability of Biocartis's products due to regulatory barriers (for further information, see "*—Biocartis's business could be significantly and negatively affected by substantial government regulations, particularly in the European Union and the United States*");
- market perception of the reliability and quality of Biocartis's products;
- quality of the service and maintenance organisation that Biocartis will put in place in order to support customers;
- price and reimbursement level from third party payors;
- the ability to demonstrate to potential customers the benefits and cost-effectiveness of the products and services relative to others available on the market;
- the ability of Biocartis to develop relationships with key opinion leaders;
- the ability of Biocartis to hire new sales and marketing personnel and their effectiveness in executing its business strategy; and
- other potential advantages and disadvantages over alternative (MDx) products and services.

These and other factors present obstacles to commercial market acceptance of Biocartis's current products, as well as any further products launched, for which Biocartis will have to spend substantial time and resources to overcome. Failure, or any substantial delay, in gaining significant commercial market acceptance of the Idylla™ platform and its menu of assays on a timely basis, or at all, could have a materially adverse effect on Biocartis's business, financial condition and results of operations.

***Delays in the development of a broad and clinically relevant menu of assays may occur and may result in increased costs and/or jeopardise Biocartis's ability to obtain market acceptance and/or relevant regulatory approvals in line with its strategy. Biocartis cannot assure you that it will launch at least four to five new assays per year.***

To date, the Idylla™ platform has only been commercialised on a limited basis with a single assay, the Idylla™ BRAF Mutation Test, both of which were launched in September 2014, in the European Union and those countries recognising CE-marked IVD devices.

The availability of a broad and clinically relevant menu of assays is an important decision factor to acquire and use a diagnostic platform, and management believes that offering a compelling, broad menu of assays in addition to the Idylla™ BRAF Mutation Test will be a key driver of demand for the Idylla™ platform. The continued development and commercialisation of additional assays is therefore a key part of Biocartis's strategy. In addition, Biocartis intends to seek regulatory approval for the Idylla™ platform and its menu of assays in a broad range of jurisdictions (including in the United States).

Although Biocartis has a dedicated and experienced research and development team in place to efficiently develop assays, there can be no assurance that it will be able to launch at least four to five new assays per year. Biocartis's in-house team is complemented by external development parties intended to develop assays compatible with the Idylla™ platform. Additionally, Biocartis

has established strategic partnerships to develop and commercialise Idylla™ compatible assays with key industry players such as Janssen Pharmaceutica NV, a Johnson & Johnson company, (“J&J” or “JPNV”) and Abbott Molecular, a division of Abbott Laboratories (“Abbott Molecular”) and, in some cases, will also allow them to distribute the Idylla™ instruments and consoles (for further, see “*Business—Material Contracts*”). Biocartis intends to enter into additional (strategic) relationships with third parties for future assays. However, establishing (strategic) relationships can be difficult and time-consuming and may not be successful. To the extent Biocartis agrees to work exclusively with a party in a given area, opportunities to collaborate with others or develop opportunities independently could be limited. Furthermore, the development and commercialisation of Idylla™ compatible assays via partners is outside of Biocartis’s control.

Biocartis may experience unexpected delays or difficulties in the remaining stages of development and commercialisation of its menu of assays, which may jeopardise and/or delay market acceptance of the Idylla™ platform. Such delays may occur due to a variety of factors, including:

- the launch of competitor’s assays with similar or better performance or target range, which could require a new development phase for Biocartis’s assays in order to add the necessary new features;
- technical or performance setbacks that require additional development work to be performed on one or more of the various components of its menu of assays;
- Biocartis’s partners may have different strategies (including due to conflicts of interests), may not exercise the same level of diligence, or may have a lower success rate than Biocartis, when developing assays for the Idylla™ platform, or may choose to stop developing assays with Biocartis altogether;
- delayed results of validation studies (the final step before seeking regulatory approval) for any number of reasons, including a lack of sufficient numbers of testing samples, or a failure to meet the clinical endpoints in a validation study;
- unexpected manufacturing or process flaws, which may require modifications; and
- a changing regulatory environment, or delays in obtaining regulatory approval (for further information, see “—*Biocartis’s business could be significantly and negatively affected by substantial government regulations, particularly in the European Union and the United States*”).

Each of these factors could result in increased costs for Biocartis and/or jeopardise Biocartis’s ability to obtain market acceptance of, or relevant regulatory approvals for, the Idylla™ platform and its menu of assays in line with its strategy, which could have a materially adverse effect on Biocartis’s business, financial condition and results of operations.

***Biocartis has only limited experience in commercialising MDx platforms and assays 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 key personnel, or making appropriate arrangements with distributors and other parties, to execute the commercial deployment of the Idylla™ platform and assays.

Biocartis currently has a limited commercialisation infrastructure, which it intends to expand. To commercialise the Idylla™ platform and assays, Biocartis will need to expand its distribution chain in order to ensure timely delivery of its products to customers and will need to continue to build a maintenance and service organisation in order to ensure adequate installation and servicing of instruments and consoles. Biocartis will also need to coordinate commercialisation with its partners, distributors and other third parties outside of its control. For further on Biocartis’s, see “*Business—Customers, Marketing and Sales—Channels to Market*”.

In addition, relative to some of its competitors and partners, Biocartis is limited in size and resources. It may not be able to compete under favourable conditions when it comes to selling



the Idylla™ platform in comparison with larger companies that are able to propose to customers several MDx platforms simultaneously, together with financing solutions which reduce customers' capital expenditure.

If Biocartis fails in further growing its commercialisation infrastructure successfully, this will have a materially adverse effect on Biocartis's business, financial condition and results of operations.

***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's revenues and other operating results 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 each of these components is currently performed in-house at Biocartis's facilities in Mechelen (Belgium).

Although Biocartis has manufactured over 100,000 cartridges to date, Biocartis expects to be required to significantly increase cartridge manufacturing as commercialisation of its expanded assay menu progresses. Management believes that Biocartis's in-house commercial production line for Idylla™ cartridges will provide it with sufficient capacity to meet volume projections for 2015 and 2016 by adding work stations and operating in multiple shifts. In accordance with its longer term strategy and to meet expected demand after 2016, Biocartis intends to initiate the design and construction of a high volume, automated, production line for Idylla™ cartridges in partnership with a global, top tier contract manufacturing partner ("CMO"). For further, see "Business—Production—Cartridges".

Management believes that Biocartis's in-house manufacturing capacity for the Idylla™ consoles and instruments can easily be expanded, but similarly intends to outsource the production of its consoles and instruments under a long-term supply contract with a CMO in the course of 2015. Until then, if demand outstrips manufacturing capacity, or if there are any unexpected stoppages or interruptions in production caused by, among other things, mechanical breakdown, a fire or other incident at Biocartis's facilities in Mechelen, or a delay in supply of components, this may lead to Biocartis failing to meet its obligations under any future supply contracts it enters into, customer complaints and delays in Biocartis's ability to realise revenues, which may have a materially adverse effect on Biocartis's business, financial condition and results of operations.

There can be no assurance that the contracted CMO will deliver manufacturing facilities on time, or in compliance with the standards that are required by the relevant regulatory authorities, or that it will be able to manufacture Biocartis's products in sufficient quantities, to the same exacting standards and at an economically attractive cost compared to Biocartis's competitors, or at all. In all these cases, the successful commercialisation of Biocartis's products may be adversely affected, which may have a materially adverse effect on Biocartis's business, financial condition and results of operations.

***Biocartis relies on multiple suppliers to produce the individual components required for its Idylla™ platform, some of whom are single source suppliers. If any such parties fail to deliver product components in a timely manner, sufficient quantity or quality at a competitive price, Biocartis's manufacturing ability would be impaired.***

The nature of Biocartis's 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. The individual components required for the Idylla™ instrument and console are currently supplied by approximately 45 suppliers, and the individual components required for Idylla™ cartridges are supplied by approximately ten suppliers.

Although management currently believes that current capacity and required production tooling at Biocartis's suppliers is sufficient to support Biocartis's initial commercial supply of the

Idylla™ platform, there can be no assurance that its suppliers will be able to continue to provide it with the components it needs, at suitable prices or in sufficient quantity or quality. If Biocartis needs alternative sources for key components, for any reason, these component parts may not be available on short notice, on acceptable terms, or at all. Biocartis will need to enter into contractual relationships with manufacturers for future increased demand of its products, and cannot provide any assurance that it will be able to do so on a timely basis, in sufficient quantities or on commercially reasonable terms. Accordingly, Biocartis may not be able to establish or maintain reliable, high-volume manufacturing at commercially reasonable costs. This may have an adverse impact on Biocartis's manufacturing ability, which may, in turn, have a material adverse effect on Biocartis's business, financial condition and results of operations.

***The MDx industry is highly competitive and subject to rapid technological changes. If Biocartis's current or future competitors develop superior, alternative or more widespread solutions and technologies, or obtain regulatory clearance or approval before Biocartis does, or obtain greater intellectual property protection, Biocartis's competitive position and operations would be negatively impacted.***

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. 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). In terms of assays, Biocartis's key competitors are as follows: Roche cobas and Qiagen (for the BRAF Mutation Test and the KRAS and NRAS assays), Diacarta (for the NRAS/BRAF and NRAS/BRAF/EGFR492 assays), Promega (for the MSI assay), Sysmex Inostics' digital PCR service (called "BEAMing") (for liquid biopsy testing), T2 Biosystems with its T2Dx system (for Idylla™-Enrich and the sepsis assay), Focus Diagnostics and Hologic (Prodesse) (for Biocartis's first respiratory panel assay, known as Influenza Virus—Respiratory Syncytial Virus), BioFire Defense (BioFire FilmArray), Luminex (xMap) and Autogenomics (for the Respiratory MP (mixed panel) assay), Roche, Abbott, Novartis and Siemens (for the human immunodeficiency virus ("HIV"), hepatitis B ("HBV") and hepatitis C virus ("HCV") viral load assays) and Cepheid, bioMérieux and Roche (for the Ebola assay). Some competitors have substantially greater financial resources and larger, more established marketing, sales and service organisations than those of Biocartis. Biocartis's primary competitors include:

- large and established companies in MDx with existing installed bases of high-throughput batch-based MDx instruments and existing menus of assays;
- clinical service laboratories that provide entire service solutions to customers, including assays, which they may themselves perform on commercially available instruments and assay platforms or on internally-developed manual protocols, also known as "homebrew" tests;
- companies that market and/or develop integrated random-access systems that may directly compete with Idylla™;
- companies that market and/or develop sequencing-or mass spectrometry based detection systems; and
- companies developing assays for the above mentioned systems.

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's present or future solutions obsolete or uneconomical. In addition, the introduction or announcement of new solutions by Biocartis, or others, could result in a delay of, or decrease in, sales of existing solutions, as Biocartis, or others, await regulatory approvals and as customers

evaluate these new solutions. Biocartis's future commercial success in a rapidly evolving market place, where new and possibly better technologies or solutions are regularly introduced, depends on its ability to compete effectively with current and future technologies or solutions. Failure to compete successfully may have a material adverse effect on Biocartis's business, financial condition and results of operations.

***Biocartis faces uncertainties over the reimbursement for its products by third parties and may be subject to strict price controls. Biocartis's potential customers are in part dependent on such reimbursement from third-party payors, and inadequate coverage of reimbursement may compromise Biocartis's commercial success, which may adversely affect its future profitability.***

The commercial success of Biocartis's Idylla™ platform and menu of assays will depend, 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's first wave of assays all involve biomarkers for which reimbursement is already established, reimbursement procedures in most countries in the European Union are highly complex and third-party payor health plans are fragmented, which makes systematic reimbursement arrangements difficult to establish. As a result, Biocartis will need to expend significant effort and expense to establish, and may never succeed in establishing, widespread or systematic reimbursement arrangements in the European Union.

Reimbursement of MDx tests has also been an issue for several years in the United States, driven by the fact that most tests did not have a current procedural terminology ("CPT") code, which is required information to have a claim reimbursed. However, in 2013 test specific CPT codes were introduced in the United States, as well as the Improving Diagnostic Innovations Act, aimed at establishing a fair compensation for innovative IVD tests. Notwithstanding these developments, there continues to be some uncertainty around the reimbursement status of new IVD tests in the United States and in other countries in which Biocartis operates, or intends to operate in the future.

Because Biocartis will not have direct reimbursement arrangements with most public or private third-party payors, it will instead generally rely on such arrangements with its distributors, and therefore may not be able to continue to receive payments from a particular third-party payor if the agreement with a given distributor is terminated or expires.

If Biocartis's products fail to obtain a reasonable level of reimbursement, purchasers or users may forego or reduce their use which, in turn, may have a materially adverse effect on Biocartis's business, financial condition and results of operations. Furthermore, legislative or regulatory effects to control or reduce healthcare costs or reform healthcare programmes may result in lower prices for Biocartis's products, and such price controls could limit Biocartis's ability to generate future revenues.

***If Biocartis's products are defective, or otherwise pose safety risks, the relevant governmental authorities could require their recall, or Biocartis may initiate a recall of Biocartis's 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's products would divert managerial and financial resources and have a material adverse effect on Biocartis's business, financial condition and results of operations. In addition, any product recall may result in irreparable harm to Biocartis's reputation. Any product recall could impair Biocartis's ability to produce Biocartis's products in a cost-effective and timely manner in order to meet Biocartis's customers' demands. Biocartis may also be required to bear

other costs, or take other actions that may have a negative impact on Biocartis's future revenue and Biocartis's ability to generate profits. Biocartis may initiate voluntary recalls involving Biocartis's products in the future that Biocartis determines does not require notification of the relevant regulatory body. If a governmental agency disagrees with Biocartis's determination, they could require Biocartis to report such actions as recalls. A future recall announcement could harm Biocartis's reputation with customers and may have a material adverse effect on Biocartis's business, financial condition and results of operations. In addition, the relevant authority could take enforcement action for failing to report the recalls when they were conducted.

If Biocartis's products cause or contribute to a death or a serious injury, or malfunction in certain ways, Biocartis will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. Any corrective action, whether voluntary or involuntary, as well as defending Biocartis in a lawsuit, would require the dedication of Biocartis's time and capital, distract management from operating Biocartis's business, and may materially harm Biocartis's reputation, business, financial condition and results of operations.

***Biocartis faces an inherent risk of product liability claims and may not have adequate insurance cover.***

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 maintains product liability insurance at levels which management believes is in line with market practice. However, not all claims and damage may be covered fully, or at all, in case of a product liability lawsuit. As a consequence, Biocartis might have to face liabilities for a claim that may not be covered by its insurance or its liabilities could exceed the limits of its insurance, which may materially harm Biocartis's business, financial condition and results of operations. Moreover, product liability claims may require significant financial and managerial resources and may limit or prevent the further development or commercialisation of Biocartis's products.

While the Idylla™ platform was only launched in September 2014, to date, no product liability claim has been initiated against Biocartis. However, Biocartis cannot provide any assurance that it will be able to maintain sufficient insurance coverage on commercially acceptable terms in the future, or that its insurance coverage will provide adequate protection against all potential risks. In addition, Biocartis's insurance policies will not protect Biocartis against any reputational harm that it may suffer if the market perceives its products to be unreliable or defective.

***Biocartis's 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 assay, the Idylla™ BRAF Mutation Test, for commercial sale in the European Union and countries recognising CE-marked IVD devices in September 2014, and 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's products, including the Idylla™ platform and its menu of assays, 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.

In the EU, market clearance for Biocartis's products is achieved through CE-marking. The European Directive 98/79/EC (in vitro diagnostic medical devices) (the "IVD Directive") subdivides IVD devices into different classes. Whilst high-risk products can only be CE-marked after

certification by a notified body, other products, including the Idylla™ platform and the Idylla™ BRAF Mutation Test, can be CE-marked following a self-certification process conducted by the manufacturer. Although the Idylla™ platform and the Idylla™ BRAF Mutation Test are currently CE-marked IVD devices, a new European Regulation governing the safety and performance of IVD devices (the “**IVD Regulation**”) (currently expected to come into force in 2016 with a transitional period of compliance of between three and five years) is expected to classify oncology assays as high-risk, thereby requiring the services of a notified body for their CE-marking. Management currently anticipates that obtaining CE-marking clearance from a notified body will increase the time it takes to bring a product to market in the European Union by, on average, one to two quarters. There can also be no assurance that any notified body will provide the requisite certification for the Idylla™ BRAF Mutation Test, or any of Biocartis’s other products which may require certification from a notified body in the future, on a timely basis, or at all. Any failure or material delay in obtaining such certification for a new product could have a material adverse impact on Biocartis’s business, financial condition and results of operations while any failure or material delay in obtaining such certification for the Idylla™ BRAF Mutation Test, or any other tests which Biocartis commercialises in the European Union between now and the entry into force of the Regulation, may require Biocartis to cease marketing or recall those tests until certifications in compliance with the IVD Regulation are obtained.

In the United States, the Idylla™ platform and nearly all of Biocartis’s assays will require FDA 510(k) clearances or premarket approval (“**PMA**”), either of which require a number of technical or clinical studies from the FDA prior to marketing in the United States (for further information, see “*Business—Regulation*”).

Although Biocartis has made its first preliminary notification file to the FDA regarding the Idylla™ platform, it is yet to obtain FDA 510(k) clearance for this, or any of its other products. The required scope and size of a study may be larger than expected. Studies performed for such regulatory clearance are expensive and time-consuming. In addition, the commencement or completion of any study may be delayed or halted for any number of reasons. There can be no assurance that FDA 510(k) or PMA clearance will be obtained for any of Biocartis’s products, on a timely basis, or at all. Any failure or material delay in obtaining clearance or approval may have a material adverse effect on Biocartis’s business, financial condition and results of operations. In addition, once an FDA 510(k) or PMA clearance has been obtained, any subsequent modifications to such product (which may be required due to evolving treatment protocols or standards of care), may require new FDA 510(k) clearances or PMA, or may require Biocartis to cease marketing or recall the modified products until clearances are obtained, which may have a material adverse effect on Biocartis’s business, financial condition and results of operations.

Similarly, even if Biocartis obtains the relevant approvals in the European Union or the United States, Biocartis may not obtain regulatory approvals or certifications elsewhere on a timely basis, if at all.

If Biocartis fails to receive necessary approvals to commercialise Biocartis’s products in relevant jurisdictions on a timely basis, or at all, Biocartis’s business, financial condition and results of operations could be adversely affected.

In addition to the regulatory approval processes for Biocartis’s products, Biocartis and its partners, distributors and their respective staff are, or may be, subject to numerous other ongoing regulations in the countries in which they operate, such as anti-bribery, anti-corruption, competition, fraud, insider trading, data protection, health information privacy and security, environmental and health and safety laws. The costs of compliance with applicable regulations, requirements or guidelines could be substantial, and failure to comply could result in sanctions, which could significantly increase Biocartis’s costs, delay the development and commercialisation of its products and may have a material adverse impact on its reputation, business, financial condition and results of operations.

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’s ability to obtain or maintain approval of its products, or to comply with ongoing regulations in the countries in which it operates, which, in turn, may have a material adverse effect on its business, financial condition and results of operations.

***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's products. In addition, regulations and guidance are often revised or reinterpreted in ways that may significantly affect Biocartis's products. 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.

For instance, the US Patient Protection and Affordable Care Act, as amended by the US Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA"), substantially changed the way that US healthcare was financed by both governmental and private insurers, encouraged improvements in the quality of US healthcare items and services, and significantly impacted the US medical device industry. The PPACA included, among other things, the following measures:

- an excise tax on any entity that manufactures or imports medical devices offered for sale in the United States;
- a new Patient-Centred Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on device manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers (referred to as the Physician Sunshine Payment Act), which reporting requirements are difficult to define, track and report;
- payment system reforms including a national pilot programme on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- an independent payment advisory board that submits recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

Biocartis cannot predict what healthcare programmes and regulations will be ultimately implemented at the US federal or state level, or at the EU level, or within the implementing legislation of the individual EU Member States, or the effect of any future legislation or regulation. However, these types of provisions, as adopted, could materially change the way healthcare is delivered and financed, and may materially impact numerous aspects of Biocartis's business. In particular, any changes that lower reimbursements for Biocartis's products could materially adversely affect Biocartis's business, financial condition and results of operations.

In addition, in the future there may continue to be additional proposals relating to the reform of the healthcare systems of the United States, the EU, any individual Member State or any other jurisdiction where Biocartis may operate in the future. Certain of these proposals could limit the prices Biocartis is able to charge for Biocartis's products, or the amounts of reimbursement available for Biocartis's products, and could limit the acceptance and availability of Biocartis's products. The adoption of some or all of these proposals could have a material adverse effect on Biocartis's business, financial position and results of operations.

***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's 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. Such actions or liability could lead governmental agencies to conclude that Biocartis's products or services are no longer to be used or used improperly, all of which could significantly damage Biocartis's reputation and could materially impair the continued adoption of Biocartis's product offering in the market, which may have a material adverse impact on its business, financial condition and results of operations.

***The FDA and other regulatory agencies 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.***

In the markets in which Biocartis operates, Biocartis's promotional materials and training methods must comply with numerous applicable laws and regulations, including the prohibition on the promotion of an IVD device for a use that has not been cleared or approved by the relevant regulator or supervisory body. Use of a device outside of its cleared or approved indication is known as "off-label" use. If a relevant governmental authority determines that Biocartis's promotional materials or training constitute promotion of an "off-label" use, it could request that Biocartis modify Biocartis's training or promotional materials or subject Biocartis to regulatory or enforcement actions, which may include the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. Other US (federal or state), EU or other applicable foreign governmental authorities might also take action if they consider Biocartis's promotion or training materials to constitute promotion of an un-cleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, Biocartis's reputation could be damaged and adoption of Biocartis's products could be impaired. Although Biocartis trains its sales force not to promote Biocartis's products for "off-label" uses, and Biocartis's instructions for use in all markets specify that Biocartis's products are not intended for use outside of those indications cleared for use, it cannot provide any assurance that no competent regulatory agency will hold it responsible for engaging in "off-label" promotion. If Biocartis was held so responsible, this may have a material adverse impact on its business, financial condition and results of operations.

***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's business could suffer.***

Biocartis's intellectual property rights form the basis of its products and technologies. Biocartis's patent portfolio currently consists of 56 patent families, of which:

- 30 are proprietary families comprising issued and pending patents worldwide whose patent life will expire between 2020 and 2034; and
- 26 are in-licensed families.

The value of the unique Idylla™ platform is protected by a group of 49 patent families (23 of which are owned by Biocartis, with the remaining 26 being in-licensed families) and six invention disclosures, comprising issued patents and pending patent applications worldwide, covering the platform technology (basic system, fluidics, ultra-sonification, thermal control, downstream analysis and signal processing) and its associated biochemistry (assay design, reagent storage, sample intake, etc.). The Idylla™-Enrich platform is protected by a group of seven patent families (comprising issued patents and pending patent applications worldwide) owned by Biocartis, covering the hardware aspects of the platform, as well as the assay aspects of the sepsis assay.

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. Management believes that protecting the intellectual property rights that it owns and licences from other parties is critical to its success, but this will depend on a number of complex legal and factual questions. For further on Biocartis's intellectual property, see "*Business—Intellectual Property*".

Firstly, there can be no assurance that pending patent applications (whether submitted by Biocartis, or a third party licensor) will indeed result in granted patent rights, as the examination may lead to the conclusion that no patent will be granted. Secondly, once a patent has been granted, third parties may initiate opposition proceedings (for example, in the case of a patent granted under the European Patent Convention of 5 October 1973 (as amended) (a “**European Patent**”) most third parties (other than assumed infringers) usually have until nine months after publication of the grant to oppose it), or may intervene in pending proceedings, either of which may lead to the revocation of the patent. Biocartis’s patents have received two oppositions to date, both relating to European patents; regardless of the outcome of the proceedings, Biocartis does not view the outcome of these opposition proceedings to be material to its ability to conduct its business or the level of its overall intellectual property protection. In addition, even after the term for initiating opposition proceedings has expired, third parties may initiate court proceedings seeking the nullity of the relevant patent. Generally, the existing licence agreements entered into by Biocartis with third parties do not provide for any warranty as to the validity of the licensed intellectual property rights.

In addition, there can be no assurance that Biocartis’s patent rights (whether owned or licenced) will successfully preclude others from using the same or similar technologies, or that its pending patent applications will have priority over applications submitted by third parties, result in the issuance of patents, or, if issued, will be sufficiently broad to provide protection against competitors with similar technologies. In particular, recent changes to the United States patent laws may impact Biocartis’s ability to obtain and enforce its patent rights in the United States. For example, recent decisions by United States federal courts, including the United States Supreme Court, have limited the protection available for clinical diagnostic innovations that rely on naturally occurring genetic sequences and metabolic phenomena. In addition, the Leahy-Smith America Invents Act (the “**AIA**”) included a number of significant changes to United States patent law, and it is not yet clear what, if any, impact this will have on the operation of Biocartis’s business.

Biocartis may initiate patent litigation against third parties to protect or enforce its patent rights, which may be expensive and divert management’s attention from other business concerns. Litigation may also put its patents at risk of being invalidated or narrowly interpreted, and its patent applications at risk of not being granted. There can be no assurance that Biocartis would prevail in any such litigation, or that the damages or other remedies awarded, if any, would be adequate. The loss of a lawsuit, failure to obtain adequate remedies and/or negative publicity in connection with litigation could have a material adverse effect on Biocartis’s business, financial condition and results of operations.

***Biocartis is dependent on (sub)licences for key technologies from third parties and may require additional licences. There can be no assurance that Biocartis will be able to comply with its obligations under the (sub)licences, or the (sub)licensors will be able to maintain and adequately protect their intellectual property rights.***

Biocartis relies on key technologies from third parties and has entered into (sub)licence agreements with a number of (sub)licensors. The value of the unique Idylla™ platform is, in part, protected by a group of 49 patent families of which 26 are in-licensed families, comprising issued patents and pending patent applications worldwide, covering the platform technology and its associated biochemistry (for further, see “*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’s business could suffer.*” and “*Business—Intellectual Property*”).

Various licence agreements impose on Biocartis various development obligations, payment of royalties and fees obligations, as well as other obligations (for further on such licence agreements, see “*—Material contracts*”). 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, which, in turn, could have a material adverse effect on Biocartis's business, financial condition and results of operations.

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, which could have a materially adverse effect on Biocartis's business, financial condition and results of operations.

***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. Despite the efforts it has taken, Biocartis may have unknowingly infringed in the past, and may still be infringing, the proprietary rights of third parties. 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 assays. Following the publication of such patent applications, Biocartis may need to obtain additional third-party licences, but may not be able to obtain these on acceptable terms, or at all.

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's products, which could have a materially adverse effect on Biocartis's business, financial condition and results of operations.

Biocartis also relies on know-how, trade secrets, copyright and trademark laws and non-disclosure agreements and licences. These measures may not be adequate to safeguard Biocartis's competitive position, which could have a material adverse effect on Biocartis's business, financial condition and results of operations. In addition, certain of Biocartis's past and present employees were previously employed at Biocartis's competitors and executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although Biocartis tries to ensure that Biocartis's employees do not use the proprietary information or know-how of others in their work for Biocartis, Biocartis may be subject to claims that it, or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, which may have a material adverse effect on Biocartis's business, financial condition and results of operations.

***Certain technologies and patents have been developed with collaboration partners, and Biocartis may face restrictions on this jointly developed intellectual property.***

Biocartis has entered into collaboration agreements with a number of industrial and medical companies, research institutions and academic partners (for further, see "*Material contracts*"). Biocartis has, in some cases individually and, in other cases, along with Biocartis's collaboration partners, filed for patent protection for a number of technologies developed under these agreements and may, in the future, file for further intellectual property protection and/or seek to commercialise such technologies. Under some of these agreements, certain intellectual property developed by Biocartis and the relevant partner may be subject to joint ownership by Biocartis and the partner and Biocartis's commercial use of such intellectual property may be restricted, or may require written consent from, or a separate agreement with, the partner. In other cases, Biocartis may not have any rights to use intellectual property solely developed and owned by the partner. If Biocartis cannot obtain commercial use rights for such jointly-owned intellectual property or partner-owned intellectual property, Biocartis's product development and commercialisation plans may be adversely affected.

***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's existing shareholders. In addition, these securities may be sold at a discount from the market price of Biocartis's 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.

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

Biocartis is dependent, to a certain extent, on the principal members of its executive management team and its technical and scientific personnel and on their ability to develop and maintain important relationships with leading academic institutions and companies in the face of intense competition for such personnel, institutions and companies. For further, see "Management and Corporate Governance". Biocartis does not maintain "key man" insurance policies on the lives of these individuals or the lives of any other employees. The loss of any of these persons or the inability to find suitable replacements on a timely basis could potentially harm its business, financial condition, or results of operations. Competition for skilled personnel is intense and may limit Biocartis's 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. In addition, Biocartis's anticipated growth and expansion in accordance with its strategy is expected to place greater demands on its resources, requiring the addition of new skilled personnel in areas such as assay development, engineering, clinical development and sales, marketing and finance. Attracting, retaining and training personnel with the requisite skills remains 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, which in its turn may have a material adverse impact on its business, financial condition and results of operations.

***Biocartis's 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's provision for income taxes and other tax liabilities requires significant judgment, including the adoption of certain accounting policies and Biocartis's 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. Any adverse outcome of such a review may lead to adjustments in the amounts recorded in Biocartis's financial statements, and could have a materially adverse effect on Biocartis's operating results and financial condition.

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's tax structure involves a number of transfers and transfer price determinations between its parent company and its subsidiaries or other affiliates.

Biocartis's effective tax rates could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, including possible changes to the patent income deduction regime and wage withholding tax incentive for qualified research and development personnel in Belgium and other tax incentives, or the way they proportionally impact Biocartis's effective tax rate. An increase of the effective tax rates could have an adverse effect on the Biocartis's business, financial position, results of operations and cash flows.

In addition, Biocartis may not be able to use, or changes in tax regulations may affect the use of, certain tax assets or credits that it has built over the years. For instance, some of Biocartis's entities have significant tax loss carry forwards. Some of these tax loss carry forwards may be forfeited in whole, or in part in, as a result of transactions, or their utilisation may be restricted by statutory law in the relevant jurisdiction. Any corporate reorganisation within the group or relating to Biocartis's shareholding structure may result in partial or complete forfeiture of tax loss carry forwards. The tax burden would increase if profits could not be set off against tax loss carry forwards.

Biocartis's increasing international business may make it subject to income tax and other taxes in countries where it was previously not the case.

***Changes in currency exchange rates could have a material negative impact on the profitability of Biocartis.***

Biocartis records its transactions, prepares its financial statements and incurs substantially all of its costs in Euros, but it expects to enter into certain sale and purchase transactions in US dollars and other currencies in the future. In addition, in view of Biocartis's strategy and the range of markets in which it intends to operate, future agreements may be entered into and certain purchases made by Biocartis may be in foreign currencies. The relationships between different currencies may be volatile and vary based on a number of interrelated factors, including the supply and demand for each currency, political, economic, legal, financial, accounting and tax matters and other actions that Biocartis cannot control. If the currencies in which Biocartis earns its revenues and/or holds its cash balances weaken against the currencies in which it incurs costs and expenses, this could lead to Biocartis suffering exchange rate losses, and declines in such currencies against the euro would negatively impact Biocartis's results when translated into euro for reporting purposes. Any of the foregoing could have a materially adverse effect on Biocartis's financial condition and results of operations.

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

Biocartis makes significant efforts to maintain the security and integrity of Biocartis's product source code and computer systems. The risk of a security breach or disruption, particularly through cyber-attack or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. These threats include identity theft, unauthorised access, domain name system attacks, wireless network attacks, viruses and worms, advanced persistent threat, application centric attacks, peer-to-peer attacks, phishing, backdoor trojans and distributed denial of service attacks. Any of the foregoing could attack Biocartis's products and computer systems. Despite significant efforts to create security barriers to such programmes, it is virtually impossible to entirely eliminate this risk. Like all software products and computer systems, Biocartis's software products and computer systems are vulnerable to such cyber-attacks. The impact of cyber-attacks could disrupt the proper functioning of Biocartis's software products and computer systems (including Idylla™ Connect), cause errors in the output of Biocartis's systems, allow unauthorised access to sensitive, proprietary or confidential information of Biocartis, its customers or the patients that Biocartis and Biocartis's customers serve. If any of the foregoing were to occur, Biocartis's reputation may suffer, customers may stop buying Biocartis's products, Biocartis could face lawsuits and potential liability, and Biocartis's business, financial condition and results of operations could be materially adversely affected.

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

Although all of the data on the Idylla™ platform is designed to be anonymised and patient details should only be available at the point of test, 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.

Biocartis's failure to accurately anticipate the application or interpretation of such laws as Biocartis develops its products, a failure to comply with their requirements (such as evolving encryption and security requirements) or an allegation that defects in Biocartis's products have resulted in non-compliance by Biocartis's customers, could create material civil and criminal liability, resulting in adverse publicity and materially negatively affecting Biocartis's business. Any legislation or regulation in the area of privacy and security of personal information could affect the way Biocartis operates and could harm Biocartis's business. The costs of compliance with, and the other burdens imposed by, these and other laws or regulatory actions may prevent Biocartis from selling its products, or increase the costs associated with selling its products, and may affect Biocartis's ability to invest in, or jointly develop, Biocartis's products in the United States, the European Union and in foreign jurisdictions. Further, Biocartis cannot ensure that Biocartis's privacy and security policies and practices will be found sufficient to protect it from liability or adverse publicity relating to the privacy and security of personal information.

***Biocartis may face risks associated with the spin-out of its Evaluation™ business unit into MyCartis NV and continued minority shareholding, or any other previous or future acquisitions and disposals of companies, solutions and technologies, and its business could be harmed if Biocartis is unable to address these risks.***

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 €26.6 million, distributing the shares to Biocartis's shareholders. Following the exercise by Debiopharm Diagnostics of a put option in December 2014 Biocartis reacquired in January 2015 and continues to hold approximately 13% of the share capital in MyCartis NV. For further information on the disposal of MyCartis NV, see Note 3.12 to the Financial Statements. 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.

The processes by which Biocartis acquires or disposes of businesses, licences assets or technologies may be lengthy and complex and may result in a diversion of management's attention from other business concerns.

All of the foregoing could have a materially adverse effect on Biocartis's financial condition and results of operations.

## **Risks relating to the shares and the Offering**

***The fact that no minimum amount is set for the Offering may affect the Issuer's investment plans.***

The Issuer has the right to proceed with a capital increase in a reduced amount. There is no minimum amount set for the Offering. The actual number of shares subscribed for, or placed, will be confirmed on the Issuer's website and by press release together with the Offer Price. As a result only a reduced number of shares could be available for trading on the market which could limit the liquidity of the shares, and the Issuer's financial means in view of the uses of proceeds as described in "Use of Proceeds" may be reduced. If this were to be the case, the Issuer may have to reduce its level of investments or look for further external funding.

***There has been no prior public market for the Issuer's shares and there may not be an active market for the shares.***

Prior to the Offering, there has been no public trading market for the shares. No assurance can be given that an active trading market for the shares will develop or, if developed, can be sustained or will be liquid following the closing of the Offering. Furthermore, the Offer Price is not necessarily indicative of the prices at which the shares will subsequently trade on the stock exchange. If an active trading market is not developed or maintained, the liquidity and trading price of the shares could be adversely affected.

***The market price of the shares may fluctuate widely in response to various factors.***

Publicly traded securities from time to time experience significant price and volume fluctuations that may be unrelated to the results of operation or the financial condition of the companies that have issued them. In addition, the market price of the shares may prove to be highly volatile and may fluctuate significantly in response to a number of factors, many of which are beyond the Issuer's control, including:

- market expectations for the Issuer's financial performance;
- actual or anticipated fluctuations in the Issuer's business, results of operations and financial condition;
- changes in the estimates of the Issuer's results of operations by securities analysts;
- investor perception of the impact of the Offering on the Issuer and its shareholders;
- potential or actual sales of blocks of shares in the market or short selling of shares;
- the entrance of new competitors or new products in the markets in which the Issuer operates;
- volatility in the market as a whole or investor perception of the Issuer's industries and competitors;
- changes in market valuation of similar companies;
- announcements by the Issuer or its competitors of significant contracts;
- acquisitions, strategic alliances, joint ventures, capital commitments or new products or services;
- loss of major customers;
- additions or departures of key personnel;
- any shortfall in revenue or net income or any increase in losses from levels expected by securities analysts;
- future issues or sales of ordinary shares;
- stock market price and volume fluctuations;
- new government regulation;

- general economic, financial and political conditions; and
- the risk factors mentioned above.

The market price of the shares may be adversely affected by most of the preceding or other factors regardless of the Issuer's actual results of operations and financial condition.

***Future sales of substantial amounts of the Issuer's shares, or the perception that such sales could occur, could adversely affect the market value of the shares.***

A sale of a significant number of shares on the regulated market of Euronext Brussels, or the perception that such sale will occur, may adversely affect the market price of the shares. The Issuer cannot make any predictions as to the sale or perception on the market price of the shares. The current shareholders of the Issuer (excluding some minority shareholders holding in the aggregate of 1.65% of the currently outstanding shares) and each of the members of the executive management agreed to lock up their shares for two consecutive periods of six months, being a period of 12 months in total, following the Listing Date, as described in "*Plan of distribution—Lock-up arrangements.*" Following the expiration of these lock-up provisions (or if the Global Coordinator consents to a sale during the second six month period), future sales of the shares could be made by the relevant existing shareholders or the relevant warrant holders, or the perception that such sales could occur, may adversely affect the market price of the shares.

***The Issuer has no fixed dividend policy.***

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

Currently, the board of directors of the Issuer expects to retain all earnings, if any, generated by the Issuer's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future. Furthermore, as the Issuer is primarily a parent company (holding the shares of Biocartis S.A. and indirectly of Biocartis NV and Biocartis B.V. and rendering head office functions to such companies) with no external revenues, its ability to pay dividends and the level of any dividends is subject to the extent to which it receives funds, directly or indirectly, from its subsidiaries.

In addition, under Belgian law and the articles of association, before it can pay dividends, the Issuer must allocate an amount of 5% of its annual net profit (*nettowinst/bénéfices nets*) pursuant to generally applicable accounting rules and principles in Belgium ("**Belgian GAAP**") to a legal reserve in its stand-alone statutory accounts until the reserve equals 10% of the Issuer's share capital. The Issuer's legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Issuer's ability to pay out dividends to its shareholders. As a consequence of these factors, there can be no assurance as to whether dividends or similar payments will be paid out in the future or, if they are paid, their amount.

***Certain significant shareholders of the Issuer after the Offering may have different interests from the Issuer and may be able to control the Issuer, including the outcome of shareholder votes.***

Following the closing of the Offering and listing of its shares, the Issuer will have a number of significant shareholders. For an overview of the Issuer's current significant shareholders see "*Principal shareholders*".

Currently, the existing shareholders have entered into a shareholders' agreement (the "**Shareholders' Agreement**"), containing amongst others terms regarding the Issuer's business and governance, as well as pre-emptive rights and other transfer restrictions regarding the

Issuer's shares. The Issuer is a party to this Shareholders' Agreement. The Shareholders' Agreement will be terminated effective as of the closing of the Offering. The Issuer is not aware that any of its current shareholders will enter into a new shareholders' agreement with respect to their shares and the exercise of their voting rights in the Issuer after the closing of the Offering (other than certain lock-up arrangements as described above in "*—Future sales of substantial amounts of the Issuer's shares, or the perception that such sales could occur, could adversely affect the market value of the shares.*") Nevertheless, they could, alone or together, have the ability to elect or dismiss directors, and, depending on how broadly the Issuer's other shares are held, take certain other shareholders' decisions that require, or require more than, 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such items are submitted to voting by the shareholders. Alternatively, to the extent that these shareholders have insufficient votes to impose certain shareholders' decisions, they could still have the ability to block proposed shareholders' resolutions that require, or require more than, 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings were such decisions are submitted to voting by the shareholders. Any such voting by the shareholders may not be in accordance with the interests of the Issuer or the other shareholders of the Issuer.

***Any future capital increases by the Issuer could have a negative impact on the price of the shares.***

The Issuer is expected to agree pursuant to the Underwriting Agreement (as defined below) (which is expected to be entered into on or about 30 April 2015) to a standstill on the issuance of new shares and issuance of new warrants (which would not affect the issue of new shares upon exercise of existing outstanding warrants) for a period of 12 months following the Listing Date, as described in "*Plan of distribution—Lock-up arrangements*". After such period, or within that period with the Global Coordinator's consent and at least one other Underwriter, the Issuer may increase its share capital against cash or contributions in kind to finance any future acquisition or other investment or to strengthen its balance sheet. In connection with such transactions, the Issuer may, subject to certain conditions, limit or cancel the preferential subscription rights of the existing shareholders otherwise applicable to capital increases through contributions in cash, while no preferential subscription rights apply to capital increases through contributions in kind. Such transactions could therefore dilute the stakes in the Issuer's share capital held by the shareholders at that time and could have a negative impact on the share price, earnings per share and net asset value per share.

***Certain transfer and selling restrictions may limit shareholders' ability to sell or otherwise transfer their shares.***

The Issuer has applied for an admission of all of its existing and new shares to public trading in Belgium, but has not registered the shares under the US Securities Act or securities laws of other jurisdictions, including Canada, Australia and Japan, and it does not expect to do so in the future. The shares may not be offered or sold in the United States, Canada, Australia, Japan or in any other jurisdiction in which the registration or qualification of the shares is required but has not taken place, unless an exemption from the applicable registration or qualification requirement is available or the offer or sale of the shares occurs in connection with a transaction that is not subject to such provisions.

***If securities or industry analysts do not publish research reports about the Issuer, or if they change their recommendations regarding the Issuer's shares in an adverse way, the market price of the shares may fall and the trading volume may decline.***

The trading market for the Issuer's shares may be influenced by the research reports that industry or securities analysts publish about the Issuer or its industry. If one or more of the analysts who cover the Issuer or its industry, downgrades its recommendation, the market price of the Issuer's shares may fall. If one or more of the analysts ceases to cover the Issuer or fails to publish research reports about the Issuer on a regular basis, the Issuer may lose visibility in the financial markets, which in turn could cause the market price of the Issuer's shares or trading volume to decline.

***Investors resident in countries other than Belgium may suffer dilution if they are unable to participate in future preferential subscription rights offerings.***

Under Belgian law and the Issuer's constitutional documents, shareholders have a waivable and cancellable preferential subscription right to subscribe pro rata to their existing shareholdings to the issue, against a contribution in cash, of new shares or other securities entitling the holder thereof to new shares, unless such rights are limited or cancelled by resolution of the Issuer's general shareholders' meeting or, if so authorised by a resolution of such meeting, the board of directors. The exercise of preferential subscription rights by certain shareholders not residing in Belgium (including those in the United States, Australia, Canada or Japan) may be restricted by applicable law, practice or other considerations, and such shareholders may not be entitled to exercise such rights, unless the rights and shares are registered or qualified for sale under the relevant legislation or regulatory framework. In particular, there can be no assurance that the Issuer will be able to establish an exemption from registration under the US Securities Act, and the Issuer is under no obligation to file a registration statement with respect to any such preferential subscription rights or underlying securities or to endeavour to have a registration statement declared effective under the US Securities Act. Shareholders in jurisdictions outside Belgium who are not able or not permitted to exercise their preferential subscription rights in the event of a future preferential subscription rights, equity or other offering may suffer dilution of their shareholdings.

***Takeover provisions in Belgian national law may make it difficult for an investor to change management and may also make a takeover difficult.***

Public takeover bids on the Issuer's shares and other voting securities are subject to the Belgian Act of 1 April 2007 on public takeover bids, as amended (the "**Belgian Takeover Act**"), and to the supervision by the FSMA. Public takeover bids must be made for all of the Issuer's voting securities, as well as for all other securities that entitle the holders thereof to the subscription for, the acquisition of or the conversion in voting securities. Prior to making a bid, a bidder must issue and disseminate a prospectus, which must be approved by the FSMA. The bidder must also obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of the Issuer.

The Belgian Takeover Act provides that, in principle, a mandatory bid will be triggered if a person, as a result of its own acquisition or the acquisition by its affiliates, by persons acting in concert with it or by persons acting on their account, directly or indirectly holds more than 30% of the voting securities in a company that has 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 Royal Decree of 27 April 2007 on public takeover bids (the "**Belgian Takeover Decree**"). The mere fact of exceeding the relevant threshold through the acquisition of one or more shares will, in principle, give rise to a mandatory bid, irrespective of whether or not the price paid in the relevant transaction exceeds the current market price.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose important shareholdings, merger control and authorised capital, that may apply to the Issuer and which may make an unsolicited tender offer, merger, change in management or other change in control, more difficult. These provisions could discourage potential takeover attempts that third parties may consider and that other shareholders may consider to be in their best interest and could adversely affect the market price of the shares. These provisions may also deprive the shareholders of the opportunity to sell their shares at a premium (which is typically offered in the framework of a takeover bid).

***Shareholders in jurisdictions with currencies other than the euro face additional investment risk from currency exchange rate fluctuations in connection with their holding of shares.***

The Issuer's shares will be quoted only in euro and any future payments of dividends on shares, as the case may be, will be denominated in euro. An investment in the shares by an investor whose principal currency is not the euro exposes such investor to currency exchange rate risk which may impact the value of the investment in the shares or of any dividends.



***Any future sale, purchase or exchange of shares may become subject to the Financial Transaction Tax.***

On 14 February 2013, the EU Commission adopted a proposal for a Council Directive (the “**Draft Directive**”) on a common financial transaction tax (“**FTT**”). The intention is for the FTT to be implemented via an enhanced cooperation procedure in 11 Member States (Austria, Belgium, Estonia, France, Germany, Greece, Italy, Portugal, Spain, Slovakia and Slovenia, together, the “**Participating Member States**”).

Pursuant to the Draft Directive, the FTT will be payable on financial transactions provided at least one party to the financial transaction is established or deemed established in a Participating Member State and there is a financial institution established or deemed established in a Participating Member State which is a party to the financial transaction, or is acting in the name of a party to the transaction. The FTT shall, however, not apply to (inter alia) primary market transactions referred to in article 5(c) of Regulation (EC) No 1287/2006, including the activity of underwriting and subsequent allocation of financial instruments in the framework of their issue.

The rates of the FTT will be fixed by each Participating Member State but for transactions involving financial instruments other than derivatives shall amount to at least 0.1% of the taxable amount. The taxable amount for such transactions shall in general be determined by reference to the consideration paid or owed in return for the transfer. The FTT will be payable by each financial institution established or deemed established in a Participating Member State which is either a party to the financial transaction, or acting in the name of a party to the transaction or where the transaction has been carried out on its account. Where the FTT due has not been paid within the applicable time limits, each party to a financial transaction, including persons other than financial institutions, shall become jointly and severally liable for the payment of the FTT due.

Investors should therefore note, in particular, that following implementation any future sale, purchase or exchange of shares will be subject to the FTT at a minimum rate of 0.1% provided the above mentioned prerequisites are met. The investor may be liable to pay this charge or reimburse a financial institution for the charge, and/or the charge may affect the value of the shares. The issuance of new shares should not be subject to the FTT.

A statement made by the Participating Member States (other than Slovenia) indicates that a progressive implementation of the FTT is being considered, and that the FTT may initially apply only to transactions involving shares and certain derivatives, with implementation occurring by 1 January 2016. However, full details are not available.

The Draft Directive is still subject to negotiation among the Participating Member States and therefore may be changed at any time. Moreover, once the Draft Directive has been adopted (the “**Directive**”), it will need to be implemented into the respective domestic laws of the Participating Member States and the domestic provisions implementing the Directive might deviate from the Directive itself.

Investors should consult their own tax advisers in relation to the consequences of the FTT associated with subscribing for, purchasing, holding and disposing of the shares.

***Investors' rights as shareholders of the Issuer will be governed by Belgian law and may differ in some respects from the rights granted to shareholders in other companies under the laws of other jurisdictions.***

The Issuer is a limited liability company (*société anonyme/naamloze vennootschap*) organised under the laws of Belgium. The rights of holders of the Issuer's shares are governed by Belgian law and by the Issuer's articles of association. These rights may differ in material respects from the rights of shareholders in companies organised outside of Belgium.

***Investors may not be able to recover in civil proceedings for US securities laws violations.***

The Issuer's directors and members of senior management may not be resident in the jurisdiction of investors and the Issuer's assets and the assets of its directors and senior

management may be located outside the jurisdiction of investors. As a result, it may be difficult for investors to prevail in a claim against the Issuer or to enforce liabilities predicated upon the securities laws of jurisdictions outside of Belgium and, in general, for investors outside of Belgium to serve process on or enforce foreign judgments against the Issuer, its directors or its senior management. In addition, there is uncertainty as to the enforceability in Belgium of original actions or in actions for enforcement of judgments of United States courts of civil liabilities predicated solely upon the federal securities laws of the United States. See *"Jurisdiction and service of process in the United States and enforcement of foreign judgments in Belgium"*.

***The shares will be listed and traded on the regulated market of Euronext Brussels on an "if-and-when-issued and/or delivered" basis from the Listing Date until the Closing Date. Euronext Brussels NV/SA may annul all transactions effected in the shares if they are not issued and delivered on the Closing Date.***

From the Listing Date until the Closing Date, the shares will be listed and traded on the regulated market of Euronext Brussels on an "if-and-when-issued and/or delivered" basis, meaning that trading of the shares will begin prior to the closing of the Offering. The Closing Date is expected to occur on the third Euronext Brussels trading day following the Listing Date. Investors that wish to enter into transactions in the shares prior to the Closing Date, whether such transactions are effected on the regulated market of Euronext Brussels or otherwise, should be aware that the closing may not take place on the expected date, or at all, if certain conditions or events referred to in the Underwriting Agreement (as defined below) are not satisfied or waived or do not occur on or prior to such date. Euronext Brussels NV/SA may annul all transactions effected in the shares if they are not issued and delivered on the Closing Date. Euronext Brussels NV/SA cannot be held liable for any damage arising from the listing and trading on an "if-and-when-issued and/or delivered" basis as of the Listing Date until the Closing Date.

***The Issuer may become a passive foreign investment company, which could result in adverse US federal income tax consequences to US investors.***

The Issuer believes that it is not a passive foreign investment company (a "PFIC") for US federal income tax purposes. However, because the Issuer's status as a PFIC must be determined annually and depends upon the nature of the Issuer's income, the composition and quarterly average value of the Issuer's assets and the market price of the shares, there is no assurance that the Issuer will not be a PFIC for the current taxable year or any future taxable year. If the Issuer were treated as a PFIC for any taxable year during which a US investor held the shares, certain adverse US federal tax consequences could apply to such US investor. Further information about the PFIC rules is set out in *"Taxation—Certain US federal income tax considerations—Passive foreign investment company rules"*.

## USE OF PROCEEDS

### Expenses of the Offering

The aggregate of the administrative, legal and audit expenses as well as the other costs in connection with the Offering (including but not limited to legal publications, printing and translation of the Prospectus and Offering related documents) and the remuneration of the FSMA and Euronext Brussels NV/SA, is expected to amount to approximately €2.3 million. Additionally, fees and commissions payable to the Underwriters by the Issuer are expected to be approximately €3.6 million assuming a full placement of the New Shares and that the Offer Price is at the midpoint of the Price Range, or €4.2 million assuming a full placement of the Offered Shares (including the exercise in full of the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, in each case not including a size fee of 0.5% and a discretionary fee of up to 1.0% of the gross proceeds of the Offering.

### Use of Proceeds

Assuming a full placement of the New Shares and that the Offer Price is at the midpoint of the Price Range, the gross proceeds from the issue of the New Shares are estimated to be approximately €93.5 million. Assuming a full placement of the Offered Shares (including the exercise in full of the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, the gross proceeds from the issue of the Offered Shares are estimated to be approximately €107.5 million.

Based on the aforementioned assumptions and the expenses of the Offering (see "*Expenses of the Offering*"), the Issuer estimates to receive net proceeds of approximately €87.6 million in case of a full placement of the New Shares and approximately €101.0 million in case of a full placement of the Offered Shares (including the exercise in full of the Over-allotment Option). The principal purposes of the Offering are to obtain additional capital to support the execution of Biocartis's strategy (as described in "*Business—Strategy*"). Of the net proceeds from the Offering that it will raise, the Issuer currently anticipates to use, in order of importance and based on the aforementioned assumptions:

- approximately 50% to develop and launch new proprietary assays, including strengthening the research and development team to support this development. Biocartis intends to launch at least four to five assays per year, complemented by additional assays developed in conjunction with its partners, including J&J and Abbott Molecular. See also "*Business—Overview—Menu of assays*";
- approximately 15% to expand its sales and marketing team;
- approximately 15% for further system developments, including Idylla™—Enrich, Idylla™—Retrieve, and Idylla™ Connect and a solution for high volume testing (for further information, see "*Business—Future developments*" and "*Business—Primary other future developments*"); and
- any remaining funds, approximately 20%, for general corporate purposes, such as working capital needs, general and administrative expenses, and the additional costs associated with being a public company.

As of the date of this Prospectus, the Issuer cannot predict with certainty all of the particular uses for the proceeds from the issue of the Offered Shares, or the amounts that it will actually spend on the uses set forth above. The amounts and timing of the Issuer's actual expenditures will depend upon numerous factors, including the progress, costs, timing and results of its research and development, regulatory or competitive developments, the net proceeds actually raised by it in the Offering, any amounts received by way of grants and the Issuer's operating costs and expenditures. The Issuer's management will have significant flexibility in applying the net proceeds from the issue of the Offered Shares and may change the allocation of these proceeds as a result of these and other contingencies. Pending the use of the proceeds from this Offering, the Issuer intends to invest the net proceeds in interest bearing, cash and cash equivalents instruments or short term certificates of deposit.

Furthermore, the Issuer has the right to proceed with a capital increase in a reduced amount, with no minimum amount set for the Offering. In the case that the Issuer would proceed with the capital increase in a reduced amount, the Issuer might have to reduce its level of investment or look for further external funding in order to fund the above proposed uses. However, it is anticipated that the proportional allocation of proceeds would remain similar to the allocations set forth above.

## DIVIDEND AND DIVIDEND POLICY

### Dividends

The Issuer's existing shares and the Offered Shares carry the right to participate in dividends declared after the Closing Date, in respect of the financial year ending 31 December 2015 and future years. All of the Issuer's shares participate equally in the Issuer's profits, if any. In general, the Issuer may only pay dividends with the approval of the general shareholders' meeting, although pursuant to the Issuer's articles of association, the board of directors may declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The maximum amount of the dividend that can be paid is determined by reference to the Issuer's stand-alone statutory accounts prepared in accordance with Belgian GAAP.

Under Belgian law and the Issuer's articles of association, the Issuer must allocate an amount of 5% of its Belgian GAAP annual net profit (*nettowinst/bénéfices nets*) to a legal reserve in its stand-alone statutory accounts until the reserve equals 10% of the Issuer's share capital. The Issuer's legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Issuer's ability to pay out dividends to its shareholders.

Assuming that the Offer Price is at the mid-point of the Price Range and all Offered Shares are placed (including the exercise in full of the Over-allotment Option), the Issuer's share capital will amount to €404,483.60. There will be no distributable reserves will nor will there be a legal reserve, as of the closing of the Offering.

### Dividend policy

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

Currently, the board of directors of the Issuer expects to retain all earnings, if any, generated by the Issuer's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future. Furthermore, as the Issuer is primarily a parent company (holding the shares of Biocartis S.A. and indirectly of Biocartis NV and Biocartis B.V. and rendering head office functions to such companies) with no external revenues, its ability to pay dividends and the level of any dividends is subject to the extent to which it receives funds, directly or indirectly, from its subsidiaries.

As a consequence of all these factors, there can be no assurance as to whether dividends or similar payments will be paid out in the future or, if they are paid, their amount.

## CAPITALISATION AND INDEBTEDNESS

### Capitalisation and indebtedness

The following table sets forth Biocartis's consolidated capitalisation as of 31 December 2014. This table should be read in conjunction with "Selected financial information", "Operating and financial review—Capital resources and indebtedness", and the consolidated financial statements of the Issuer as of and for the period ending 31 December 2014. The adjustments reflected in the table relate to the additional funding that the Issuer received in the context of the completion of the second tranche (amounting to €21,512,795) of the €64,538,390 F-round financing received on 15 January 2015. Except for the second tranche of the F-round financing, there have been no material changes to Biocartis's capitalisation and indebtedness since 31 December 2014. The information regarding adjustments is based on unaudited numbers.

(in €000)	As of 31 December 2014	Adjustments	As Adjusted
<b>Total current debt</b>	<b>5,057</b>	—	<b>5,057</b>
Guaranteed	—	—	—
Secured <sup>(1)</sup>	1,161	—	1,161
Guaranteed and secured <sup>(2)</sup>	3,895	—	3,895
Unguaranteed/unsecured	—	—	—
<b>Total non-current debt</b>	<b>8,528</b>	—	<b>8,528</b>
Guaranteed	—	—	—
Secured <sup>(1)</sup>	1,821	—	1,821
Guaranteed and secured <sup>(2)</sup>	—	—	—
Unguaranteed/unsecured	6,707	—	6,707
<b>Total indebtedness<sup>(3)</sup></b>	<b>13,585</b>	—	<b>13,585</b>
<b>Shareholders' equity</b>			
Legal share capital	222,268	20,488	242,756
Historical share capital adjustment	(221,232)	—	(221,232)
Share premium	166,592	1,025	167,617
Share based payment reserve	1,166	—	1,166
Accumulated deficit	(148,513)	—	(148,513)
<b>Total equity</b>	<b>20,280</b>	<b>21,513</b>	<b>41,793</b>

#### Notes:

- (1) Security represented by a debt service reserve account of €2.5 million decreasing over time. For further information, see Note 3.22 to the Financial Statements.
- (2) Guaranteed by Biocartis S.A. and secured by a pledge of newly generated intellectual property assets related to the Idylla™ platform in The Netherlands. For further information, see Note 3.22 to the Financial Statements.
- (3) As set forth in Notes 3.31.1 and 3.31.2 to the Financial Statements, the Biocartis group (on a consolidated basis) has a number of commitments in relation to investments in leasehold improvements and property, plant and equipment, and has entered into a number of operating leases in relation with its building facilities as well as in relation to employee cars. Other than the foregoing, as of 31 December 2014 and as of the date of this Prospectus, the Biocartis group did not have any material off-balance sheet transaction, defined as assets or debts that do not appear on the Biocartis Group's balance sheet but that are considered as firm, non-cancellable commitments such as long term maintenance and service contracts, financing commitments or financial obligations of unconsolidated subsidiaries.

The following table sets out the net consolidated indebtedness of Biocartis as at 31 December 2014 both actual and as adjusted for the second tranche of the F-round financing:

(in €000)	<u>As of 31 December 2014</u>	<u>Adjustments</u>	<u>As Adjusted</u>
Cash at bank and on hand .....	9,419	21,513	30,932
Total restricted cash <sup>(1)</sup> .....	1,500	—	1,500
<b>Cash and cash equivalents</b> .....	<b>10,919</b>	<b>21,513</b>	<b>32,432</b>
<b>Total liquidity</b> .....	<b>10,919</b>	<b>21,513</b>	<b>32,432</b>
<b>Current financial debt</b> .....	<b>(5,057)</b>	<b>—</b>	<b>(5,057)</b>
<b>Net current liquidity</b> .....	<b>5,862</b>	<b>—</b>	<b>27,375</b>
<b>Non current financial indebtedness</b> .....	<b>(8,528)</b>	<b>—</b>	<b>(8,528)</b>
<b>Net financial indebtedness/liquidity</b> .....	<b>(2,666)</b>	<b>—</b>	<b>18,847</b>

Note:

(1) 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 via KBC lease.

### Working capital statement

On the date of this Prospectus, the Issuer is of the opinion that, taking into account its available cash and cash equivalents, it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months from the date of the Prospectus.

However, the Issuer is of the opinion that the proceeds of the Offering (together with its available cash and cash equivalents) will (in the event the Offering is completed) provide the Issuer with sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months from the date of the Prospectus.

In case the Issuer would not be able to attract additional funds (beyond its existing cash and cash equivalents and excluding any proceeds of the Offering or receipt of the committed F-round financing in the amount of €21.5 million), it expects to run out of working capital by 31 December 2015.

The Issuer's 12 month working capital shortfall in the event the Issuer would not be able to attract any such additional funds is projected to be approximately € 20 million. In the event the Issuer would not be able to attract any additional funds pursuant to the Offering, the Issuer will rely on the third and final tranche of the committed F-round financing in the amount of € 21.5 million, providing the milestone to trigger this tranche will be met in the course of 2015, which the Issuer believes is likely. (In the event the Offering does proceed, the F-round investors have committed to subscribe for €21.5 million in shares subject to the closing of the Offering.)

## SELECTED FINANCIAL INFORMATION

The following selected financial information should be read together with the other information contained in this Prospectus, including “*Operating and financial review and prospects*” and the Financial Statements and related notes included elsewhere in this Prospectus. This financial information is historical and not necessarily indicative of results to be expected in any future period.

The following selected financial information, and the Financial Statements included in this Prospectus from which it is derived, have been prepared in accordance with IFRS, in effect at the time of preparing the relevant financial statements. For more information on the content and interpretation of this information, see “*Presentation of financial and other information—Financial statements*”.

### Comprehensive income

	Year ended 31 December		
	2014	2013	2012
	<i>(in €000)</i>		
<b>Revenue</b>			
Collaboration revenue .....	3,218	6,247	2,102
Product sales revenue .....	5,260	2,086	1,449
	<b>8,478</b>	<b>8,333</b>	<b>3,551</b>
<b>Other operating income</b>			
Grants and other income .....	1,889	3,504	2,632
<b>Operating expenses</b>			
Costs of goods sold .....	(4,251)	(1,962)	(1,168)
Research and development expenses .....	(25,014)	(27,838)	(33,991)
Marketing and distribution expenses .....	(3,095)	(1,155)	(691)
General and administrative expenses .....	(7,180)	(7,255)	(6,131)
	<b>(39,540)</b>	<b>(38,210)</b>	<b>(41,981)</b>
<b>Operating loss for the period</b> .....	<b>(29,173)</b>	<b>(26,373)</b>	<b>(35,798)</b>
Financial income .....	60	126	104
Financial expense .....	(933)	(981)	(836)
Foreign exchange gains/(losses), net .....	(88)	(212)	16
<b>Financial result, net</b> .....	<b>(961)</b>	<b>(1,067)</b>	<b>(716)</b>
<b>Loss for the year before taxes from continuing operations</b> .....	<b>(30,134)</b>	<b>(27,440)</b>	<b>(36,515)</b>
Income taxes .....	947	(2)	(4)
<b>Loss for the year after taxes from continuing operations</b> .....	<b>(29,187)</b>	<b>(27,442)</b>	<b>(36,519)</b>
Gain (loss) for the year after taxes from discontinued operations ....	19,472	(8,178)	(7,912)
<b>Loss for the year</b> .....	<b>(9,715)</b>	<b>(35,620)</b>	<b>(44,431)</b>
attributable to owners of the Issuer .....	(9,118)	(35,620)	(44,431)
attributable to non-controlling interest .....	(598)	0	0

## Balance sheet data

	As at 31 December		
	2014	2013	2012
	<i>(in €000)</i>		
<b>Assets</b>			
<b>Non-current assets</b>			
Intangible assets . . . . .	9,652	9,985	10,278
Property, plant and equipment . . . . .	9,154	11,199	10,994
Participating interests . . . . .	0	245	0
Other long term receivables . . . . .	117	107	106
Deferred tax assets . . . . .	947	0	0
	<b>19,870</b>	<b>21,536</b>	<b>21,378</b>
<b>Current assets</b>			
Inventory . . . . .	3,583	1,116	183
Trade receivables . . . . .	15,793	3,082	1,442
Other receivables . . . . .	148	993	793
Other current assets . . . . .	2,700	4,371	1,898
Cash and cash equivalents . . . . .	10,919	29,047	40,494
	<b>33,142</b>	<b>38,609</b>	<b>44,810</b>
<b>Total assets . . . . .</b>	<b>53,012</b>	<b>60,145</b>	<b>66,188</b>
<b>Equity and liabilities</b>			
<b>Capital and reserves</b>			
Legal share capital . . . . .	222,268	926	795
Historical share capital adjustment . . . . .	(221,232)	0	0
Share premium . . . . .	166,592	175,946	146,394
Gains and losses on defined benefit plans . . . . .	0	(309)	(379)
Share based payment reserve . . . . .	1,166	1,023	0
Accumulated deficit . . . . .	(148,513)	(145,631)	(110,010)
<b>Total equity attributable to the owners of the Issuer . . . . .</b>	<b>20,280</b>	<b>31,955</b>	<b>36,800</b>
<b>Non-current liabilities</b>			
Financial debt . . . . .	8,528	12,822	10,089
Deferred income . . . . .	4,534	1,711	5,002
Retirement benefit obligation . . . . .	0	267	490
Accrued charges . . . . .	1,955	1,741	2,026
	<b>15,017</b>	<b>16,541</b>	<b>17,607</b>
<b>Current liabilities</b>			
Financial debt . . . . .	5,057	3,373	1,250
Trade payables . . . . .	4,265	5,847	8,454
Deferred income . . . . .	5,100	772	1,320
Other current liabilities . . . . .	3,293	1,657	757
	<b>17,714</b>	<b>11,649</b>	<b>11,781</b>
<b>Total equity and liabilities . . . . .</b>	<b>53,012</b>	<b>60,145</b>	<b>66,188</b>



## Cash flow statement data

	As at 31 December		
	2014	2013	2012
	<i>(in €000)</i>		
<b>Operating activities</b>			
Loss for the period .....	(9,715)	(35,620)	(44,431)
<b>Adjustments for</b>			
Depreciation and amortisation .....	4,437	3,557	2,622
Depreciation and amortisation included in discontinued operations .....	81	181	156
Impairments .....	37	0	0
Tax income in profit and loss .....	(947)	0	0
Financial result, net .....	897	1,065	600
Net movement in retirement benefit obligation .....	108	(153)	25
Gain on disposal MyCartis NV .....	(26,624)	0	0
Share based payment expense .....	143	1,023	0
<b>Changes in working capital</b>			
Net movements in inventories .....	(2,524)	(933)	(10)
Net movement in trade and other receivables and other current assets .....	(2,736)	(4,313)	818
Net movement in trade payables and other current liabilities .....	1,860	(1,992)	244
Net movement in deferred income .....	(746)	(3,839)	(1,286)
Interests paid .....	(155)	(155)	0
<b>Cash flow from operating activities</b> .....	<b>(35,884)</b>	<b>(41,179)</b>	<b>(41,262)</b>
<b>Investing activities</b>			
Interest received .....	60	100	102
Purchases of property, plant and equipment .....	(1,927)	(3,138)	(7,313)
Purchases of intangible assets .....	(840)	(512)	(350)
Acquisition shares in other companies .....	0	(245)	0
Disposal shares in other companies .....	245	0	0
Acquisition of a subsidiary .....	7,514	0	0
Proceeds from sale and rent back of property, plant and equipment .....	0	0	1,904
<b>Cash flow from investing activities</b> .....	<b>5,052</b>	<b>(3,795)</b>	<b>(5,657)</b>
<b>Financing activities</b>			
Proceeds from issue of common equity shares .....	0	29,682	53,117
Proceeds from issue of preference shares F .....	21,244	0	0
Proceeds from sale and lease back of property, plant and equipment .....	0	5,000	0
Disposal of MyCartis NV to capital owners of the parent .....	(5,138)	0	0
Repayment of borrowings .....	(3,378)	(894)	0
Bank charges .....	(1)	(18)	0
<b>Cash flow from financing activities</b> .....	<b>12,727</b>	<b>33,770</b>	<b>53,117</b>
<b>Net increase in cash and cash equivalents</b> .....	<b>(18,105)</b>	<b>(11,204)</b>	<b>6,198</b>
Cash and cash equivalents at the beginning of the period .....	29,047	40,494	34,357
Effects of exchange rate changes on the balance of cash held in foreign currencies .....	(23)	(243)	(61)
<b>Cash and cash equivalents at the end of the period</b> .....	<b>10,919</b>	<b>29,047</b>	<b>40,494</b>

## OPERATING AND FINANCIAL REVIEW AND PROSPECTS

*The following is a review of Biocartis's financial condition and results of operations as of and for the three years ended 31 December 2014, 2013 and 2012. This section should be read in conjunction with the section entitled "Selected financial information" and the Biocartis audited financial statements and notes to those financial statements, included elsewhere in this Prospectus. The figures used in this section refer to financial statements which have been prepared in accordance with IFRS. Certain statements in this section are forward-looking and should be read in conjunction with "Forward-looking statements".*

### Overview

Biocartis has developed an innovative and proprietary MDx platform that offers accurate, highly-reliable molecular information from a wide variety of biological sample types, enabling fast and effective diagnostics treatment selection and treatment monitoring. Biocartis is using its CE-IVD marked Idylla™ platform to develop and market a broad set of high value clinical assays in the oncology and infectious diseases segments.

Biocartis, founded in 2007, is focused on the US\$5 billion (2013 estimate) MDx market. The MDx market is estimated to be one of the fastest growing segments of the US\$53 billion (2013 estimate) IVD market. For further information, see "Industry".

Biocartis's market opportunity is driven by an increasing use of MDx in the management of cancer, infectious diseases, and other severe conditions and, in particular, the growing adoption of personalised medicine that requires advanced diagnostics tests to be carried out rapidly and cost effectively enabling key clinical decisions to be made on a timely basis. Currently, most clinical molecular testing involves a series of complex, labour intensive, time-consuming and relatively costly steps (each of which needs to be conducted in a specialised, dedicated laboratory environment), including the preparation of clinical samples, isolation of human or pathogenic genetic material (such as DNA) from the sample, amplification, detection and quantification of this genetic material, and result delivery and interpretation. Biocartis's Idylla™ platform fully automates these otherwise complex and costly steps, enabling low- to mid-volume, high clinical value molecular testing to take place at the point-of-need. Biocartis focuses on assays in the fields of oncology and infectious diseases, the two largest application areas for MDx. Disease areas with significant unmet needs and/or characterised by high prevalence, and where management believes the Idylla™ solution can make a real difference by virtue of its unique features.

The Idylla™ platform, launched as a CE-marked product in September 2014, is a fully-automated, real-time polymerase chain reaction ("PCR") based MDx system, designed to offer physicians fast access to highly reliable MDx information. The Idylla™ platform comprises three components: the console, the instrument and the cartridge. All cartridges share a common design, but are made application-specific for each assay by their reagent content, assay execution protocol (software), and labelling.

Biocartis is developing a broad menu of assays for use with the Idylla™ platform. Biocartis intends to launch at least four to five new assays per year, complemented by additional assays developed in conjunction with its partners, including J&J and Abbott Molecular.

To date, Biocartis has primarily funded its operations through:

- €181.4 million from specialist private equity investors, strategic investors and private companies;
- €10.0 million from subsidised loans from the Flemish investment institution ParticipatieMaatschappij Vlaanderen NV ("PMV") and the Dutch government agency Senter Novem ("Senter Novem");
- €7.9 million from proceeds of a sale and lease back transaction with KBC Lease Belgium NV;
- €26.2 million in upfront licensing fees and milestone payments; and

- €13.2 million of grants received from the Flemish government, the Dutch government, the European Commission and other grant bodies.

From 1 January 2012 through 31 December 2014, Biocartis incurred €86.8 million in research and development expenses associated with the Idylla™ platform and its accessory technologies, €4.9 million in marketing and distribution expenses, €20.6 million in general and administrative expenses and €7.4 million in costs of goods sold. As of 31 December 2014, Biocartis held €10.9 million in cash and cash equivalents. As of 31 March 2015, Biocartis held €35.5 million in cash and cash equivalents.

### **Factors affecting the results of operations**

Going forward the financial and operational performance of Biocartis is dependent on the successful and timely commercialisation of its Idylla™ platform and the development and deployment of its menu of assays.

Set forth below is a discussion of factors that management believes will materially impact the results of Biocartis in future periods.

### **Revenues**

To date, revenues of Biocartis have been generated primarily from product sales, collaboration revenues, grants and other income.

- Product sales relate to sales of Idylla™ instruments and consoles as well as Idylla™ cartridges to customers and collaboration partners.
- Collaboration revenues include revenues corresponding to certain research and development services, licence fees and milestone payments.
- Biocartis's revenues also include several grants received from the Flemish Government for research and development projects, for strategic investment and for training support.

Product sales became the biggest part of operating income of Biocartis in 2014, with an incremental increase in product sales in the fourth quarter after the commercial launch. Prior to the commercial launch in September 2014, sales were for research and development purposes. In the future, Biocartis will mainly seek to generate revenues from a combination of direct sales of Idylla™ consoles, instruments and its proprietary assays, of royalties on Idylla™ assay sales from its partners and of sales of consoles, instruments and cartridges to its partners. In addition, Biocartis intends to generate revenues from new collaborations and from existing and new grants and other subsidised funding.

Biocartis expects that its future revenue will increase annually driven by the commercial roll-out of Idylla™ platform and compatible assays.

### **Research and development expenses**

Biocartis's research and development expenses mainly reflect salaries of research and development personnel and the costs of certain outsourced research and development services, working on (i) manufacturing, engineering and operations not included in the cost of goods sold, (ii) research and development programmes focused on the expansion of the assay menu and (iii) system engineering. It also includes the costs of reagents and assay cartridges that are used in the research and development of assays and other experiments with either of Biocartis's platforms or technologies, costs of consultants, as well as expenses related to quality assurance, clinical, regulatory and medical affairs, ICT applications, and to filing new patents and maintaining Biocartis's intellectual property. Finally, it also includes the annual depreciation expenses related to production equipment, laboratory and engineering equipment, capitalised instruments and consoles for internal use, amortisation of intangible fixed assets such as technology licences acquired from third parties and for software, as well as depreciation related to the share of Biocartis's offices and facilities used in research and development activities.

Biocartis expenses all costs associated with its research and development as they are incurred.

To date, research and development costs have mainly consisted of the development of the Idylla™ platform and associated assays along with other pipeline products. The Idylla™ platform has been the largest proportional expense to date. With the commercial launch of the Idylla™ platform in September 2014, the emphasis of research and development expenditure has shifted primarily to further assay development as Biocartis intends to launch at least four to five new assays per year and, to a lesser extent, other complementary pipeline products, including Idylla™—Enrich which is a dedicated pre-enrichment platform for bloodstream infections, intended to be used in conjunction with an accompanying sepsis assay compatible with the Idylla™ platform. For further information, see “*Business—Future developments—Idylla™—Enrich, a product line extension of the Idylla™ platform*”.

### ***Marketing and distribution expenses***

The principal components of marketing and distribution expenses include staff costs (20 employees as at 31 December 2014), subcontracting, business development, and travel, training, office and other. Prior to 2014, Biocartis incurred limited marketing and distribution expenses, as operations were in a pre-commercial phase. Marketing and distribution expenses increased in 2014 in connection with the commercial launch of the Idylla™ platform. Biocartis expects to increase sales and marketing expenses to support the expanded commercial roll-out of the Idylla™ platform. Biocartis expects to increase its marketing and distribution staff from 20 at the year end 2014 to approximately 30 by the end of 2015.

### ***General and administrative expenses***

The principal components of general and administrative expenses are salaries and related costs for personnel in executive, finance, accounting, tax, audit, legal and human resources functions and their respective external advisers. Moreover, it includes the costs related to the general information and communication technologies as well as lease, rental and utilities expenses. General and administrative expenses are expected to increase with the expansion of Biocartis’s activities. General and administrative expenses are also expected to increase with the additional responsibilities related to becoming a listed entity and in line with the growth of the business.

### ***Costs of goods sold***

Costs of goods sold primarily comprises staff costs and materials, and to lesser extent related depreciation and amortization, royalty expense, lab consumables and small equipment, rent and licenses. Biocartis incurred €7.4 million in costs of goods sold in the three years ended 31 December 2014, while prior to 2012 production activity was still an integral part of the research and development expenses.

### ***Taxation***

Since its inception in 2007, Biocartis has not made profits and, as a result, has not paid corporate income taxes. Its accumulated losses totalled €86.8 million as of 31 December 2014. Losses may be carried forward over an unlimited period in time for the Belgian portion of the tax losses (€34.6 million) and for a maximum of seven years for the Swiss portion of the tax losses (€51.2 million), and may be generally used to offset future profits if and when they are made during the respective period. The Swiss tax losses have expiration dates between 2019 and 2020.

In 2014, Biocartis NV, a wholly owned consolidated subsidiary of the Issuer, obtained a tax ruling from the Belgian ruling commission with respect to the application of the Belgian patent income deduction regime. The respective ruling relates to five consecutive accounting years, starting as of 2015. Subject to the applicable rules, Biocartis NV will be able to deduct 80% of the respective qualifying patent income from its taxable basis, resulting in an effective tax rate of maximum 6.8% on the respective qualifying patent income.

### ***Analysis of operating results***

The following table includes information relating to Biocartis’s results for the years ended 31 December 2014, 2013 and 2012.

## Statement of comprehensive income

	Year ended 31 December		
	2014	2013	2012
	<i>(in €000)</i>		
<b>Revenue</b>			
Collaboration revenue	3,218	6,247	2,102
Product sales revenue	5,260	2,086	1,449
	<b>8,478</b>	<b>8,333</b>	<b>3,551</b>
<b>Other operating income</b>			
Grants and other income	1,889	3,504	2,632
<b>Operating expenses</b>			
Costs of goods sold	(4,251)	(1,962)	(1,168)
Research and development expenses	(25,014)	(27,838)	(33,991)
Marketing and distribution expenses	(3,095)	(1,155)	(691)
General and administrative expenses	(7,180)	(7,255)	(6,131)
	<b>(39,540)</b>	<b>(38,210)</b>	<b>(41,981)</b>
<b>Operating loss for the period</b>	<b>(29,173)</b>	<b>(26,373)</b>	<b>(35,798)</b>
Financial income	60	126	104
Financial expense	(933)	(981)	(836)
Foreign exchange gains/(losses), net	(88)	(212)	16
<b>Financial result, net</b>	<b>(961)</b>	<b>(1,067)</b>	<b>(716)</b>
<b>Loss for the year before taxes from continuing operations</b>	<b>(30,134)</b>	<b>(27,440)</b>	<b>(36,515)</b>
Income taxes	947	(2)	(4)
<b>Loss for the year after taxes from continuing operations</b>	<b>(29,187)</b>	<b>(27,442)</b>	<b>(36,519)</b>
Gain (loss) for the year after taxes from discontinued operations	19,472	(8,178)	(7,912)
<b>Loss for the year</b>	<b>(9,715)</b>	<b>(35,620)</b>	<b>(44,431)</b>
attributable to owners of the company	(9,118)	(35,620)	(44,431)
attributable to non-controlling interest	(598)	0	0

### **Revenues and other operating income**

Biocartis's total revenue and other operating income increased from €6.2 million in 2012 to €11.8 million in 2013. This increase was primarily attributable to a €4.1 million increase in collaboration revenues. In addition, Biocartis had a €0.6 million increase in product sales and a €0.9 million increase in grants and other income.

Total revenue and other operating income decreased from €11.8 million in 2013 to €10.4 million in 2014. Operating income decreased in 2014 due to a decrease in collaboration revenues and grants and other income, partially offset by growth in product sales in 2014.

Biocartis recognised revenues from two customers representing at least 10% of the total revenues. One of these customers (US) accounted for €1.2 million, €3.7 million and €8.4 million in 2012, 2013 and 2014, respectively, while the other customer (France) accounted for €2.3 million, €4.6 million and no revenues in 2012, 2013 and 2014, respectively.

### **Collaboration revenues**

Biocartis's collaboration revenues have been derived from its research and development services, licence fees and milestone payments.

Research and development services decreased from €815 thousand in 2012 to €226 thousand in 2013, then increased to €271 thousand in 2014.

Licence fees changed from €1.3 million in 2012 to €4.0 million in 2013 to €1.9 million in 2014. Licence fees are primarily related to the recognition of deferred upfront payments received from partners.

In addition, Biocartis received milestone payments of €2.0 million and €1.0 million which were recognised in 2013 and 2014, respectively.

### **Product sales revenue**

Product sales revenue comprises sales of Idylla™ consoles and instruments as well as Idylla™ cartridges to customers and collaboration partners. Product sales revenue can be categorised as either revenue from in vitro diagnostics sales or sales for research and development purposes. Product sales revenue increased from €1.4 million in 2012 to €2.1 million in 2013 to €5.3 million in 2014. In 2012 and 2013 and prior to September 2014 sales related only to sales of cartridges, instruments and consoles to collaboration partners for research and development purposes. Biocartis received its first revenues from in vitro diagnostic sales in amount of €2.0 million in 2014.

Prior to September 2014, sales related to sales to collaboration partners (J&J and Biomérieux) for research and development purposes, Biocartis has sold its products to date primarily to customers with parent companies in the United States and France.

Product sales consist of system (instruments and consoles) and cartridge sales. System sales increased from €0.3 million in 2012 to €0.5 million in 2013 to €3.7 million in 2014; sales of cartridges remained relatively flat at €1.2 million, €1.6 million and €1.5 million in 2012, 2013 and 2014.

### **Grants and other income**

Grants and other income changed from €2.6 million in 2012 to €3.5 million in 2013 to €1.9 million in 2014 due to corresponding changes in research and development project support, strategic investments and training support and other revenues.

Biocartis received four grants for research and development projects from the Flemish Government and recognised €1.3 million, €1.7 million and €1.5 million in 2012, 2013 and 2014, respectively. These grants were provided for the development of Idylla™ platform and oncology assays as well as hyperplexing technologies and feasibility studies.

Biocartis also received two grants from the Flemish Agency of Entrepreneurship (Hermes) for the strategic and training support and recognised €900 thousand and €1.4 million of these grants in 2012 and 2013, respectively.

The other income remained relatively stable from 2012 to 2014, increasing from €400 thousand in 2012 to €491 thousand in 2013 and decreasing to €407 thousand in 2014.

### **Costs of goods sold**

Costs of goods sold increased from €1.2 million in 2012 to €2.0 million in 2013 and again to €4.3 million in 2014, primarily as a result of increases in each of staff costs and materials as more systems were sold to collaboration partners (prior to commercial launch in September 2014) and to collaboration partners and customers following commercial launch.

### **Research and development expenses**

The table below provides a breakdown of Biocartis's research and development expenses:

	Year ended 31 December		
	2014	2013	2012
	<i>(in €000)</i>		
Staff costs . . . . .	(12,634)	(10,948)	(8,208)
Subcontracting . . . . .	(4,031)	(7,371)	(16,692)
Laboratory expenses . . . . .	(1,385)	(932)	(934)
Cartridge, instrument and consoles . . . . .	(350)	(2,163)	(3,219)
Consultancy . . . . .	(968)	(2,136)	(586)
Quality and regulatory . . . . .	(95)	(249)	(182)
Intellectual property . . . . .	(782)	(470)	(855)
Facilities . . . . .	(1,003)	(878)	(766)
Travel, training, office and other . . . . .	(1,503)	(1,114)	(576)
Depreciation and amortisation . . . . .	(3,336)	(2,425)	(1,972)
Internally capitalised instruments . . . . .	1,072	847	0
<b>Total . . . . .</b>	<b>(25,014)</b>	<b>(27,838)</b>	<b>(33,991)</b>

Total research and development expenses decreased from €34.0 million in 2012 to €27.8 million in 2013 to €25.0 million in 2014 as the Idylla™ platform passed the design freeze and verification phases and moved into commercialisation in 2014.

Staff costs over the periods under review increased from €8.2 million in 2012, to €10.9 million in 2013 to €12.6 million in 2014, while subcontracting costs decreased from €16.7 million to €7.4 million to €4.0 million during the same periods. This reflects the shift from subcontracting of various research and development activities to increasingly in-house development by Biocartis's own professional staff.

Laboratory expenses, flat in 2012 and 2013 at €934 thousand and €932 thousand, respectively, increased to €1.4 million in 2014 as a result of the increased focus on assay development activities.

Expenses related to cartridges, instruments and consoles decreased from €3.2 million in 2012 to €2.2 million in 2013 to €350 thousand in 2014 as a result of the transition of prototype test to robust industrial materials that are being capitalised as assets. In addition in 2014 Biocartis internally capitalised instruments of €1.0 million as a result of the establishment of an installed base of instruments and consoles destined for continued internal use.

Consultancy expenses increased from €586 thousand in 2012 to €2.1 million in 2013 as a result of the need for highly specialised expertise during the final phases of the Idylla™ platform development. This amount declined again to €968 thousand in 2014 as a result of the completion of the Idylla™ platform development.

The other research and development expenses increased from €4.4 million in 2012 to €5.1 million in 2013 to €6.7 million in 2014.

#### ***Marketing and distribution expenses***

Marketing and distribution expenses increased over the periods under review from €691 thousand in 2012 to €1.2 million in 2013 to €3.1 million in 2014. This growth is primarily linked with the commercial roll-out of the Idylla™ platform in September 2014, and particularly with the growth in staff costs in 2014 to €2.0 million (compared to €364 thousand in 2012 and €757 thousand in 2013) and €302 thousand in subcontracting expenses (previously nil). Biocartis expects to increase these costs to support the expanded commercial roll out of the Idylla™ platform.

#### ***General and administrative expenses***

General and administrative expenses increased from €6.1 million in 2012 to €7.3 million in 2013 and €7.2 million in 2014 as a result of the growth in its overall activities and headcount. General and administrative headcount increased from 19 FTEs as of 31 December 2012 to 24 FTE's as of 31 December 2014.

#### ***Operating loss***

As a result of the foregoing, the operating loss decreased from €35.8 million in 2012 to €26.4 million in 2013 and increased to €29.2 million in 2014.

#### ***Net financial result***

Financial result (net) arises principally from interest earned on cash invested and cash equivalent investments from deposit accounts at market rates as well as from interest payable on Biocartis's borrowings and from net foreign exchange gains/losses. The financial result remained relatively stable over the periods under review, slightly increasing from a net financial loss of €0.7 million in 2012 to a net financial loss of €1.1 million in 2013 and decreasing to a net financial loss of €1.0 million in 2014, which corresponds to higher interest expense on certain loans and foreign exchange losses. These fluctuations also reflect changes in the mix of financial instruments.

***Loss before taxes (from continuing operations)***

As a result of the foregoing, the loss before tax decreased from €36.5 million in 2012 to €27.4 million in 2013 and increased to €30.1 million in 2014.

***Income tax expense***

As Biocartis incurred losses in all of the relevant periods, it had no taxable income and therefore incurred no taxes. In 2014, Biocartis has research and development tax credit carry-forwards in Belgium for a total amount of €947 thousand.

***Gain (loss) for the year after taxes from discontinued operations***

On 11 November 2014, Biocartis S.A. finalised the spin off of its former Evaluation™ business into a separate company called "MyCartis NV" in order to enable Biocartis to focus on the Idylla™ platform. Prior to November 2014, Biocartis has been developing a separate life sciences multiplex platform, called Evaluation™. The gain after taxes from discontinued operations amounted to €19.5 million in 2014. For further information on the spin off, see Note 3.12 to the Financial Statements.

***Loss for the year***

As a result of the foregoing, the loss incurred by Biocartis decreased from €44.4 million in 2012 to €35.6 million in 2013 to €9.7 million in 2014.



## Balance sheet data

The following table sets forth selected balance sheet data of Biocartis for the years ended 31 December 2014, 2013 and 2012.

	As at 31 December		
	2014	2013	2012
		(in €000)	
<b>Assets</b>			
<b>Non-current assets</b>			
Intangible assets	9,652	9,985	10,278
Property, plant and equipment	9,154	11,199	10,994
Participating interests	0	245	0
Other long term receivables	117	107	106
Deferred tax assets	947	0	0
	<b>19,870</b>	<b>21,536</b>	<b>21,378</b>
<b>Current assets</b>			
Inventory	3,583	1,116	183
Trade receivables	15,793	3,082	1,442
Other receivables	148	993	793
Other current assets	2,700	4,371	1,898
Cash and cash equivalents	10,919	29,047	40,494
	<b>33,142</b>	<b>38,609</b>	<b>44,810</b>
<b>Total assets</b>	<b>53,012</b>	<b>60,145</b>	<b>66,188</b>
<b>Equity and liabilities</b>			
<b>Capital and reserves</b>			
Legal share capital	222,268	926	795
Historical share capital adjustment	(221,232)	0	0
Share premium	166,592	175,946	146,394
Gains and losses on defined benefit plans	0	(309)	(379)
Share based payment reserve	1,166	1,023	0
Accumulated deficit	(148,513)	(145,631)	(110,010)
<b>Total equity attributable to the owners of the company</b>	<b>20,280</b>	<b>31,955</b>	<b>36,800</b>
<b>Non-current liabilities</b>			
Financial debt	8,528	12,822	10,089
Deferred income	4,534	1,711	5,002
Retirement benefit obligation	0	267	490
Accrued charges	1,955	1,741	2,026
	<b>15,017</b>	<b>16,541</b>	<b>17,607</b>
<b>Current liabilities</b>			
Financial debt	5,057	3,373	1,250
Trade payables	4,265	5,847	8,454
Deferred income	5,100	772	1,320
Other current liabilities	3,293	1,657	757
	<b>17,714</b>	<b>11,649</b>	<b>11,781</b>
<b>Total equity and liabilities</b>	<b>53,012</b>	<b>60,145</b>	<b>66,188</b>

## Assets

Biocartis's non-current assets consist mainly of intangible assets and tangible assets:

As at 31 December:	Intangible assets—Net book amount		
	Patents and licences	ICT and software	Total
	<i>(in €000)</i>		
2012 .....	9,856	422	<b>10,278</b>
2013 .....	9,356	629	<b>9,985</b>
2014 .....	9,223	429	<b>9,652</b>

As of 31 December 2014, Biocartis's intangible assets represent primarily the portfolio of patents and licences that Biocartis recorded pursuant to its intellectual property assignment and licensing agreement with Philips in February 2010 for €10.0 million, as well as certain software licences related to Biocartis's enterprise resource system and other software licences.

As at 31 December:	Tangible assets—Net book amount									
	ICT equipment	Laboratory equipment	Manufacturing equipment	Internally produced systems	Furniture and fixtures	Leasehold improvements	Other property and equipment	Equipment under construction	Assets held under Leases	Total
	<i>(in €000)</i>									
2012 .....	579	570	8,327	0	346	936	6	231	0	<b>10,994</b>
2013 .....	562	686	2,174	805	385	870	4	20	5,694	<b>11,199</b>
2014 .....	477	623	1,307	1,640	276	570	2	20	4,239	<b>9,154</b>

As at 31 December 2014, Biocartis's tangible assets primarily include assets held under leases, internally produced systems, manufacturing equipment, laboratory equipment, leasehold improvements and ICT equipment. Assets held under lease relate to the Idylla™ semi-automated cartridge manufacturing line which was refinanced on 8 March 2013 by KBC Lease Belgium NV. The other manufacturing equipment is related to the Idylla™ instrument and console manufacturing tooling and moulds, and the Idylla™ platform pilot line and internally produced Idylla™ instruments and consoles. Leasehold improvements mainly relate to the construction of cleanroom and warehouse facilities in Mechelen to host the cartridge manufacturing line. As at 31 December 2014 Biocartis's internally produced systems consisted of 24 Idylla™ consoles and 120 Idylla™ instruments.

As at 31 December 2014, Biocartis's current assets consisted essentially of €15.8 million of trade receivables, including €4.5 million of research and development income receivables and €11.2 million related to collaboration revenue, €10.9 million of cash and cash equivalents, €3.6 million of inventory and €2.7 million of other current assets. The €6.2 million decrease from 2012 to 2013 and the €5.5 million decrease from 2013 to 2014 were primarily related to the decrease in cash and cash equivalent partially offset by an increase in trade receivables.

## Equity

Biocartis's total equity decreased from €36.8 million as at 31 December 2012 to €32.0 million as at 31 December 2013 to €20.3 as at 31 December 2014, which primarily related to an increase of accumulated deficit from €110.0 million as at 31 December 2012 to €145.6 million as at 31 December 2013 to €148.5 million as at 31 December 2014 partially offset by changes in share premium from €146.4 million as at 31 December 2012 to €175.9 million as at 31 December 2013 to €166.6 million as at 31 December 2014. For further information on the Issuer's share capital, see "*Share Capital and Articles of Association*".

## Liabilities

As at 31 December 2014, non-current liabilities included €8.5 million borrowings. This relates to the debt of €6.7 million of the subsidised loan from PMV (€5.0 million in principal amount plus accrued interest expenses), and to €1.8 million of the €7.9 million lease from KBC Lease Belgium NV.

Biocartis's current liabilities relate primarily to trade payables from its outsourced research and development projects and indebtedness under loan agreements.

Deferred income includes a total of €9.6 million upfront fees, of which €1.7 million relates to upfront payments received in 2010 in relation to licensing, development and commercialisation collaborations, which are recognised over a 7 year period, and €7.9 million of other partner fees, which are partially recognised over 18 months and partially over 36 months.

## **Liquidity and capital resources**

### ***General***

Biocartis's liquidity requirements relate primarily to the funding of research and development expenses, marketing and distribution expenses, general and administrative expenses, capital expenditures, and working capital requirements. Historically, Biocartis was funded from equity capital, subsidised loans, licensing payments and grants. For further details, see "*—Overview*".

Following the Offering, and the application of the proceeds as described in "*Use of Proceeds*", Biocartis's principal sources of funds are expected to be cash on hand and cash generated from Biocartis's revenues.

## Cash flows

The following table includes information relating to Biocartis's cash flow statements for the years ended 31 December 2012, 2013 and 2014.

	As at 31 December		
	2014	2013	2012
	<i>(in €000)</i>		
<b>Operating activities</b>			
Loss for the period	(9,715)	(35,620)	(44,431)
<b>Adjustments for</b>			
Depreciation and amortisation	4,437	3,557	2,622
Depreciation and amortisation included in discontinued operations	81	181	156
Impairments	37	0	0
Tax income in profit and loss	(947)	0	0
Financial result, net	897	1,065	600
Net movement in retirement benefit obligation	108	(153)	25
Gain on disposal MyCartis NV	(26,624)	0	0
Share based payment expense	143	1,023	0
<b>Changes in working capital</b>			
Net movements in inventories	(2,524)	(933)	(10)
Net movement in trade and other receivables and other current assets	(2,736)	(4,313)	818
Net movement in trade payables and other current liabilities	1,860	(1,992)	244
Net movement in deferred income	(746)	(3,839)	(1,286)
Interests paid	(155)	(155)	0
<b>Cash flow from operating activities</b>	<b>(35,884)</b>	<b>(41,179)</b>	<b>(41,262)</b>
<b>Investing activities</b>			
Interest received	60	100	102
Purchases of property, plant and equipment	(1,927)	(3,138)	(7,313)
Purchases of intangible assets	(840)	(512)	(350)
Acquisition shares in other companies	0	(245)	0
Disposal shares in other companies	245	0	0
Acquisition of a subsidiary	7,514	0	0
Proceeds from sale and rent back of property, plant and equipment	0	0	1,904
<b>Cash flow from investing activities</b>	<b>5,052</b>	<b>(3,795)</b>	<b>(5,657)</b>
<b>Financing activities</b>			
Proceeds from issue of common equity shares	0	29,682	53,117
Proceeds from issue preference shares F	21,244	0	0
Proceeds from sale and lease back of property, plant and equipment	0	5,000	0
Disposal of MyCartis NV to capital owners of the parent	(5,138)	0	0
Repayment of borrowings	(3,378)	(894)	0
Bank charges	(1)	(18)	0
<b>Cash flow from financing activities</b>	<b>12,727</b>	<b>33,770</b>	<b>53,117</b>
<b>Net increase in cash and cash equivalents</b>	<b>(18,105)</b>	<b>(11,204)</b>	<b>6,198</b>
Cash and cash equivalents at the beginning of the period	29,047	40,494	34,357
Effects of exchange rate changes on the balance of cash held in foreign currencies	(23)	(243)	(61)
<b>Cash and cash equivalents at the end of the period</b>	<b>10,919</b>	<b>29,047</b>	<b>40,494</b>

**Cash flow from operating activities** represented net cash outflows of €41.3 million, €41.2 million and €35.9 million in 2012, 2013 and 2014, respectively. Over the periods under review, Biocartis's loss for the period decreased though working capital increased due to the increase in inventory and trade and other receivables.

**Cash flow from investing activities** represented net cash outflows of €5.7 million and €3.8 million in 2012 and 2013, respectively, and net cash inflow of €5.1 million in 2014. The decrease in net cash outflow in 2013 compared to 2012 resulted from the decrease in purchases of property, plant and equipment from €7.3 million to €3.1 million partially offset by the decrease in proceeds from sale and rent back of property, plant and equipment from €1.9 million to nil. A reversal from net cash outflow in 2013 to net cash inflow in 2014 resulted from recognition of a gain from an acquisition of a subsidiary of €7.5 million and the decrease in purchases of property, plant and equipment from €3.1 million to €1.9 million. For further information on the acquisition of the subsidiary, see Note 3.12 to the Financial Statements.

**Cash flow from financing activities** represented net cash inflows of €53.1 million, €33.8 million and €12.7 million in 2012, 2013 and 2014, respectively. The net cash inflows resulted from the capital increases Biocartis did as part of its equity fund raisings of €53.1 million, €29.7 million and €21.2 million in 2012, 2013 and 2014, respectively, net of direct issuance costs. In 2013, Biocartis received a €5.0 million instalment under sale and lease back arrangement with KBC Lease Belgium NV. In 2014, Biocartis repaid borrowings of €3.4 million and recognised a loss of €5.1 million from the disposal of MyCartis NV. For further information on the disposal of the subsidiary, see Note 3.12 to the Financial Statements.

### Indebtedness

Biocartis had indebtedness (including in relation to the grants and other government funding it was awarded) as follows:

	As at 31 December		
	2014	2013	2012
	<i>(in €000)</i>		
<b>Non-current</b>			
PMV .....	6,707	6,268	5,858
Senter Novem .....	0	3,566	4,226
KBC Lease .....	1,821	2,983	0
Other .....	0	5	5
<b>Total non-current</b> .....	<b>8,528</b>	<b>12,822</b>	<b>10,089</b>
Senter Novem .....	3,895	2,250	1,250
KBC Lease .....	1,161	1,123	0
<b>Total current</b> .....	<b>5,057</b>	<b>3,373</b>	<b>1,250</b>

### Contractual maturities

An analysis of maturities of Biocartis's liabilities is as follows:

As at 31 December 2014	Less than 1 month	1-3 months	3 months to 1 year	1-5 years	5+ years	Total
	<i>(in €000)</i>					
Trade payables .....	4,265	0	0	0	0	4,265
Financial debt .....	0	287	4,770	8,528	0	13,585
Other current liabilities and accrued expense .....	3,293	0	0	711	1,244	5,248
<b>Total as at 31 December 2014</b> .....	<b>7,558</b>	<b>287</b>	<b>4,770</b>	<b>9,239</b>	<b>1,244</b>	<b>23,098</b>

### Capital expenditures

The following table sets forth Biocartis's capital expenditures in property, plant and equipment for the periods under review:

	For the years ended			
	2014	2013	2012	Total
	<i>(in €000)</i>			
Manufacturing equipment .....	177	1,465	4,776	6,418
Leasehold improvements .....	90	219	1,413	1,722
Internally produced systems .....	1,072	847	0	1,919
Other equipment .....	588	607	1,124	2,319
<b>Total property, plant and equipment</b> .....	<b>1,927</b>	<b>3,138</b>	<b>7,313</b>	<b>12,378</b>

The investments in manufacturing equipment in the reported years were mainly related to the Idylla™ cartridge, instrument and console production lines, tooling, moulds and internally produced equipment. The investments in the leasehold improvements in the reported years were mainly related to the cleanroom construction to host the Idylla™ cartridge production. The investments in other equipment in the reported years were mainly related to laboratory and office equipment, ICT hardware and furniture.

Biocartis expects that its capital expenditures will increase in 2015 as a result of its further expansion of its production capabilities, its assay development activities and the growth of its selling, general and administrative functions.

#### **Disclosures about currency, interest rate, credit and market risk**

Currently Biocartis's foreign currency risk is limited in size and scope, and it has not entered into any currency hedging arrangements in order to cover its currency exposure. In the future Biocartis may receive more material revenues in foreign currencies and as such its currency hedging policy may change. See *"Risk factors—Changes in currency exchange rates could have a material negative impact on the profitability of Biocartis."*

Biocartis has limited interest rate risk as it has only a small amount of borrowings, and these borrowings have fixed interest rates.

Management also believes that its credit risk relating to receivables is limited given the creditworthiness of its counterparties, primarily J&J, none of which are impaired or overdue.

For further information on "Market risk", see Note 3.27.3 to the Financial Statements.

#### **Critical accounting estimates 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 valuation and impairment of property, plant and equipment and intangible assets, the valuation and impairment of financial assets, the valuation of the share-based payment transactions, the valuation of employee benefits and actuarial assumptions underlying such calculations and the valuation of deferred tax assets. 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 future consolidated financial statements. These critical accounting estimates and assumptions are discussed below. In addition, investors should refer particularly to Note 3.2.1 to the Financial Statements, which notes that the financial statements have been established on a "going concern" basis and the implications thereof, as well as to *"Capitalisation and indebtedness—Working capital statement"* and the disclosures related thereto elsewhere in this Prospectus.

#### **Estimations of post-employment benefit obligations**

Biocartis 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 3.22 of the Financial Statements. The defined benefit pension plan was disposed of with the sale of the Evaluation™ business to MyCartis NV.

The Belgian defined contribution pension plans are by law subject to minimum guaranteed rates of return, currently 3.25% on employer contributions and 3.75% on employee contributions. These rates, which apply as an average over the entire career, may be modified by a Royal Decree in which case the new rates apply to both the accumulated past contributions as

from the date of modification onwards. In theory these plans qualify as defined benefit plans. However, when taking into account the historical discussions on how to account for these specific type of plans where the contributions paid are subject to a minimum guaranteed return at the level of IFRIC, management believes the application of the projected unit credit method to these plans is troublesome and will not provide a faithful representation of the liability with respect to these promises.

Therefore, Biocartis accounts for those plans as a defined contribution plan, and at each reporting date, compares the “walk away liability” or the vested rights at reporting date with the fair value of the plan assets. If the vested rights are higher as compared to the fair value of the plan asset, a provision is recognised for the shortage.

### ***Share-based payments***

Biocartis has several equity-settled shared 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 grant. 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 3.20 to the Financial Statements.

### ***Deferred tax assets***

Deferred tax assets are recognised for unused tax losses and deductible temporary differences to the extent that it is probable that taxable profit will be available against which the losses can be utilised. Significant management judgment is required to determine the amount of deferred tax assets that can be recognised, based upon the likely timing and the level of future taxable profits together with future tax planning strategies.

Biocartis had as of 31 December 2014 €86.8 million of tax losses carry forwards. Losses for a total of €51.2 million related to Biocartis S.A. and have expiration dates between 2019 and 2020. Losses for a total of €34.6 million related to the Belgian subsidiary have no expiration dates. Biocartis assessed that it does not meet the recognition criteria as it is not probable that those tax loss carry forward will be utilised in the near future.

Biocartis also has research and development tax credit carry-forwards in Belgium for a total amount of €947 thousand for which a deferred tax asset has been recognised in 2014 as the recognition criteria are met.

Further details on taxes are disclosed in Note 3.26 to the Financial Statements.

### ***Recognition of development costs as intangible assets***

Consistent with what it believes to be industry practice, management concluded that development costs incurred do not meet the recognition conditions until the regulatory procedures required by healthcare authorities have been finalised.

### ***Revenue recognition***

For revenue recognition, the significant estimates and judgments relate to allocation of value to the separate elements in our multiple-element arrangements. With respect to the allocation of value to the separate elements, Biocartis is using the stand-alone selling prices or management 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.

Management has signed an amended development and licence agreement during 2014 with a partner which includes the following elements: development services, distribution rights, sale of instruments, consoles and cartridges. Biocartis has determined that the several elements of the agreement represent management's best estimate of selling price to determine fair value of each separate element. As such, an upfront payment received to prioritise the development of the prototype Ebola assay was recognised in full during 2014 as the development of the prototype Ebola assay was completed prior to year-end. Fees of €7.9 million from a partner in relation to the development of a future assay, the right to distribute such assay and the right to purchase instruments, consoles and cartridges were deferred in full at the end of 2014.

### **Off-balance sheet transactions**

As set forth in Notes 3.31.1 and 3.31.2 to the Financial Statements, Biocartis (as a group) has a number of commitments in relation to investments in leasehold improvements and property, plant and equipment, and has entered into a number of operating leases in relation with its building facilities as well as in relation to employee cars. Other than the foregoing, during the years ended 31 December 2014, 2013 and 2012 and as of the date of this Prospectus, the Biocartis group did not have any material off-balance sheet transaction, defined as assets or debts that do not appear on the Biocartis group balance sheet but that are considered as firm, non-cancellable commitments such as long term maintenance and service contracts, financing commitments or financial obligations of unconsolidated subsidiaries

### **Events after the statement of financial position**

On 15 January 2015, Biocartis received €21.5 million as the second tranche of €64.5 million series F-round against an issuance of 2,519,855 new Preferred F shares at a price of €8.5373 each. The issuance of the shares by Biocartis Group NV was completed on 15 January 2015 as part of the second tranche of series F-round.

Debiopharm Diagnostics has, by virtue of a letter dated 11 December 2014 exercised its put option on shares of MyCartis NV, as provided for in the put option agreement dated 25 August 2014, as restated and amended on 25 November 2014.

On 15 January 2015, Biocartis established an option plan, pursuant to which an additional 217,934 options were issued. This plan was cancelled on 13 April 2015 and replaced by a new stock option plan (the "**2015 Plan**") in relation to 262,934 new shares. Each option entitles its holder to subscribe to one ordinary share of Biocartis. See also "*Management and corporate governance—Description of share plans—2015 Plan*".

In execution of a decision of the board of directors of Biocartis S.A. of 24 April 2014, 100,000 options on shares of the Issuer were granted by Biocartis S.A. 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 Issuer and the Issuer's shares instead of shares in Biocartis S.A. The options, called "*WHC Warrants*", were formally granted by an award letter on 14 April 2015. For further information, see also "*Share capital and articles of association—Outstanding warrants—Whitemarsh capital warrants*".

Between 1 January and 31 March 2015, Biocartis sold an additional 5 instruments. Further, an additional 7 distributor agreements have been signed, representing commitments by distributors to buy at least 76 instruments over the next three years, and bringing the total of such commitments to 127. For further information, see also "*Business—Customers, marketing and sales—Channels to market*".



## INDUSTRY

### Overview

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 disease predisposition, presence 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 predisposition, point to the early development of a disease (possibly before symptoms are apparent), and can help better define the exact type, status or stage of a disease, or help care providers select drugs that a patient is likely to respond, to or to rule out potentially useless or harmful drugs. In particular, in the fields of oncology and infectious diseases, measuring the presence of specific biomarkers has proven of high clinical value for individual patients, since it can objectively establish the presence, type and/or state of disease and help care providers select the best combinations and duration of treatments, or predict, or monitor the clinical outcome of a treatment. MDx is the primary tool (next to immunochemistry) used to identify such biomarkers and is continuing to transform disease diagnosis and prognosis, paving the way for much more molecular-driven, high-precision personalised medicine and healthcare management.

MDx combines tools from genomics to study patterns of genetic alterations, or gene expression, in order to diagnose and monitor human diseases, including infectious diseases, oncology, pharmacogenomics and genetic disease screening. MDx technologies rely on the extraction, amplification, detection and reading of nucleic acids (such as DNA or RNA) as the basis for diagnostic assays.

### Market size and market outlook

The MDx market is estimated to be one of the fastest growing segments<sup>(1)</sup> of the approximately US\$53 billion (2013 estimate) IVD market.<sup>(2)</sup> The global MDx market is expected to grow from approximately US\$5 billion in 2013 to approximately US\$8 billion in 2018, representing a compound annual growth rate ("CAGR") of 9.7%.<sup>(3)</sup>

### By application

By application, the largest MDx segment in 2013 was infectious disease, representing 45.3% of the MDx market, followed by oncology (14.5%), blood screening (14.3%), genetics (9.4%), microbiology (9.1%) and others (7.4%).<sup>(4)</sup> Biocartis focuses on assays in the two largest fields: infectious diseases and oncology.

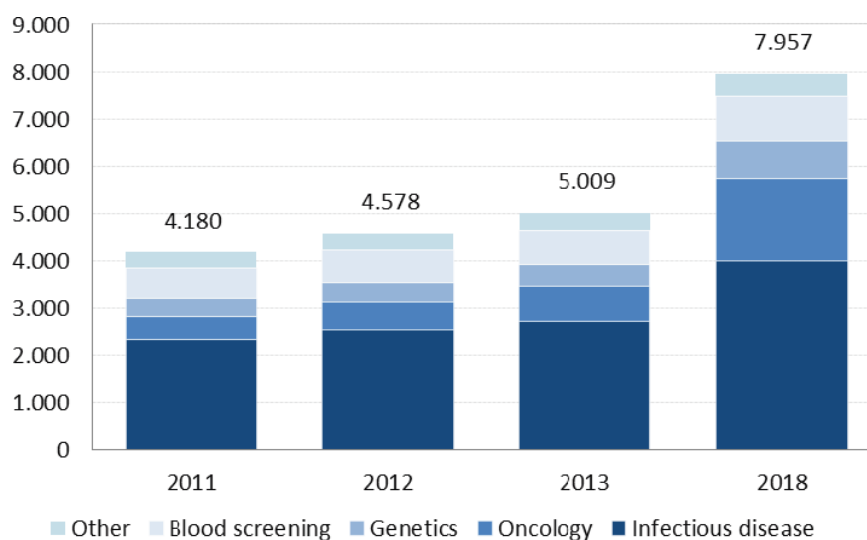
The world is facing an increasing frequency of outbreaks of infectious diseases, whose reach has expanded as a result of frequent international travel. Viral and bacterial pathogen vectors move into new geographies as a result of climate change and international travel and trade. In addition, as stated in the global surveillance report by the World Health Organization, there is a global crisis in antibiotic resistance as a result of decades of inappropriate use of these lifesaving drugs.<sup>(5)</sup> As there is a more than two decade gap in the successful discovery and development of new antibiotic classes to target bacteria and fungi that have become resistant to existing agents, regulatory authorities have recently started with incentive programmes to stimulate industry to re-engage in the development of novel species-specific antibiotics, such as the Longitude Prize, developed and run by Nesta, the United Kingdom's innovation foundation.<sup>(6)</sup> Such species-specific antibiotics require rapid and accurate diagnostic tools to drive therapy decisions.

As a result of the foregoing and as modern molecular tests offer considerable advantages over traditional methods of pathogen detection (such as microbiological blood culture), the MDx infectious disease segment is expected to continue to dominate the MDx market and to grow with a CAGR of 7.6% in the period 2013-2018.<sup>(7)</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 assays (i.e., "syndromic panels") are expected to continue to drive growth and the adoption of MDx in decentralised settings.

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 National Institutes of Health (“NIH”) estimated the overall costs associated with cancer in 2009 in the United States were US\$217 billion.<sup>(8)</sup> In a 2012 report, the association of Pharmaceutical Research and Manufacturers of America described nearly 1,000 experimental cancer therapies and vaccines to be under clinical development.<sup>(9)</sup> Many cancer therapies include a diagnostic component.<sup>(10)</sup> In 2013, 18.5% of all FDA approved new molecular entities were approved with associated biomarkers.<sup>(11)</sup> The global market for companion diagnostics is estimated to grow with a CAGR of 17.9% through 2019.<sup>(12)</sup> Oncology drugs have the highest share in the companion diagnostics market, with approximately 95% of companion diagnostics sales related to an oncology indication, and oncology is currently the leading indication for pipeline drug-diagnostic combinations.<sup>(13)</sup> Industry experts believe that in the coming decade the vast majority of new drugs in development will require an associated diagnostic test. This acceleration in the development of companion diagnostics for oncology is one of multiple push-pull factors driving a more personalised medicine for oncology. Biomarker discovery is similarly critical for prognostic and monitoring use.

As a result of the foregoing, oncology, the second largest MDx segment in 2013, is expected to show the highest growth rate, resulting in a CAGR of 19.2% in the period 2013-2018.<sup>(14)</sup> However, this market share estimate (corresponding to a 2013 market size of US\$726 million) only takes into account IVD-labelled assays sold by IVD companies. It does not include the significant proportion of service testing and assays which are currently still performed with in-house non-standardised and mostly unregistered protocols, generally referred to as “homebrew tests” or laboratory developed tests (“LDTs”) that, although used for clinical diagnostic purposes, to a large extent make use of research use only kits and/or single reagents.

*Development Molecular Diagnostics Market by Application (in US\$ billions)<sup>(15)</sup>*



### **By geography**

Geographically, the MDx market is currently broadly divided, with North America having approximately a 45-50% share, Europe a 25-28% share and Asia a 15-17% share in 2013.<sup>(16)</sup>

North America is expected to grow at a CAGR of 9% in the period 2013-2018 and is expected to continue to be the largest MDx market as a result of high awareness and growing acceptance of personalised medicine, as well as the rising incidence of chronic diseases and the availability of various payment schemes for these tests. Europe is expected to show similar growth at a CAGR of 8.6% in the period 2013-2018, despite modest economic growth and related investments in capital equipment. Asia is expected to show the highest growth at 12.2% CAGR 2013-2018 due to enhanced purchasing power, improved healthcare systems and an increased focus on health.<sup>(17)</sup>

### ***By customer***

Molecular testing, until recently limited to only large, high-complexity laboratories staffed with highly trained individuals, is migrating to routine hospital laboratories with less skilled labour as new automated MDx platforms simplify testing procedures. Hospital-based and reference laboratories were the major end-users of molecular tests globally and, collectively, held 90% of the market in 2013, with hospitals accounting for a dominant share at 55%.<sup>(18)</sup> Management expects, in the not too distant future, MDx tests to be performed at the hospital bedside or in a doctor's office, as the features of such platforms allow testing in such settings.

### ***By technology***

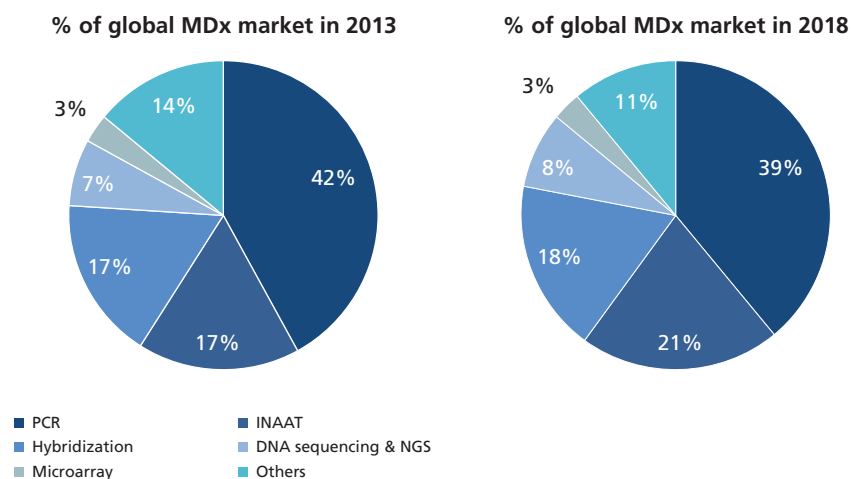
In terms of technology employed, the MDx market can be divided into PCR-based, which is the technology employed by Biocartis and which constituted 42% of the global MDx market in 2013, followed by isothermal nucleic acid amplification technology ("INAAT") (17%), hybridisation (also referred to as in situ hybridisation and fluorescence in situ hybridisation, or "FISH") (17%), DNA sequencing/next generation sequencing ("NGS") (7%) and others.<sup>(19)</sup>

PCR is a well-established and versatile technology that laid the basis for the MDx field. Its success stems from the sensitivity and specificity by which it allows the detection and quantification of nucleic-acid targets. PCR is an exponential sequence-specific amplification methodology, wherein specific genomic regions are copied billion-fold in a very short timeframe (typically within one hour). Most PCR approaches require prior knowledge of the nucleic acid sequence of interest.

NGS is widely regarded as a potentially transformative diagnostic tool. Driven by the US\$1,000 human genome race and large genome-wide studies, over recent years there has been a significant reduction in the cost of NGS technology to quickly sequence whole genomes. However, the cost reductions achieved have come at the cost of flexibility and cost-effective analysis of individual clinical samples. Whereas the adoption of NGS technology can be expected in major reference and clinical centres, several factors still hamper wider global adoption, in particular in the community hospital and decentralised healthcare settings. NGS has a very complex workflow, and processes are lengthy, require specialised skills, extensive laboratory infrastructure and have not yet achieved a high level of automation, let alone full integration. For use in high sensitivity mutation detection, NGS has a poor reproducibility, which makes it less suitable for routine diagnostic use. In addition, NGS produces huge amounts of data which need to be analysed correctly. Furthermore, current NGS systems require significant capital investments, although further technological development is likely to result in price decreases. As a result of the foregoing, management expects NGS to be complementary to PCR. Whereas NGS is expected to be used to identify a driver mutation, management expects PCR to be used for confirmatory and monitoring tests alongside decentralised testing, especially for applications where time to result is critical (such as infectious diseases).

The PCR market is expected to continue to maintain the largest share of the MDx market through to at least 2018, by which time the PCR market is estimated to be worth over US\$3 billion.<sup>(20)</sup>

*Expected development of technologies within global molecular diagnostics market<sup>(21)</sup>*



### Market dynamics

A number of key trends and drivers are expected to converge and lead to accelerated development of assays and diagnostic technologies, further expanding the MDx 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 precise molecular biomarker-assisted tailored treatment, personalised medicine, driven by a better understanding of diseases, health economic studies, access to advanced technologies and better informed patients. This move towards personalised medicine was highlighted in US President Obama’s State of the Union Address, given in January 2015, announcing the administration’s “Precision Medicine Initiative”, described as a “new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients”, and reflected in a budget proposal for research initiatives and regulatory modernisation to support personalised medicine.

This shift to more tailored therapies based on personalised medicine has also resulted in a paradigm shift from diagnostics that traditionally helped to confirm/screen the presence of a disease, towards testing specific biomarkers that are able to predict the risk of developing a certain disease, its course and response to a specific drug treatment (companion diagnostics). For instance, today, cancer drugs are increasingly twinned with a diagnostic test that can determine whether a patient will respond to the drug based on the tumour’s genetic characteristics. Several cancer drugs—crizotinib (Xalkori®, Pfizer), vemurafenib (Zelboraf®, Roche), dabrafenib (Tafinlar®, GlaxoSmithKline), and trametinib (Mekinist®, GlaxoSmithKline)—have each been approved for use in patients whose tumours have specific genetic characteristics that are identified by a companion diagnostic test. These exemplify how diagnostics can rule out non-responders and prevent spending on ineffective and potentially harmful therapies, enhancing judicious use of medical care.

The rise of personalised medicine is expected to result in increased demand for diagnostic tests and/or companion diagnostics at throughput rates that correspond to smaller volumes of patient-specific or treatment-specific individual situations. Key to the success of this more personalised medicine is the practical implementation of high quality, standardised and validated tests to be made available to physicians who intend to use these results for targeted therapies.

- Enhanced biomarker identification and molecular techniques:** Certain key scientific developments over the last decade, particularly the rise of NGS, have significantly accelerated biomarker discovery in clinical research, the elucidation 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:** The continuing trend towards personalised medicine has led to the realisation that accurate diagnostic information needs to be made available in a timely manner; creating a pull towards near-patient testing and away from testing by the 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:** Faced with rising healthcare costs (among other factors, due to a globally ageing population and increasing survival rates) and budget constraints, a more intelligent approach towards patient care is required to optimise the use of healthcare resources. MDx provide physicians with more and better information, enhancing their 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.

### Considerations regarding competing MDx testing solutions

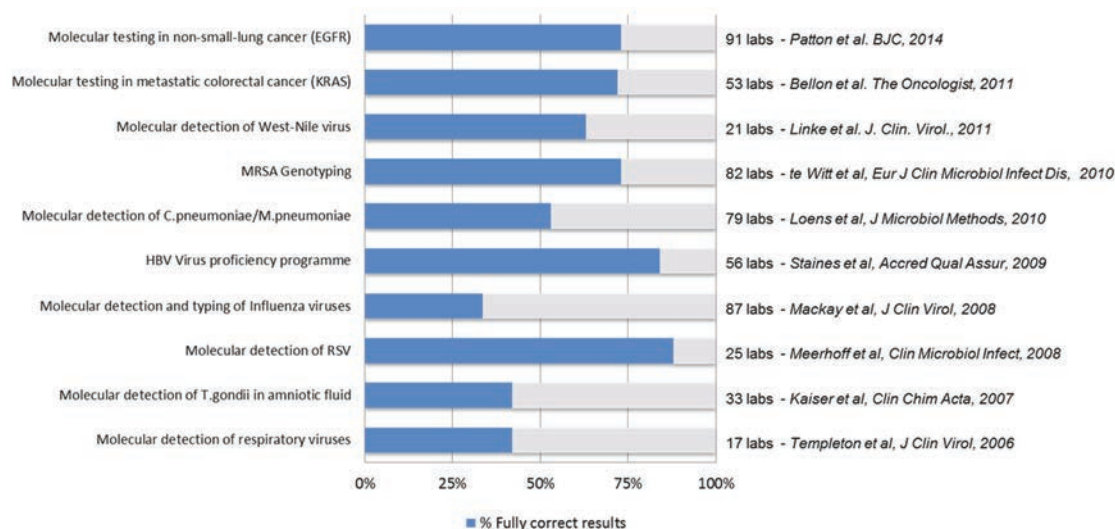
Clinical molecular testing currently involves a series of complex, labour intensive and relatively costly steps, including preparation of clinical samples, isolation of human or pathogenic genetic material, such as DNA, from the sample, amplification, detection and quantification of this genetic material, and result delivery and interpretation. A significant driver for the trend towards automated sample-to-result MDx systems is that most current solutions are either high volume robotic systems, or solutions that are derived from “open” life science research instruments. Both require a significant amount of manual labour in an expert laboratory setting with highly trained personnel. Furthermore, laboratory infrastructure requires significant investments, which proves to be cost-prohibitive for many hospitals. Management estimates that only 10%-20% of Western hospitals are currently sophisticated and large enough to accommodate molecular testing in-house, and the majority of hospitals and doctors send out their samples for external testing to specialised centralised MDx laboratories.

The need for more automated MDx systems is further increased by a growing shortage of skilled laboratory technicians. The laboratory technician workforce is confronted with fast average ageing, expensive training, high stress levels, exposure to dangerous pathogens or chemicals and rapid turnover, as experienced employees are attracted by higher salaries in other life science related organisations.<sup>(22)</sup> Therefore, in order to address the growing demand for molecular information, much smarter sample-to-result MDx systems are needed.

Furthermore, many assays are currently still performed as LDTs, either in-house or in commercial service laboratories. Reproducibility between LDTs is often poor due to differences in methodology (e.g., pre-analytical sample preparation variations, assay designs, reagent quality and stability) and by user-induced variability. Numerous so-called “proficiency” studies, whereby samples are “subdivided” and each “sub sample” is sent to ISO certified laboratories and laboratories certified in accordance with the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”), have shown that, depending on the study and diagnostic target, between 2% and 65% of such laboratories reported erroneous first results.<sup>(23)</sup> A recent study in 91 laboratories over 30 countries concluded that up to 28% of EGFR mutation testing was erroneous.<sup>(24)</sup> In the long run, management believes LDTs are not sustainable and the need for standardisation is evident. CLIA laboratories using LDTs can have problems with respect to pre-analytical processes,

methods validation, interpretation of raw data, assay limitation analysis, sample contamination, and assay design. Given the often poor reproducibility of LDT results, and as diagnostic results increasingly play a pivotal role in clinical treatment decisions and impact the management of disease and health, it is likely that many diagnostic systems and tests will be subject to higher regulatory scrutiny all over the world, creating a more level playing field.

### Overview of multi-lab proficiency studies showing poor accuracy and reproducibility of lab-developed testing



The MDx solutions and testing technologies required to automate low-volume, high clinical value MDx assays at or close to the point of clinical decision are in many respects different from the solutions for the current high volume test settings. In light of the competing offerings' limitations, management believes that there is a need for integrated, automated technologies that would enable low-volume, high clinical value assays to take place at the point-of-need.

### Biocartis's position within the MDx market

The MDx market is a competitive market with a number of companies that offer solutions and technologies that can be categorised as follows:

- large and established companies with existing installed bases of high-throughput batch-based MDx instruments and MDx existing menus of assays;
- clinical service laboratories that provide entire service solutions to customers, including assays, which they may perform themselves on commercially available instruments and assay platforms, or on internally-developed manual protocols, also known as "homebrew" tests or LDTs;
- companies that market and/or develop integrated random-access systems that may directly compete with the Idylla™ platform;
- companies that market and/or develop sequencing-or mass spectrometry based detection systems; and
- companies developing assays for the above mentioned systems.

The global MDx market is dominated by large companies that have developed and commercialised instrument and test platforms for MDx for more than a decade and continue to expand their offerings on their installed bases of instruments. Such companies include Roche Diagnostics (estimated market share of 31% of the global MDx market in 2013), Novartis (10%), Gen-Probe (now part of Hologic) (10%), Qiagen (9%), Abbott Diagnostics (7%), and others like Cepheid.<sup>(25)</sup>

Typically, these companies offer high-throughput platforms designed to run batches of assays and to be operated in large laboratories with skilled personnel. Management believes that the trends in the MDx industry described above, in particular the use of low throughput high

clinical value assays for personalised patient monitoring, will favour the smaller throughput, random access platforms like the Idylla™ platform, in the future. Several of the large MDx companies have added (like Becton Dickinson, Roche, bioMérieux and Luminex with the acquisitions of respectively HandyLab, iQuum, BioFire, and GenturaDx) a random access platform to their product range.

Clinical diagnostics service laboratories that are commercialising testing services include a wide range of specialty laboratories capable of performing MDx assays in their facilities. Such MDx assays can either be performed on one of the established instruments and assay platforms from one of the larger MDx companies, or manually as an LDT. Despite the spread of instrument and assay platforms, the poor reproducibility of and the need for skilled labour in the performance of LDTs, LDTs continue to retain an important share of the MDx market as they are typically cheaper than the assays sold as approved IVD devices. The large clinical diagnostics services companies compete on the basis of price and service as they propose to customers total outsourcing solutions for an entire menu of assays and are able to collect a large number of samples and perform a large number of assays at a relatively low cost per assay out of their centralised laboratory facilities.

The Idylla™ platform is a sample-to-result platform, and several other companies have brought such platforms to the market. Idylla's™ key competitors in this field are Cepheid (with its GeneXpert system), bioMérieux (BioFire with its FilmArray system), Luminex (GenturaDx with its Ariès 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).

In terms of assays, Biocartis's key competitors are as follows: Roche cobas and Qiagen (for the BRAF Mutation Test and the KRAS and NRAS assays), Diacarta (for the NRAS/BRAF and NRAS/BRAF/EGFR492 assays), Promega (for the MSI assay), Sysmex Inostics' digital PCR service (called "BEAMing) (for liquid biopsy testing), T2 Biosystems with its T2Dx system (for Idylla™—Enrich and the sepsis assay), Focus Diagnostics and Hologic (Prodesse) (for Biocartis's first respiratory panel assay, known as Influenza Virus—Respiratory Syncytial Virus), bioMérieux (BioFire FilmArray), Luminex (xMap) and Autogenomics (for the Respiratory MP (mixed panel) assay), Roche, Abbott, Novartis and Siemens (for the HIV, HBV, and HCV viral load assays) and Cepheid, BioFire Defense and Roche (for the Ebola assay).

In the longer term, management believes that technologies that are currently confined to research laboratories will be used in the clinical diagnostics markets. Such technologies include NGS technologies, mass spectrometry-based technologies (or variants thereof), which are currently the standard to analyse proteins, and last generation flow cytometry technologies, which are currently the standard to analyse circulating cells.

In order to compete effectively, Biocartis will need to demonstrate the advantages of its solutions over alternative established or emerging solutions. It will also need to demonstrate the potential economic value of its solutions relative to alternative solutions, and services offered by clinical diagnostics service laboratories.

Management believes that the principal competitive factors affecting sales of MDx systems include the menu of available assays, the quality of the assay results, integrated functionality, turn-around time and portability/footprint of the equipment, ease of use, price, market acceptance of the technology, regulatory approvals, and key opinion leader support, as well as the ease and quality of their maintenance and other customer services. More broadly, companies also compete through their ability to provide customers with a wide range of clinical diagnostics instruments, reagents and laboratory information management systems and on their ability to capitalise on the resulting economies of scale.

For further information on competition within the industry as it relates to specific assays, see the assay descriptions within "*Business—Assay menu*".

## BUSINESS

### Overview

Biocartis has developed an innovative and proprietary MDx platform that offers accurate, highly-reliable molecular information from a wide variety of biological sample types, 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 assays in the oncology and infectious diseases segments.

Biocartis, founded in 2007, is focused on the US\$5 billion (2013 estimate) MDx market.<sup>(26)</sup> The MDx market is estimated to be one of the fastest growing segments of the approximately US\$53 billion (2013 estimate) IVD market.<sup>(27)</sup> For further information, see "*Industry*".

Biocartis's market opportunity is driven by an increasing use of MDx in the management of cancer, infectious diseases, and other severe conditions and, in particular, the growing adoption of personalised medicine that requires advanced diagnostics tests to be carried out rapidly and cost effectively enabling key clinical decisions to be made on a timely basis. Currently, most clinical molecular testing involves a series of complex, labour intensive, time-consuming and relatively costly steps (each of which needs to be conducted in a specialised, dedicated laboratory environment), including the preparation of clinical samples, isolation of human or pathogenic genetic material (such as DNA) from the sample, amplification, detection and quantification of this genetic material, and result, delivery and interpretation. Biocartis's Idylla™ platform fully automates these otherwise complex and costly steps, enabling low-to mid-volume, high clinical value molecular testing to take place at the point-of-need. Biocartis focuses on assays in the fields of oncology and infectious diseases, the two largest application areas for MDx and disease areas with significant unmet needs and/or characterised by high prevalence, and where management believes the Idylla™ solution can make a real difference by virtue of its unique features.

### ***Idylla™ platform***

The Idylla™ platform, launched as a CE-marked product in September 2014, is a fully-automated, self-contained real-time PCR-based MDx system, designed to offer physicians fast access to highly reliable MDx information. The Idylla™ platform is differentiated by its ability to perform tests on-demand in virtually any setting, from a wide variety of biological sample types without the need for pre-processing, and its capacity to detect multiple biomarkers from a single sample. It also drastically limits the number and duration of operator steps that have traditionally led to high labour costs and risks of errors, even allowing molecular results to be rapidly generated outside of laboratory settings with highly-reliable, reproducible results. The Idylla™ platform covers the entire process from sample-to-result in 35 to 150 minutes (depending on the type of assay), with a hands-on time of around two minutes. Therefore, management believes that the Idylla™ platform is best-in-class.

The Idylla™ platform includes three components: the console, the instrument and the cartridge. All cartridges share a common design, but are made application-specific for each assay by their reagent content, assay execution protocol (software), and labelling.

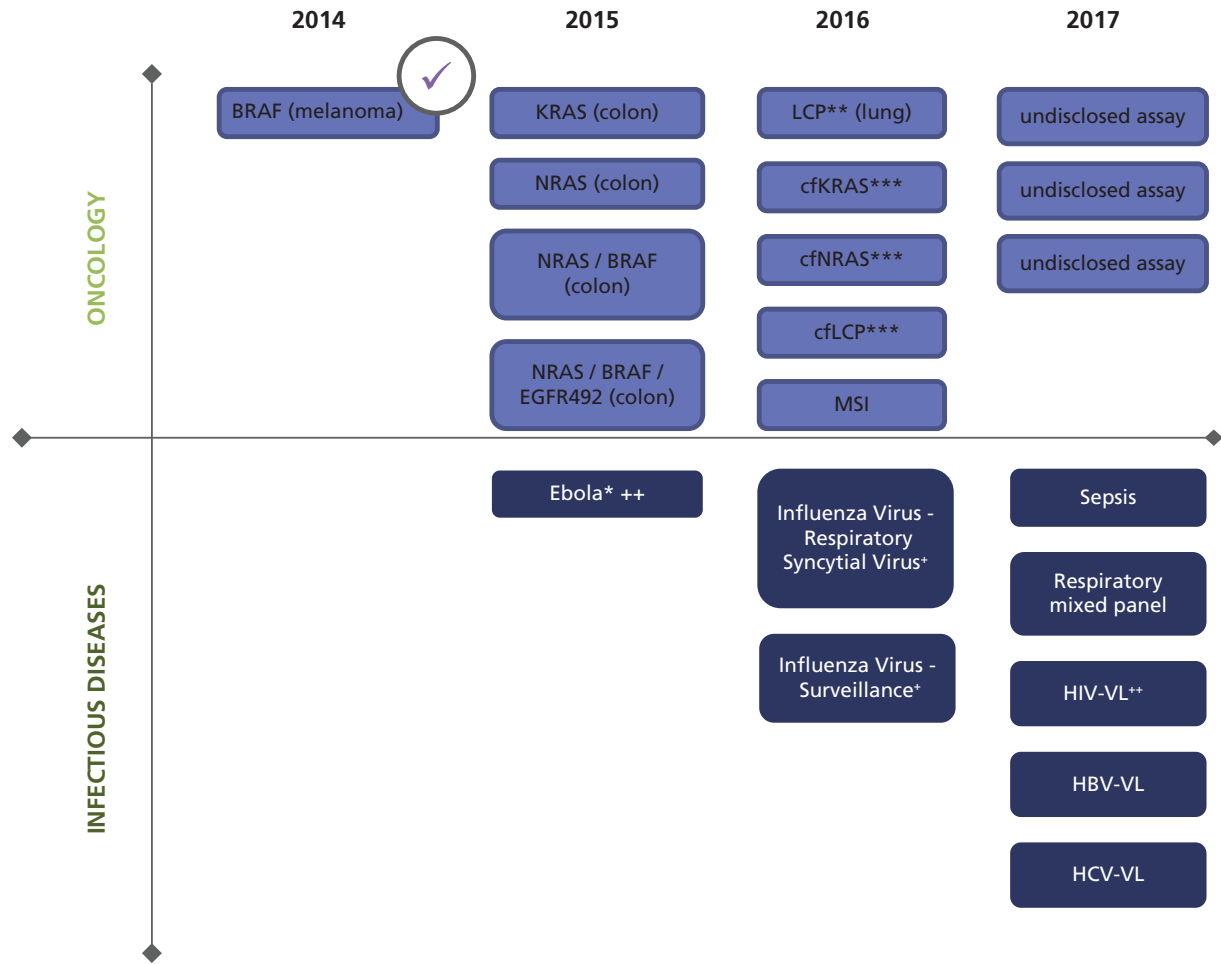
### ***Menu of assays***

Biocartis is developing a broad menu of assays for use with the Idylla™ platform, focusing on disease areas with significant unmet needs and/or characterised by high prevalence, and where management believes the Idylla™ solution can make a real difference by virtue of its unique features. As such, Biocartis focuses on oncology and infectious diseases. Oncology is the fastest growing MDx market segment with an estimated 2013-2018 CAGR of 19.2% and a total market size in 2013 of over US\$726 million<sup>(28)</sup> (only taking into account IVD-labelled assays sold by IVD companies). Oncology is also currently a disease area with significant unmet needs. Infectious diseases is the largest MDx market segment, with an estimated 2013-2018 compound CAGR of 7.6% and a total market size in 2013 of over US\$2.2 billion<sup>(29)</sup>, and is a disease area characterised by high prevalence. Biocartis intends to launch at least four to five new assays per year,



complemented by additional assays developed in conjunction with its strategic partners, including J&J and Abbott Molecular. In September 2014, Biocartis successfully launched its first oncology assay, the Idylla™ BRAF Mutation Test and expects to launch a series of oncology assays and other assays (such as sepsis and Ebola) in the coming years.

**Pipeline of assays (indicated timing as per launch in CE-IVD countries)**



- \* Emergency use authorization label
- \*\* LCP is the code name for a lung cancer panel assay
- \*\*\* Research use only
- + J&J assay
- ++ Biocartis assay in collaboration with J&J

**Strengths**

- **Commercial stage company, having successfully launched an innovative CE-marked MDx system, the Idylla™ platform, in September 2014.** The Idylla™ platform is a fully automated MDx system, designed to enable on-demand MDx testing in virtually any setting. The Idylla™ platform has reduced manual interaction to four simple steps, together generally taking no longer than two minutes and eliminating the need for expert users or a specialised laboratory. This makes it possible to generate MDx results in non-expert settings and closer to the point-of-impact, such as the Intensive Care Unit (“ICU”) of a hospital, where it could be used by caregivers without specific laboratory training. The Idylla™ platform is broadly applicable to a wide range of different assays, being equipped with powerful sample preparation functionalities enabling it to process a wide diversity of primary clinical sample types. The Idylla™ platform is also equipped with a top-class PCR system, which features five independently controlled PCR chambers and an advanced optical system capable of detecting six fluorescence channels in each of

the five PCR chambers. These features make it possible to detect multiple molecular biomarkers from a single sample ("multiplexing"). In addition, the Idylla™ platform is compatible with, and Biocartis has access to, a wide range of PCR detection technologies, making the platform usable for many different diagnostic applications. The system is designed to provide rapid and reliable results, with actionable results being generated within 35 minutes (for genetic assays) to 150 minutes (for highly complex assays), and reduces the rate of occurrence of erroneous results due to the integration of all analytical sub-steps in a standardised cartridge.

- **Successfully launched first oncology assay, the Idylla™ BRAF Mutation Test, in September 2014; the frontrunner of a broad Idylla™ assay menu that Biocartis expects to make available as of 2015.** The Idylla™ BRAF Mutation Test is a CE-marked IVD assay for the detection of BRAF V600 mutations in formalin fixed, paraffin embedded ("FFPE") samples, originally targeted for metastatic melanoma patients. Biocartis's new product launches planned from 2015 onwards include extensions of the Idylla™ BRAF Mutation Test in lung, colorectal and thyroid cancers and new panels, such as RAS and MSI targeting colorectal cancers. MDx in oncology is a very attractive market as it is the fastest growing segment within MDx and relevant assays command high prices. Management believes that the Idylla™ platform is well placed to benefit from the growing adoption of personalised medicine for oncology as none of its large direct competitors can directly process FFPE tissue.
- **Strong pipeline of oncology and infectious disease assays, with an expected launch rate of at least four to five new assays per year, complemented by partner assays.** Biocartis has a dedicated, experienced research and development team in place to efficiently develop assays for both oncology and infectious diseases. This in-house team is complemented by external development parties that will develop assays compatible with the Idylla™ platform. These combined efforts are expected to result in the launch of at least four to five new assays per year. In addition, Biocartis has established strategic partnerships with key industry players to further expand its proprietary assay menu.
- **A new, disruptive, product line extension of the Idylla™ platform dedicated to bloodstream infections.** Biocartis is developing a new product line extension of the Idylla™ platform, known internally as "Idylla™-Enrich", which is a dedicated pre-enrichment platform for bloodstream infections, intended to be used in conjunction with an accompanying sepsis assay compatible with the Idylla™ platform. With the Idylla™-Enrich solution, Biocartis intends to significantly reduce the current sample-to-result time for bloodstream infections from the current time of more than 24 hours down to two hours, and to reduce the rate of occurrence of erroneous results. Given the very high mortality rate associated with delays in treating sepsis and the current length of time from sample-to-result, physicians typically start treatment of at-risk patients with broad spectrum antibiotics before test results are available, which can be ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. Using the Idylla™-Enrich solution, physicians will, for the first time, be able to change the paradigm of experience-based treatment selection to evidence-based clinical decisions for bloodstream infections.
- **Achieved breakthrough in liquid biopsy testing.** Liquid biopsy testing, using plasma or urine, for example, has many advantages over tissue sample testing, including that it enables repeated testing of patients (for instance, during therapy) to monitor response and relapse of disease, does not require prior information of the location of a tumour and allows the generation of clinically relevant molecular information without the need for the patient to undergo an invasive tissue sampling procedure. Biocartis's novel chemistries and protocols include improved and automated methods for picking up circulating free tumour DNA fragments that are shed in the bloodstream. Benefiting from the enhanced sensitivity of the Idylla™ platform, management believes Biocartis will be able to develop novel, non-invasive liquid biopsy tests, opening up a whole new area in cancer monitoring, and ultimately, cancer screening.
- **Partnerships with key industry players.** Biocartis has strategic partnerships in place for assay development and commercialisation with key industry players, such as J&J and Abbott Molecular. These partnerships are expected to accelerate the Idylla™ assay menu

expansion and boost the installed base and assay sales. The partnership with J&J is focused on “complementary”, as well as companion diagnostics, while Abbott Molecular has selected Biocartis as its partner to develop companion diagnostic PCR assays for its customers (pharmaceutical and biotechnology companies).

- **Well-defined global commercialisation strategy in place aimed at establishing a global sales and distribution network.** Biocartis is currently rolling out its well-developed commercialisation strategy in countries where market access is enabled by CE-marking, by building up a direct presence in Western Europe and by building up, in parallel, a strong and dedicated distribution network in other key countries where the CE-mark is accepted. Biocartis continues to expand its own sales and marketing team, currently comprising over 15 dedicated and experienced employees, and continues to sign up new distributors. Biocartis can clearly identify its key target customers (on a global scale accounting for approximately 4,000 pathology laboratories for its oncology assays, and 6,000 decentralised rapid response laboratories and 4,000 microbiology laboratories for its infectious disease assays), allowing them to market and sell the Idylla™ platform and assays in a focused and efficient way. In other countries where additional regulatory requirements apply, Biocartis will opt for a direct sales model, a distributor model or a partnership model. For example, in the United States it is expected to use a partnership model (whereby distributors will be supported by a limited number of Biocartis employees, with support including marketing, clinical and regulatory affairs, logistics and high level sales support). The US strategy is expected to be rolled out in 2016 upon the anticipated receipt of regulatory approvals for the Idylla™ platform and alongside product availability
- **Biocartis is a fully integrated company with all of the experience, know-how and resources to conduct in-house commercial scale manufacturing of its products.** Biocartis has state of the art FDA-compliant in-house manufacturing facilities for all components of the Idylla™ platform (i.e., cartridges, instruments and consoles). As of 31 March 2015, Biocartis had manufactured over 100,000 cartridges, 445 instruments and 210 consoles at its facilities in Mechelen. Management believes that Biocartis’s current capacities are sufficient to meet the expected demand for its products in the near term. Additionally, it has identified opportunities to expand capacity and reduce costs by outsourcing the production of some components of the Idylla™ platform to specialised contract manufacturing organisations. To this end, Biocartis intends to outsource instrument and console production in the course of 2015.
- **Management team with proven track record.** Biocartis’s management team has significant experience in relevant areas of activity. Each member of the team has also been involved in the establishment, development and/or management of various other life science businesses, including devGen, Galapagos, J&J, Philips, ThermoFisher, Tibotec and Virco. The team consists of people with relevant industry experience and skills and is diverse with respect to nationalities and gender. For further information, see “Management and corporate governance”.
- **Renowned, committed shareholders.** Since Biocartis was founded in July 2007, shareholders have continued to show their commitment, investing a total of €240 million to date (including all tranches of the F-round of financing (including pre-commitments in the Offering by the Participating Shareholders (see also “The Offering—Pre-commitment by the Participating Shareholders”) and, of which, approximately €40 million was attributable to the Evaluation™ platform, which was spun out in November 2014).

## Strategy

Biocartis aims to become a global leading player in MDx 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 and thereby enabling fast and effective diagnosis, treatment selection and treatment monitoring. Biocartis recognises the growing need for rapid, easy to use, multiplexed MDx close to the point-of-impact and believes that its flagship product, the Idylla™ platform, meets all of these needs. Biocartis intends to create a compelling, broad menu of assays capable of providing high quality, reproducible

results, focused on disease areas with significant unmet needs and/or characterised by high prevalence, in which management believes the Idylla™ solution can make a real difference by virtue of its unique features.

Biocartis is currently developing assays in two focal areas. Its predominant focus is oncology (the fastest growing MDx market segment and a disease area with significant unmet needs), while its second focus is infectious diseases (the largest MDx market segment and a disease area characterised by high prevalence). In addition to the unmet needs, size of market and expected growth in these markets, Biocartis is focusing on these areas because it believes the Idylla™ platform uniquely meets these areas' needs because:

- the Idylla™ platform is ideally suited for highly sensitive, multiplexed assays;
- management believes the Idylla™ platform is the only fully integrated platform capable of processing both FFPE tissue (which is the standard tissue type for solid tumour diagnostics) and fresh (frozen) tissue samples;
- most oncology tests are low volume, high value tests particularly suited for the Idylla™ platform, whereas most MDx systems used in this area are tailored to higher throughputs; and
- with respect to infectious diseases, the Idylla™ platform can make a difference by enhancing turn around times and ease of use and multiplexing of a range of disease causing agents in a syndromic panel without compromising diagnostic performance.

Biocartis's targeted oncology assays are predominantly higher value MDx tests, whereas the targeted infectious disease assays typically have a faster time to market, higher volumes and a complementary customer base (compared to the oncology assays). Biocartis intends to launch at least four to five new assays per year, complemented by additional assays developed in conjunction with its strategic partners, including J&J and Abbott Molecular. Biocartis's first assays all involve biomarkers for which reimbursement is already established.

Biocartis intends to develop its oncology menu in two waves, starting with a series of solid tumour assays, including BRAF, KRAS, NRAS, and MSI (and expected to be followed by more tumour panels in the future), followed by 'liquid biopsy' assays that enable early diagnosis and monitoring. Management believes that liquid biopsy assays are well positioned to transform current clinical practice as sample taking is non-invasive, does not require prior information of the location of the tumour and is suitable for repeat sampling.

In the infectious diseases area, Biocartis intends to initially focus on sepsis and other rapid response laboratory assays, such as a respiratory tract panel assay, as well as viral load assays such as HIV and HCV. Biocartis aims to differentiate itself from most current infectious disease tests by offering syndromic panels. Idylla's™ multiplex capability allows testing for not only the common agents of a particular syndrome, but also for less common agents. While for many syndromes there are three to four common etiologic agents, there is also a long "tail" of less common pathogens that may be important to identify. In response to the 2014 Ebola outbreak, Biocartis is also currently developing an Ebola assay.

Biocartis is seeking to obtain, as fast as possible, critical mass in menu availability for each of its core customer groups: a compelling menu of oncology assays for pathologists/oncologists, followed by a menu of infectious disease assays for rapid response and microbiology laboratories. Therefore, Biocartis has opted from the start to team up with leading industry partners, e.g., J&J and Abbott Molecular, to accelerate menu development and speed up commercial reach. In addition, Biocartis is now seeking to team up with external development parties to further expand menu development. Biocartis works regularly with external (academic) research institutions, facilitating access to novel and innovative biomarkers to further support the assay menu pipeline.

Biocartis is moving fast to establish a global sales and distribution network for Biocartis's products. Following the CE-marking of its Idylla™ platform and the Idylla™ BRAF Mutation Test, and their successful launch in 2014, Biocartis has built, and continues to expand, a direct sales

presence in Western Europe. In parallel, Biocartis intends to first build a strong and dedicated distributor network in the key countries where the CE-mark is accepted. In other countries where additional regulatory requirements apply, Biocartis will opt for a direct sales model, a distributor model or a partnership model. For example, in the United States, a partnership model is expected to be used, which is expected to be rolled out in 2016. In order to accelerate the generation of revenue and create traction in the market, in specific geographies, Biocartis plans to make certain of its assays available as research use only assays initially, prior to obtaining full regulatory approval.

## History

Biocartis was founded in July 2007 by Dr. Rudi Pauwels, Professor Philippe Renaud and Mr. Nader Donzel. Biocartis began its operations from the Science Park of the Swiss Federal Institute of Technology (Ecole Polytechnique Fédérale de Lausanne, or “EPFL”), a world renowned academic centre in micro- and nanotechnology, in Lausanne, Switzerland. Later that year, Biocartis acquired the patent rights for a multiplex detection platform from the University of Ghent (Belgium) and Tibotec-Virco (a Johnson & Johnson company), and started to develop a multiplex detection platform called “Evaluation™”.

Having started in 2007 with an initial investment of €62,500, Biocartis sought further funding to carry on its operations, raising €1.25 million in July 2008, and a further €10.0 million in a Series A financing (backed by several specialist private equity investors as well as Dr. Pauwels’s investment company, Benaruca S.A. (“Benaruca”)) in October 2009. In September 2008, Biocartis achieved first proof of concept for multiplexed immunoassays using its proprietary digitally encoded micro particle technology, followed by achieving first proof of concept for multiplexed molecular detection of DNA and RNA-based biomarkers in September 2009. At the end of 2009, Biocartis established a subsidiary at a high tech campus in Eindhoven (The Netherlands).

In 2010, Biocartis acquired a technology platform for automated DNA/RNA MDx testing (codenamed “Apollo”, now trademarked as the “Idylla™ platform”) from Koninklijke Philips Electronics N.V. (“Philips”), completed another successful fundraising (a €44.0 million Series B financing which was backed by existing shareholders, Debiopharm Diagnostics SA and two new strategic investors (bioMérieux and Johnson & Johnson Innovation – JJDC, Inc. (“JJDC”)) and entered into a strategic partnership with bioMérieux to co-develop and co-distribute assays, pursuant to which bioMérieux acquired a €9.0 million equity stake in Biocartis (included in the Series B financing). Biocartis also entered into a strategic licensing, development and commercialisation agreement with J&J, setting out the parties’ aims to co-develop assays and pursuant to which J&J obtained the worldwide commercialisation rights for assays for neurodegenerative disease and certain viral infectious diseases.

In mid-2011, Biocartis’s research and development activities were relocated from Eindhoven to the Intercity Business Park in Mechelen (Belgium), where a pilot cartridge manufacturing production line was established. In August 2011, Biocartis acquired the core intellectual property for Idylla™-Enrich (a dedicated platform for enrichment of pathogen DNA from blood coming from patients with a suspected blood stream infection) from Philips. In September 2011, Biocartis was named a 2012 Technology Pioneer by the World Economic Forum and, in November 2011, it conducted another successful round of financing, raising €58.6 million in a Series C financing.

In 2012, Biocartis entered into collaborations with each of: Philips, Genome Research Limited and the Wellcome Trust (for the development of technology for an automated blood based assay-system for monitoring tumour load); and Immunexpress and Debiopharm International SA (for the grant of a worldwide, exclusive, royalty-bearing licence for the late-stage development and commercialisation in the field of personalised management of sepsis in adults, excluding any use in military settings, of SeptiCyte Triage, a set of host cell RNA expression biomarkers that help to triage patients with suspected sepsis). At the end of 2012, Biocartis raised €34.5 million pursuant to a Series D financing backed by existing shareholders (including Benaruca).

In 2013, Biocartis’s MDx platform was named “Idylla™”, Biocartis ended its collaboration with bioMérieux (and regained all the rights relating to the use of its platform in the microbiology

field), entered into new collaborations and licence agreements with Hospital del Mar and the Vlaams Instituut voor Biotechnologie/Flemish Institute for Biotechnology (“VIB”) (in connection with its aim to develop assays for several cancers using new biomarkers), and raised a further €30.0 million.

In November 2014, Biocartis entered into a strategic collaboration with Abbott Molecular to develop and commercialise companion diagnostics tests; spun out “Evaluation™”, its life sciences multiplex platform, into a separate company called “MyCartis NV” in order to enable Biocartis to focus on the Idylla™ platform; launched the Idylla™ platform and its first oncology assay, the Idylla™ BRAF Mutation Test; and raised commitments for a further €64.5 million pursuant to the F-round financing (with three equal tranches, of which two tranches have been contributed and the third is contingent, in relevant part, on closing of the Offering) backed by JJDC, Hitachi Chemical, PMV Tina Fund and Benaruca, among others.

In October 2014, Biocartis’s strategic licensing, development and commercialisation agreement with J&J was restated to be aligned with the current needs of both parties. In particular, the restated agreement provides Biocartis with greater flexibility in respect of the development of its assay menu and enables J&J to collaborate with Biocartis on companion diagnostic assays for its pharmaceutical compounds. Exclusive field rights granted to J&J in 2010 reverted to Biocartis.

In November 2014, pursuant to a group restructuring, Biocartis Group NV (a Belgian holding company) became the group’s new holding company.

In March 2015, Biocartis and Microbiome a spin-off of the VU University Medical Center Amsterdam, announced that they have entered into a worldwide license and collaboration agreement for the development of an integrated multiplex real-time PCR assay for rapid detection of bloodstream infections. Under the terms of the collaboration and license agreement, Microbiome’s multiplex PCR assay for identification of sepsis-causing microorganisms will be further developed as an integrated multiplex real-time PCR assay on Biocartis’s Idylla™ platform for use in conjunction with Idylla™—Enrich, discussed below.

## Products

### *Idylla™ platform*

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 assays) and 150 minutes (for highly complex assays). The Idylla™ platform is composed of three physical components: a console, an instrument and a disposable cartridge.

The Idylla™ platform provides the features to enable MDx to be performed by non-expert personnel (such as nurses) in a non-specialised laboratory environment close to the patient. Management therefore believes it 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.

### *The Idylla™ platform components*

The three components of the Idylla™ platform are:

- **The console:** This is a glove-compatible touch-screen operated computer, supplemented with barcode scanning and communication capabilities. It is the Idylla™ local data collection and transmission centre 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 (for further information, see “—Future

*Developments—Idylla™ Connect, a remote connectivity solution for the Idylla™ platform") and/or the user's laboratory information system. The current console software version allows up to eight independently operating instruments to be connected to a single console to accommodate higher throughput needs.*

- **The instrument:** This is a stackable, independent driver unit that executes the entire assay procedure within the cartridge through a limited number of multipurpose instrument-cartridge interfaces. Each instrument is equipped with an on-board computer and a variety of sensors to perform all necessary in-process verifications and data analysis. 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, assay execution protocol (software), and labelling. Cartridges can be stored at ambient temperatures (between 2°C and 30°C) and do not require a cold chain during transportation (temperatures of between 30°C and 40°C can be tolerated for up to 72 hours). Each cartridge has eight available reagent containers, capable of holding different amounts of pre-filled liquid reagents, as well as five separate PCR chambers, each of which is also pre-filled with specific reagents. A six-colour fluorescent read-out expands the number of reportable biomarkers to 30 in standard mode. Precise temperature control of the PCR chambers allows the further expansion of the number of detectable biomarkers via so-called high-resolution melt analysis. The cartridge's broad sample type compatibility (including blood, plasma, serum, swab, urine, sputum, stool, FFPE and fine needle aspirate), combined with extensive sample preparation and multiplexed, real-time PCR capabilities, results in a highly versatile platform suitable to efficiently develop a wide range of real-time PCR-based assays for many disease areas.



The Idylla™ platform drastically limits the number and duration of operator steps that have traditionally led to high labour costs and risks of errors for MDx tests. The Idylla™ workflow is reduced to the following four simple steps that, together, generally take no longer than two minutes:

- **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 the assay the user intends to perform and verifies the expiration date of the specific cartridge.
- **Step 3:** The patient sample is added into the cartridge. A wide range of different primary sample types can be processed using the Idylla™ platform. After closing the lid of the cartridge, all reagents and the sample are contained in a hermetically sealed environment to prevent spills or cross-contamination.
- **Step 4:** The cartridge is inserted into one of the available instruments, which will subsequently execute the appropriate assay protocol, including the complete measurement and analysis of the data. The cartridge is subsequently disposed of as general clinical waste.



Scan sample

Scan cartridge

Load sample

Insert cartridge

### Competition

The Idylla™ platform is a sample-to-result platform, and several other companies have brought such platforms to the market. 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.

Management believes that the Idylla™ platform can be differentiated from the other sample-to-result platforms because:

- it believes the Idylla™ platform is the only sample-to-result platform able to process a wide diversity of sample types, including very complex samples such as FFPE and fresh tissue, with a single instrument and without requiring any manual sample pre-treatment, i.e., all the sample preparation functionality is integrated in the platform. In contrast, other platforms are typically only capable of processing simple (liquid) sample types, while more complex sample types typically require separate manual pre-treatment steps prior to the analysis on the platform, or require the use of different instruments. Manual pre-treatment steps not only increase the hands-on time, they also increase the risk of handling errors and make the system unsuitable for near patient testing.
- unlike its competitors, it is able to process both FFPE and fresh (frozen) tissue. Competitor solutions are heavily dependent on manual de-waxing, lysing and other sample preparation steps before the FFPE tissue can be loaded into the cartridge. Management believes the Idylla™ platform is therefore uniquely positioned to provide assays for the oncology market;
- it is a versatile platform because of its ability to detect multiple biomarkers from a single sample (the "multiplex capacity"), its ability to detect different types of biomarkers (RNA and DNA), and its ability to quantify biomarkers. This versatility allows for the



development of highly complex assays, including mutation panels, gene expression assays and viral load assays. Competitor portfolios are currently focused on less complex assays, such as MRSA assays;

- unlike a batch based system, up to eight independently operating Idylla™ instruments can be connected to a single console, meaning that each instrument can independently address different assays started at different times;
- its technologies allow sensitive multiplexing to a level that management believes is unsurpassed in routine IVD settings. Only digital droplet PCR technologies are more sensitive at competitive price levels, but these are cumbersome, expensive, single-plex assays, most often offered as a service provided by specialised commercial laboratories; and
- it has been designed for use in decentralised settings, which means it is best suited to low to medium throughput demands (24 to 192 maximum throughput based on a 60 minute test), though Biocartis is looking at developing a high throughput version (384 maximum throughput based on a 60 minute test) of the platform.

### ***Assay menu***

Biocartis is developing a comprehensive range of assays for use on the Idylla™ platform focusing on disease areas with significant unmet needs and/or characterised by high prevalence, in which management believes the Idylla™ solution can make a real difference by virtue of its unique features. This has resulted in Biocartis focusing on assays in the fields of oncology and infectious diseases.

Biocartis has a dedicated and experienced research and development team in place to efficiently develop assays, benefitting, when developing future assays, from the know-how and experience gained developing earlier assays. Complementing its in-house assay development, Biocartis intends to expand its capacity via external “content” or “diagnostic app” developers (i.e. third parties that have a track record of IVD development and the relevant in-house assay expertise) that will develop assays compatible with the Idylla™ platform. with appropriate levels of support from Biocartis. These combined efforts are expected to result in the launch of at least four to five new assays per year.

Biocartis works regularly with external (academic) research institutions, facilitating access to novel and innovative biomarkers to further support the assay menu pipeline. This avoids the need for Biocartis to invest in-house research and developments resources in biomarker identification, the most speculative aspect to assay development.

Biocartis’s near-term pipeline of assays is described below. Several further candidate assays are in various stages of evaluation and/or development. Furthermore, discussions are ongoing with several of Biocartis’s partners, including Abbott Molecular and J&J, to develop additional assays via existing and potentially new strategic research and development collaborations. The assay menu and anticipated launch dates may be modified over time to address changing market circumstances and alternative opportunities.

### ***Description of phases of Assay Development***

Biocartis’s development of assays follows a stage-gated product design and development process as established in Biocartis’s quality management system. Each assay development project starts with a short project proposal phase, in which commercial requirements for the anticipated assay are defined and a high level development plan is prepared. In phase 1, the definition and planning phase, the feasibility of the requirements is investigated by designing and developing a prototype assay. Raw materials and formulations are proposed, the manufacturability is assessed and the quality control strategy outlined. Risk analysis is performed and the design and development planning, describing the project effort for the next phases in detail, is established. During phase 2, the design optimisation and verification phase, the design of the product is optimised for safety performance, usability and manufacturability. Design verification demonstrates that prototypes satisfy the acceptance criteria that are described in the product

requirements. Phase 3, the validation and transfer phase, aims to confirm, by examination and provision of objective evidence, that the product is consistently able to meet requirements for intended use and customer needs. This includes clinical performance evaluation and reproducibility testing. In addition, the product's design transfer is finalised in this phase. The design output is translated into manufacturing procedures and specifications; processes are validated and/or qualified as applicable. Following a final design review, the assay is ready for launch, routine manufacturing and sales and servicing; and post-market surveillance is initiated.

The overall timeline to develop a new test for a known biomarker depends on the complexity of the assay (such as number of markers, required sensitivity and specificity) and the availability of samples. On average, an assay takes around 12-18 months to develop from scratch to start of validation. Validation can then take between three months and more than a year. In addition, some assays are also seasonal, so trials cannot take place the whole year. Management estimates therefore an average of just under two years from start of development to completion of validation. Development costs are dependent on the complexity of the assay, and clinical trial costs are dependent on the prevalence of the disease, the regulatory class and the intended use. The cost of development of most assays is expected to be in the range of €3-8 million, which management believes is in line with market averages, while certain assays may be cheaper or more expensive to develop and to obtain regulatory approval.

### **Oncology assays**

In the oncology field, Biocartis is developing a broad and comprehensive menu of diagnostic assays for a wide range of cancers, with an initial focus on melanoma, colorectal, and lung cancers. Assays addressing other relevant oncology fields (such as breast, ovarian, haematological, bladder and prostate cancers) are expected to be developed in the next few years. Biocartis intends to develop its oncology menu in two waves, starting with a series of solid biopsy assays (expected to be followed by more tumour panels in the future), followed by 'liquid biopsy' assays that use sample types that are easier to obtain, like plasma or urine. Such liquid biopsy based assays will facilitate monitoring therapy and disease progression and possible earlier disease detection.

#### *The Idylla™ BRAF Mutation Test (melanoma, colorectal, thyroid and lung cancers)*

##### Medical need

The BRAF gene is involved in sending signals inside cells, which are involved in directing cell growth. Mutations in the BRAF gene can induce excessive activation of MEK (a mitogen-activated protein kinase) and ERK (an extracellular signal-regulated kinase), triggering cell growth and cell division independently of normal growth factors. As such, they can induce the progression of several types of cancers, including melanoma, colorectal, lung and thyroid cancer.<sup>(30)</sup> Mutations in the BRAF gene are found in approximately 7% of all cancers and about 50% of melanoma patients.<sup>(31)</sup>

There are certain cancer drugs currently on the market approved for metastatic melanoma which specifically inhibit the BRAF protein that is mutated at the position 600 amino acid. These include vemurafenib (Zelboraf®, Roche),<sup>(32)</sup> and dabrafenib (Tafinlar®, GlaxoSmithKline) as well as cancer drugs which specifically inhibit a combination of BRAF and MEK (for example, vemurafenib/cobimetinib<sup>(33)</sup> and dabrafenib/trametinib<sup>(34)</sup>). Metastatic melanoma patients whose tumours carry the BRAF mutation gene and who are treated with these cancer drugs show improved progression free survival (a measure of progression of cancer by growth of tumour, new tumours, death from cancer or death from other causes) as well as overall survival (a measure of whether cancer patients treated with a drug live longer than patients who are not treated with the drug).<sup>(35)</sup> Conversely, patients whose tumours do not contain this cancer driving mutation do not benefit from these treatments. As a result, routine testing of metastatic melanoma tumours for BRAF V600 mutations is now included in the major molecular pathology guidelines (e.g., NCCN and ESMO).<sup>(36)</sup>

Lung cancer has been the most common cancer in terms of both incidence and mortality worldwide,<sup>(37)</sup> and 80-85% of all lung cancers are non small-cell lung cancer ("NSCLC").<sup>(38)</sup>

Mutations of the BRAF gene have been found in 0.5-3% of NSCLCs.<sup>(39)</sup> Similar to BRAF mutations in metastatic melanoma patients, BRAF mutations in NSCLCs can be treated with BRAF inhibitors. The French National Cancer Institute (“INCa”) and Roche are conducting a phase II study for the treatment of 11 different BRAF V600 mutated tumours, including NSCLC, with the BRAF kinase inhibitor, vemurafenib.<sup>(40)</sup> Management estimates that a small majority of lung cancer patients are eligible for BRAF testing.

BRAF V600E mutations have been found in 8-10% of all colon cancers, for which there are currently no targeted treatment options available. Colon cancers do not respond to BRAF inhibitors because of the rapid feedback activation of the epidermal growth factor receptor (“EGFR”), which supports continued proliferation (melanoma cells express low levels of EGFR and are therefore not subject to this feedback activation of EGFR). Patients with colon cancer and BRAF V600E mutations might benefit from combination therapy consisting of BRAF and EGFR inhibitors.<sup>(41)</sup> GlaxoSmithKline is therefore currently conducting a four part Phase I/II study for the treatment of patients with this type of colon cancer using a combination of dabrafenib/trametinib (which inhibits a combination of the BRAF gene and MEK) and the anti-EGFR antibody, panitumumab.<sup>(42)</sup>

Thyroid carcinoma is currently the fifth most common malignancy diagnosed in women in the United States, with approximately 48,000 new cases in US women alone diagnosed in 2014.<sup>(43)</sup> The National Comprehensive Cancer Network (“NCCN”) reported that molecular diagnostic testing to detect individual mutations may be useful in the evaluation of fine needle aspirate samples that are indeterminate to assist in management decisions. BRAF mutation analysis was recommended by 50% of NCCN panellists in the evaluation of thyroid nodules (not restricted to the follicular lesions). Furthermore, about 50% of the panellists would recommend BRAF testing in the evaluation of follicular lesions (11% of the 53,856 patients treated for thyroid carcinoma between 1985 and 1995).<sup>(44)</sup>

On the basis of these developments, management expects that most lung, colon and thyroid cancer tumours may be tested for BRAF mutations in the future and that, therefore, the extension of the Biocartis BRAF assay for use on lung, colorectal and thyroid samples has significant commercial potential. Tumour mutation status is usually assessed using FFPE tumour tissue. Currently, the process from sample-to-result is labour-intensive, requiring multiple steps. Most laboratories do not perform these tests in-house, but send them out to specialised centres, where samples are batched in order to optimise costs. However, because various cancers can progress unpredictably and rapidly, there is a high medical need for rapid analysis of BRAF mutations (for further information, see “—Liquid biopsies: RUO assays for detecting mutations in cell free plasma DNA for monitoring of cancer”).

### Market potential

The following table<sup>(45)</sup> sets forth the global incidences of lung, colon, thyroid and melanoma cancer as of 2014 for the United States and as of 2015 (predicted) for all other regions:

	<u>Colon</u>	<u>Melanoma</u>	<u>Lung</u>	<u>Thyroid</u>
<b>Europe</b> <sup>(1)</sup> .....	301,677	78,745	257,735	32,115
<b>USA/Canada</b> .....	162,655	81,827	252,043	68,680
<b>China</b> .....	282,707	10,849	733,280	48,650
<b>Japan</b> .....	120,111	1,429	102,004	9,559
<b>Rest of the World</b> <sup>(2)</sup> .....	553,141	70,670	620,506	152,781
<b>Total</b> .....	<b>1,420,291</b>	<b>243,520</b>	<b>1,965,568</b>	<b>311,785</b>

Notes:

- (1) Those European countries where Biocartis is commercialising directly.
- (2) Excluding developing countries in East, Middle and Western Africa.

As noted in the table above, approximately 79,000 patients annually are diagnosed with melanoma in the European countries where Biocartis is building a direct sales presence. Management estimates that 20% of melanoma patients are metastatic or require retesting and are eligible for testing. Although metastatic melanoma has a relatively low incidence rate

compared to other cancers, routine testing of metastatic melanoma tumours for BRAF V600 mutations is now included in all major molecular pathology guidelines. BRAF testing is also currently conducted on colorectal, lung and thyroid cancer tumours. BRAF testing can be performed on colorectal cancer samples, either in parallel with KRAS testing, or for KRAS wild-type samples only. Similarly BRAF can be tested in lung cancer after, or in parallel with, testing for EGFR. According to management estimates, pathologists already test for BRAF mutations in approximately half of eligible colorectal cancer tumours and are starting to test for BRAF mutations in eligible lung cancer samples. For lung cancer, in the mid- to long-term, the vast majority of all NSCLC could be tested using the Idylla™ BRAF Mutation Test. Management believes that BRAF tests are already performed routinely on approximately 25% of thyroid cancer patients, however management expects that BRAF tests will, in the future, mostly be used as prognostic/predictive test for most thyroid cancer patients, thereby potentially increasing the penetration rate.

In the future, management believes that testing for lung and colorectal cancers on the basis of BRAF mutations will constitute the majority of revenues for the Idylla™ BRAF Mutation Test, with melanoma and thyroid cancer remaining important niche markets. However, although management believes there is significant commercial potential for line extensions, particularly with respect to lung cancer, Biocartis does not currently intend to immediately pursue the CE-marking for these line extensions and will first await customer feedback. With respect to commercialisation in the United States, Biocartis has no plans to market the BRAF Mutation Test as a standalone assay, given that the NRAS/BRAF and NRAS/BRAF/EGFR492 assays (discussed below) will contain a BRAF component and are expected to be available shortly, which is expected to allow combined trials as this can be done cost effectively.

#### Description and status

The Idylla™ BRAF Mutation Test is a CE-marked IVD assay for the fully automated detection of BRAF V600 mutations (E/E2/D/K/R/M) in FFPE samples. Following successful validation studies, it was launched in Europe, alongside the Idylla™ platform, in September 2014 and is initially intended for use on melanoma samples. It has also been evaluated for use on lung, colorectal and thyroid samples.

The Idylla™ BRAF Mutation Test is a six-plex design using Taqman PCR chemistry and results in three reportable events (including controls). It is suitable for the testing of FFPE slices, or macro-dissected FFPE material (i.e., no manual deparaffinisation is required), which can be inserted directly into the Idylla™ cartridge. It has a total sample-to-result time of around 90 minutes, with a hands-on time of about two minutes. The Idylla™ BRAF Mutation Test has a sensitivity of 1% (or better) of mutant in a wild-type background for all mutations covered.

The table below provides an overview of the clinical studies performed with the Idylla™ BRAF Mutation Test for melanoma.

Study/trial	Locations	Number of samples	Concordant samples	Discordant samples	Overall concordance	Samples tested with discordance test	Concordance Idylla™ vs 3rd test	Corrected overall concordance
Verification study <sup>(1)</sup> . . . . .	Commercial reference lab	60	58	2	96.7%	2	2	100.0%
Validation study <sup>(2)</sup> . . . . .	2 University Hospitals	236	231	5	97.9%	5	5	100.0%
Beta trial <sup>(3)</sup> . . . . .	6 Regional Hospitals	138	130	8	94.2%	6	6	100.0%
Other trials <sup>(4)</sup> . . . . .	1 University Hospital	191	186	5	97.4%	5	4	99.5%
<b>Total</b> . . . . .		<b>625</b>	<b>605</b>	<b>20</b>		<b>18</b>	<b>17</b>	

Notes:

- (1) Verification study among 60 samples vs. Roche cobas® BRAF V600 test (V600E and V600K only), discordance analysis was performed on all 5 discordant samples confirming the Idylla™ result.
- (2) Validation study among 236 samples vs. Qiagen pyrosequencing, discordance analysis was performed on all 5 discordant samples confirming the Idylla™ result.

- (3) Beta trials among 6 regional hospitals and 138 samples vs. a variety of methods (Roche cobas®, Sanger, Qiagen Therascreen and LDTs), discordance analysis was performed on the 6 out of the 8 discordant samples confirming the Idylla™ result, for the remaining 2 discordant samples insufficient material was available for discordance testing.
- (4) Study among 191 samples vs. Sanger sequencing and pyrosequencing, discordance analysis performed on all 5 samples and confirmed a correct Idylla™ result in 4 out of 5 samples.

### Competition

The main competing CE-marked products for the Idylla™ BRAF Mutation Test are the Roche cobas® BRAF test, the Qiagen Therascreen BRAF test and Qiagen's pyrosequencing method. As noted in the table above, according to the performance evaluation study for the Idylla™ BRAF Mutation Test, the Idylla™ BRAF Mutation Test detected the mutation in an additional 5-10% of samples compared to the Roche cobas® test and Qiagen's pyrosequencing method. On the basis of this data, several major pharmaceutical companies have expressed interest in conducting studies with the Idylla™ BRAF Mutation Test.

The assay kit price (i.e. excluding any associated laboratory costs, which would not be applicable when using the Idylla™ BRAF Mutation Test) of competing CE-marked tests ranges from €60 to €100 per test assay kit. The total cost of performing a BRAF test for a laboratory heavily depends on the methodology used and can range from approximately €115<sup>(46)</sup> to €395.<sup>(47)</sup>

### *Extended RAS testing for colorectal cancers (KRAS, NRAS, NRAS/BRAF and NRAS/BRAF/EGFR492 assays)*

#### Medical need for extended RAS testing

The RAS/RAF/MEK/ERK pathway acts as a signal transducer between the extracellular environment and the cell's nucleus. Extracellular signals, such as hormones and growth factors, interact with their receptors to activate members of the RAS family. The KRAS protein, one of the most clinically notable members of the RAS sub-family, is involved in the EGFR signalling cascade, which is important in cell proliferation, angiogenesis, migration, cell survival and cell adhesion. When KRAS is mutated, it leads to uncontrolled cell growth and division that may result in cancer.

RAS mutations have been detected in many tumours, with mutations in exon 2, 3 and 4 of the RAS genes being found in approximately 50% of colorectal cancers,<sup>(48)</sup> of which KRAS mutations are found in codons 12 and 13 of exon 2 (40% of colorectal cancers), and extended RAS mutations are found in KRAS exons 3 and 4 and NRAS exons 2, 3 and 4 (10% of colorectal cancers).<sup>(49)</sup>

A 2013 study showed that treatment efficacy was poor in all extended RAS mutated colorectal cancers, and that these mutations were associated with inferior progression free survival and overall survival with panitumumab–FOLFOX4 treatment.<sup>(50)</sup> As a result, both the correct identification of all non-mutated tumours (for inclusion in anti-EGFR therapy) and the correct identification of all extended RAS mutations (for the exclusion of anti-EGFR therapy) is mandatory under European anti-EGFR drug labelling.<sup>(51)</sup> Extended RAS testing has become mandatory according to European labelling for colorectal cancer therapy using panitumumab (Vectribix®, sold by Amgen) and cetuximab (Erbix®, sold by Merck, Merck Serono, Bristol Meyers Squibb, and Eli Lilly).<sup>(52)</sup> More recently, a Phase III study showed that highly sensitive detection (up to 1% mutant in wild-type background) of extended RAS mutations (and excluding them) improves progression free survival.<sup>(53)</sup> Management therefore believes that highly sensitive detection of all relevant mutations in 12 codons in 6 exons in KRAS and NRAS is urgently needed, and it is targeting its assays for sensitivities of 1% (or better) of mutant in wild-type background, which has recently been shown to be clinically relevant.

Tumour mutation status is usually assessed starting from FFPE tumour tissue. Currently, the process from sample-to-result is labour-intensive, requiring multiple steps. Most laboratories do not perform these tests in-house, but send them out to specialised centres, where samples are batched in order to optimise costs, which leads to longer turnaround times. For logistics and cost reasons, extended RAS testing is currently often performed in a sequential manner. First, the

current molecular IVD test kits detecting only codon 12, 13 and/or 61 mutations of KRAS are used. If no mutations are found (which happens in approximately 60% of cases), extended KRAS testing in exon 3 and 4 is requested, often from an external laboratory. If the tumour results are negative for extended KRAS (which happens in approximately 95% of cases), extended NRAS testing is then requested. Each procedure in this three step process takes between one and three weeks and, overall, the process currently takes several weeks to months. In the meantime, a course of chemotherapy has often been initiated, but the patient cannot receive properly targeted therapy until they have received the results of the extended RAS tests. Management therefore believes that there is currently a significant need for rapid, sensitive, and integrated extended RAS testing.

#### Market potential for the KRAS, NRAS, NRAS/BRAF and NRAS/BRAF/EGFR492 assays

##### KRAS assay

As noted in the table above, each year approximately 300,000 patients are diagnosed with colorectal cancer in the European countries where Biocartis is building a direct sales presence.<sup>(54)</sup> INCa estimates that 40-60% of colorectal cancer patients are eligible for testing for KRAS mutations,<sup>(55)</sup> and management believes that between 70% and 80% of these metastatic colorectal cancer patients are currently tested for KRAS mutations in the European countries where Biocartis is building a direct sales presence. Therefore, management believes that a total of approximately 100,000 KRAS tests are performed in those countries each year. Management believes that, in other indications, such as lung cancer, KRAS test adoption rates are much lower. In addition, like BRAF, management estimates that a small majority of lung cancer patients are eligible for KRAS testing.

##### NRAS assay

In colorectal cancer it is clinically relevant to detect NRAS for KRAS wild-type tumours (approximately 55% of metastatic colorectal patients).<sup>(56)</sup> Management believes that over the course of 2013 and 2014, NRAS testing has become standard practice in most laboratories performing KRAS tests, and therefore management believes that there is significant market potential for the NRAS assay.

##### NRAS/BRAF assay

As management expects that most colon cancer tumours may also be tested for BRAF mutations in the future (for further information, see "*The Idylla™ BRAF Mutation Test*" above), management believes that there is significant market potential for the NRAS/BRAF assay, which combines the test for NRAS and BRAF into a single assay.

In addition, metastatic melanoma patients with BRAF wild-type tumours (approximately 50% of metastatic melanoma patients) are also regularly tested for NRAS mutations.<sup>(57)</sup> NRAS is the second most common mutation seen in this population, and recent studies have shown that certain kinase inhibitors are effective in NRAS mutated melanomas.<sup>(58)</sup> Further, emerging NRAS mutations lead to resistance to BRAF and MEK based therapies.<sup>(59)</sup> BRAF and NRAS testing is therefore needed to support personalised treatment, including repeated monitoring of BRAF mutations for treatment efficacy, and of NRAS mutations for emerging resistance under BRAF and MEK based therapies. Management therefore believes that the combined NRAS/BRAF assay will be an attractive option for patients with melanoma in the future.

NRAS and BRAF mutated pathways have also been detected in a wide variety of other tumours, including ovarian, thyroid, breast, squamous, and liver cancers, leukaemia, and cholangiocarcinomas, for which effective therapies may be developed based on the existing data for melanoma, colon cancer and lung cancer.

##### NRAS/BRAF/EGFR492 assay

Colorectal cancer patients that develop the EGFR S492R mutation during treatment become resistant to the anti-EGFR antibody cetuximab, but remain susceptible to panitumumab.<sup>(59)</sup> A

recent study by Amgen, among others, showed that 16% of colorectal cancer patients became resistant to cetuximab due to emerging EGFR S492R mutations.<sup>(60)</sup> As a result, management believes that there is a clear need to identify the EGFR S492R mutation in FFPE samples of patients with anti-EGFR treatment history and in plasma samples of patients undergoing cetuximab-based anti-EGFR therapy.

Description and status of the KRAS, NRAS, NRAS/BRAF and NRAS/BRAF/EGFR492 assays

The KRAS assay is a sample-to-result test that detects 21 mutations in all clinically relevant KRAS codons in colorectal cancers in one cartridge. The assay uses multi-component nucleic acid enzyme (“MNAzyme”) chemistry combined with a highly specific amplification technology called ARC primers, which management believes provides a unique combination of high multiplexing and high sensitivity. Management believes that the KRAS assay would be difficult, if not impossible, to achieve with traditional real-time PCR technologies. It accommodates the direct input of FFPE slices, or macro-dissected material, into the Idylla™ cartridge and has a total sample-to-result time of around two hours, with a hands-on time of about two minutes. The assay has an average sensitivity of 1% (or better) of mutant in a wild-type background for all clinically relevant KRAS mutations related to anti-EGFR therapy. Biocartis licensed the EGFR S492R mutation biomarker from Hospital del Mar (Barcelona, Spain) in June 2013. The verification phase, during which the finalised design was verified and mini-performance studies and alpha trials (pre-trials that occur prior to the final validation study) were performed, was completed in the first quarter of 2015. These studies have already demonstrated that the KRAS assay can detect mutations in 5-10% more samples of colorectal cancer patients compared to the Roche cobas® test. The KRAS assay was launched in early April 2015 as a research use only test in countries which accept the CE-mark and Biocartis currently expects that the KRAS assay will be launched as a CE-marked IVD in the second quarter of 2015.

The KRAS assay was launched as research use only test in countries which accept the CE-mark on the basis of several studies where limits of detection were determined and clinical samples were analysed. One such study concerned a study of 93 colorectal cancer samples available at Biocartis for which NGS (MiSeq, Illumina) or MassArray (Sequenom) data were available. This study was complemented with an alpha study performed at a commercial molecular pathology laboratory, where 103 samples were compared with the Roche cobas® KRAS mutation test. Out of 103 samples, 71 KRAS mutations were detected by Idylla™, and 65 were detected by cobas. Of 93 in-house colorectal cancer samples, 48 mutant samples were detected on Idylla™ and 41 in MiSeq/MassArray. For each study, four samples could be successfully analysed by the gold standard digital droplet PCR technology, which confirmed the Idylla™ result in all of the discordant cases. Results of these two studies are shown in the table below.

Study/trial	Locations	Number of samples	Discordant samples	Overall concordance	Samples tested with discordance test	Concordance Idylla™ vs 3rd test	Corrected overall concordance
Verification study	In-house	93	8	91.4%	4	4	100.0%
Validation study (alpha trial)	Commercial reference lab	103	6	94.2%	4	4	100.0%

The NRAS, NRAS/BRAF and NRAS/BRAF/EGFR492 assays are three sample-to-result tests for the detection of mutations in the extended series of 19 NRAS mutations (for the NRAS assay) and BRAF codon 600 (for the NRAS/BRAF assay), as well as the EGFR S492R mutation (for the NRAS/BRAF/EGFR492 assay). These assays also use the highly selective specific amplification technology ARC and MNAzyme chemistries. These assays entered into the feasibility phase of development (where the feasibility of the required assay is investigated through the design and development of a prototype assay) in the fourth quarter of 2014. Sharing a common development route, Biocartis plans to offer three distinct products (by means of diversifying labelling and software): NRAS, NRAS/BRAF, and NRAS/BRAF/EGFR492. The colon cancer panel combining the KRAS cartridge with the NRAS/BRAF/EGFR492 cartridge will allow a 55-plex detection of mutations in eight exons over four genes, with only two FFPE slices in about two hours, and will offer a full extended RAS test.

Biocartis currently expects that the NRAS, NRAS/BRAF and NRAS/BRAF/EGFR492 assays will be launched as CE-marked IVDs in the fourth quarter of 2015.

#### Competition in respect of the KRAS and NRAS, NRAS/BRAF and NRAS/BRAF/EGFR492 assays

In the case of Biocartis's KRAS and NRAS assays, management believes that the high target sensitivity of the assays (key KRAS mutations are detected at better than 1% sensitivity; with all other KRAS mutations at better than 5% sensitivity; compared to 1-25% for the Qiagen Therascreen test), combined with the new approach (in line with the latest ASCO and NCCN guidelines) of testing an extended set of RAS mutations (in the Idylla™ assay 21 mutations over six KRAS codons and 19 mutations over six NRAS codons), as opposed to the testing of only two KRAS codons by competitors at present (e.g. the Qiagen Therascreen test detects seven mutations in seven PCR tubes), means that these assays have an advantage over its competitors' tests, particularly for colorectal cancer patients.

The main competing CE-marked products for the KRAS assay are the Roche cobas® KRAS test and the Qiagen Therascreen KRAS test. The kit price (i.e. excluding any associated laboratory costs, which would not be applicable when using the Idylla™ KRAS assay) for these tests ranges from €70 to €110 per test according to management estimates. The total cost of performing a KRAS test for a laboratory heavily depends on the methodology used and can range from approximately €160<sup>(61)</sup> to €320<sup>(62)</sup> when using CE-marked kits.

The main competing CE-marked products for the NRAS assay are Qiagen's pyrosequencing NRAS kit and its extended RAS kit. The number of competing CE-marked NRAS kits is substantially lower than for KRAS as NRAS testing is relatively new and such tests are more difficult to develop than KRAS tests. Biocartis's customer feedback confirms that this also results in existing CE-marked NRAS kits generally being more expensive than KRAS kits.

Management believes that DiaCarta is currently the only company with a CE-marked NRAS/BRAF kit (which also includes cKIT) and that there are no companies with a CE-marked NRAS/BRAF/EGFR492 kit. These tests are mostly performed either separately (using a BRAF and an NRAS kit) or through NGS-based research use only tests.

#### *The MSI assay (colorectal cancers)*

##### Medical need

MSI is the mutational signature found in colorectal cancers that evolve as a result of the inactivation of the DNA mismatch repair (the "MMR") system. MSI can be found in approximately 15% of all colorectal cancers. Of this 15%, approximately 3% are a consequence of the genetic disease Lynch syndrome and nearly all Lynch syndrome colorectal cancers have MSI, and the remaining 12% represent the non-inherited form of DNA MMR inactivation.<sup>(63)</sup> MSI is one of the most important molecular biomarkers in colorectal cancers because it indicates the pathophysiological genesis of the tumour, and it provides clinical prognostic information used in patient care. For example, stage II CRC MSI-H patients may have a good prognosis and do not benefit from fluorouracil (5-FU) adjuvant therapy.<sup>(64)</sup>

BRAF mutation analysis combined with MSI analysis supports the exclusion of a diagnosis of Lynch syndrome in colorectal cancers that exhibit MSI or loss of MLH1 protein expression.<sup>(65)</sup> As a result, updated Amsterdam criteria and Bethesda guidelines, as well as the recent ESMO, ASCO and NCCN guidelines recommend MSI testing in the vast majority of colorectal cancer patients and BRAF testing in positive MSI to rule out Lynch syndrome.

##### Market potential

As noted above, each year approximately 300,000 patients are diagnosed with colorectal cancer in the European countries where Biocartis is building a direct sales presence. NCCN guidelines advise testing for MSI in all colorectal cancer patients up to 70 years and for all patients with stage II disease because of their better prognosis and lack of benefit from treatment with 5-FU.<sup>(66)</sup> However, there is still a relatively low penetration of MSI testing, which



management believes is due to the cumbersome process associated with current MSI tests available on the market, which use the technology of capillary electrophoresis, a technology only available in the largest molecular laboratories. For example, INCa performed 9,528 MSI tests in 2012 in France,<sup>(67)</sup> whereas management estimates that there were approximately 31,000 colorectal cancer patients with stage I-III MSI in France which could have been tested, meaning that only approximately 32% of eligible patients were tested. Management believes that the current underuse of MSI testing could be overcome, in part, with Biocartis's MSI assay, which it believes is much easier to use than currently available MSI tests. Management also believes that the joint availability of Biocartis's MSI assay and Idylla™ BRAF Mutation Test on the same platform should constitute a unique and attractive offering for the testing of colorectal cancer patients in the future.

#### Description and status

Biocartis entered into a licence agreement with the VIB (Dr. Diether Lambrecht's laboratory) in November 2013 to secure an entirely novel set of MSI biomarkers obtained from whole exome sequencing of 17 colon and endometrial cancers with MMR deficiency. The novel marker set is capable of detecting MSI and management believes that it can show greater specificity and selectivity than standard MSI tests.

The data generated from further clinical sample testing allowed Biocartis to isolate a panel of around 10 biomarkers that are expected to form the basis of a PCR-based MSI assay for colorectal cancers compatible with the Idylla™ platform. Biocartis began developing the MSI assay in the first quarter of 2015, with product launch as a CE-marked IVD currently scheduled for 2016.

#### Competition

There are currently no CE-marked products for the MSI assay. However, Promega does produce RUO kits. No tests are currently available which can analyse MSI by means of PCR, or which are fully integrated. The total cost of an MSI test for a laboratory heavily depends on the methodology used and can range from €150<sup>(68)</sup> to €448.<sup>(69)</sup>

*Liquid biopsies: RUO assays for detecting mutations in cell free plasma DNA ("cfDNA") for monitoring of cancer*

#### Medical need

Liquid biopsy testing (using plasma or urine, for example) has many advantages over tissue sample testing, including the following:

- it enables repeated testing of patients, for instance during therapy, to monitor response and relapse of disease;
- it allows additional diagnostic tests to be performed on patients where no additional biopsy material is available, which is particularly relevant for lung, pancreatic, and central nervous system cancers (where biopsies are often extremely small or very difficult to access) and for use in pharmaceutical clinical trials (where new therapies are often first tested as a third or fourth line of treatment, such as in melanoma);
- it does not require prior information of the location of the tumour; and
- it allows the generation of clinically relevant molecular information without the need for the patient to undergo an invasive tissue sampling procedure.

In addition to plasma, urine is a promising sample type for liquid biopsies. Urine has particular relevance for the detection of urogenital malignancies, such as kidney, bladder, prostate and cervical cancer, where tumour-derived nucleic acids are either expelled into the urine, or flushed from the urogenital tract during urination. An isolation of cfDNA from large volumes of urine is expected to enable detection of oncogene mutations at an even higher sensitivity as compared to isolation of cfDNA from 1 ml of plasma. Therefore, urine might become the sample of choice and a basis for early stage cancer screening tests and monitoring of

residual diseases after successful therapy. The latter are fields that are expected to emerge in five to ten years, but management believes that early investment is warranted in order to capture long-term growth.

### Market potential

Although it may take a number of years before liquid biopsies catch up with tissue sample testing, annual sales of such tests are expected to exceed US\$10 billion post 2020.<sup>(70)</sup> The market potential for liquid biopsy testing can be divided into three segments: tests for routine diagnosis, tests for routine monitoring and research tests.

For routine diagnosis, there is a short term market potential for patients where no biopsy material is available. The most imminent medical need is for lung cancer, where up to 25% of patients are not surgically treated for various reasons, including patient status.<sup>(71)</sup> In September 2014, the European Medicines Agency extended the drug label of Iressa (AstraZeneca) to include the detection of EGFR mutations of circulating tumour DNA in cases without an available tumour sample. The reimbursement codes for diagnosis currently in place for lung cancer in most key markets can also be used for liquid biopsies. The market for EGFR liquid biopsies is therefore expected to significantly increase to cater for up to 25% of eligible lung cancer patients. Other key factors driving an increase in liquid biopsies are the lower burden on the patient to obtain a sample and the high cost of tissue biopsies. For instance, management estimates a tissue biopsy may cost more than US\$10,000 to conduct, excluding expenses associated with complications, which can occur in around 15% of biopsies. In the longer term, this is expected to lead to the use of cheaper and less invasive liquid biopsies, in addition to current tests.

Monitoring tumour mutations during treatment can support a quicker adaptation of treatment to respond to any changes in the genetic profile of a tumour that are detected. Ultimately, personalised medicine will lead to treatment which continually adapts to the changing tumour profile. In the mid-term, management believes that lung cancer patients, patients with colorectal cancer (with wild-type extended RAS tumours) and melanoma BRAF mutant patients will be tested two to four times per year. Management believes that it will take several years for monitoring tests to become routine, as more clinical evidence is still needed and reimbursement for monitoring tests is not yet in place in most major markets.

For research purposes, liquid biopsy testing is one of the key current trends in pathology laboratories and many university hospitals are dedicating budgets to this area. This research is expected to generate substantial short term market demand for liquid biopsy tests.

### Description and status

In view of the medical need for liquid biopsy testing, Biocartis intends to develop liquid biopsy variants of some of its solid tumour assays. In its first wave of development, it intends to develop plasma versions of its KRAS assay, NRAS assay, NRAS/BRAF assay and NRAS/BRAF/EGFR492 assay described above, as well as a plasma version of a lung cancer panel assay ("LCP").

At the American Association for Cancer Research and the American Society of Clinical Oncology (ASCO) meetings in April and June 2014, respectively, Biocartis and Dr. Filip Janku (MD Anderson Cancer Center, Houston, Texas) presented an initial method of analysing purified circulating DNA by means of the Idylla™ cartridge used for the Idylla™ BRAF Mutation Test. This yielded results that showed a high concordance with tissue-based testing (88%), and complete concordance (100%) with the most sensitive digital PCR method available for plasma testing ("BEAMing," the digital PCR service developed by Sysmex Inostics).

Studies by Dr. Filip Janku and Dr. Bart Neyns (University Hospital Jette, Brussels) in melanoma patients have shown that a proposed Biocartis liquid biopsy test could predict the survival and response rates of patients in connection with certain targeting agents. Furthermore, management believes liquid biopsy tests could also indicate treatment failure or tumour growth more rapidly as compared to analysis by CT scanning.

Management expects that formal development of the first liquid biopsy assay for the detection of extended KRAS mutations will begin in the second quarter of 2015. Management currently expects that this KRAS liquid biopsy assay will be launched in the first half of 2016 as an RUO test.

### Competition

Sysmex Inostics offers its digital PCR service, called "BEAMing", for liquid biopsy testing in oncology as an LDT. Other LDTs combine Life Technologies, or Qiagen cfDNA kits with Roche or Qiagen mutation tests. BEAMing test prices range from US\$550 (for example, OncoBEAM BRAF 2, detecting BRAF V600E and K mutations) up to over US\$1,000 (for example, OncoBEAM KRAS 7, detecting 7 KRAS mutations).<sup>(72)</sup>

Qiagen has just launched a CE-marked EGFR Liquid Biopsy Test and Roche also plans to launch a test on the cobas system, but both tests still need to be combined with DNA purification kits. Several other companies focus on Circulating Tumour Cells ("CTCs") and circulating DNA, such as Biocept and Fluxion Biosciences. Other players in the oncology diagnostics market are also likely to develop offerings for liquid biopsy. However, at present, there is no fully integrated IVD solution for liquid biopsy testing. Management therefore believes that the development of the Biocartis liquid biopsy assays (including a range of RUO assays for detecting BRAF, KRAS, NRAS, EGFR and other mutations in cfDNA for monitoring of cancer) could uniquely fulfil the current clinical research needs.

### ***Infectious disease assays***

Biocartis's assays in the infectious diseases area will initially focus on sepsis and other rapid response laboratory assays, as well as viral load assays (such as HIV and HCV). Biocartis aims to focus (as of 2016) on more syndromic panels that not only detect the most common pathogens of a particular syndrome, but also less common pathogens. Management believes that such syndromic panels, which will leverage the multiplexing capability of the Idylla™ platform, will enable physicians to more rapidly assess the cause of disease in patients that manifest symptoms of a particular syndrome.

#### *Sepsis assay*

##### Medical need

Bloodstream infections, such as Staphylococcus (including MRSA), Enterococcus, and E. coli infections, all which can lead to sepsis, are the third most common cause of hospital mortality and are the seventh and eleventh leading cause of all US deaths for infants and adults, respectively.<sup>(73)</sup> In a seven-year cohort study involving 49 US hospitals reported in 2004, mortality rates directly attributable to bloodstream infections were estimated to be between 16% and 40%. According to surveillance data from US hospitals, 87% of blood stream infections are caused by a single infecting microorganism, of which gram-positive bacteria accounts for 65%, gram-negative bacteria for 25%, and fungi for 9.5%.<sup>(74)</sup> As a result, management believes that there is a high unmet need for the detection of such bacteria and fungi on a timely basis.

In particular, there is a significant unmet need for the timely diagnosis of sepsis, a severe inflammatory response to a bacterial or fungal infection, most commonly affecting immunocompromised, critical care and elderly patients. Sepsis can rapidly spiral out of control and progress to severe sepsis or septic shock, with a mortality rate of nearly 50% in the event of severe sepsis.<sup>(75)</sup> Sepsis is among the top ten leading causes of death in the United States.<sup>(76)</sup> Sepsis is typically caused by about 15 bacterial pathogens, and effective treatment requires the early detection and identification of these specific target pathogens in a patient's bloodstream. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, which can be ineffective and unnecessary and which has contributed to the spread of antimicrobial resistance. There is evidence that a delay in the effective treatment of a patient with sepsis increases mortality by 7.6% per hour in the first six hours.<sup>(77)</sup>

Current molecular tests for bloodstream infections are conducted on blood culture, which leads to a delay of 24 to 48 hours in the administration of targeted treatment and unnecessary

hospital expense. Sepsis is the most expensive hospital treated condition in the United States.<sup>(78)</sup> Moreover, blood culture tests are estimated to have a false negative rate of approximately 50%; with false negative results occurring more frequently in patients who have received prior antibiotic therapy. Management therefore believes that the entire sepsis assay process and workflow should ideally be completely automated and contained as:

- faster diagnosis leads to better patient outcomes so it is crucial that the time taken from sample-to-result is as short as possible. The ability for non-laboratory personnel (for example, nurses) to perform fully automated tests close to the patient in non-specialised laboratory environments will circumvent the usual delays in the process (such as transfer time for the sample to get to a specialised laboratory, or waiting for the availability of trained personnel); and
- manual steps increase the risk of contamination of samples with bacteria, thereby leading to a higher frequency of false positive results.

### Market potential

Sepsis affects an estimated 20-30 million people every year worldwide.<sup>(79)</sup> The American Hospital Association estimates that nearly 35 million people are admitted to over 5,000 community and Federal Government hospitals in the United States each year<sup>(80)</sup> and sepsis occurred in nearly 3% of all adult hospitalisations in the United States between 2003 and 2007.<sup>(81)</sup> According to the US Department of Health and Human Services and the Global Sepsis Alliance, sepsis accounted for approximately US\$20 billion, or 5%, of total aggregate costs associated with domestic hospital stays in 2011.<sup>(82)</sup> In 2009, the average cost per episode of sepsis per patient in the United States was between US\$18,500 and US\$33,900, with the average cost per day of treatment being US\$2,300.<sup>(83)</sup> The costs related to long-term damage resulting from sepsis are unknown. It is generally believed that rapid and accurate detection of the disease causing pathogen and the implementation of appropriate antibiotic therapy is key to reducing patient mortality rates, reducing patient days in the ICU and subsequently reducing hospital stay and cost. In the United States, a shift from a fee-for-service based reimbursement to a managed care model over the past decade has changed the way hospitals operate. These changes have encouraged cost scrutiny and incentivised hospitals to perform preventative care to mitigate costs so costs remain within reimbursement profiles. Management therefore believes that there is significant market potential for a sepsis assay which offers significantly reduced sample-to-result time.

### Description and status

Biocartis is developing Idylla™-Enrich, a dedicated platform for enrichment of pathogen DNA from blood coming from patients with a suspected blood stream infection. Biocartis is also developing on its Idylla™ platform an accompanying sepsis assay with the aim of significantly reducing the time taken between sample and result for bloodstream infections and reducing the rate of occurrence of erroneous results. For further information on Idylla™-Enrich, see “—Products—Idylla™-Enrich, a product line extension of the Idylla™ platform ” below.

Biocartis is working with Microbiome (a life-sciences company specialising in molecular microbiology and headquartered in Houten, The Netherlands), which is currently developing an assay for bloodstream infections intended for expert users only i.e., at this stage of development the assay will be used as a manual kit to be used in conjunction with Idylla™-Enrich. In the second stage, the assay will be used on the Idylla™ platform, and Biocartis has licenced the assay technology. The manual kit assay is expected to be withdrawn as a combined package with Idylla™-Enrich when the sepsis assay for use on the Idylla™ platform is launched.

The sepsis assay, which is expected to be launched in 2017, is expected to be able to detect 15 of the most prevalent sepsis-causing pathogens, such as Pneumococci, Staphylococci and E. coli. It is also expected to contain a module for generic detection of gram-positive, gram-negative and fungal infections (“molecular gram stain”), which management believes covers over 90% of all bloodstream infections. In addition, the sepsis assay is expected to be able to detect a number of key antibiotic resistance genes. As a result, management believes that the sepsis assay will enable physicians to make an informed choice regarding the first line of treatment.

The Idylla™-Enrich platform has been extensively tested with blood samples from critically ill patients through academic collaborations with laboratories in Amsterdam and Den Bosch (The Netherlands). Results show that the Idylla™-Enrich sample enrichment platform is capable of handling a wide range of blood volumes (between 0.5-10 ml). Analysis of varying volumes of blood samples spiked with fixed concentrations of pathogen cells show the ability of the Idylla™-Enrich platform to handle larger sample volumes. Very few bacteria may be present in the blood of sepsis patients, and, therefore, most DNA that is extracted from blood is of human origin. Pathogen-specific PCRs are inhibited in the presence of large amounts of human DNA. This therefore limits the ability to detect bacteria or fungi in blood sample volumes higher than 1 ml. However, the Idylla™-Enrich platform selectively enriches pathogen DNA via a new generic proprietary chemistry that does not involve target specific capture probes. It therefore allows the use of much larger sample volumes, which results in a proportional improvement of PCR results. Tests comparing Idylla™-Enrich enriched samples that have been subsequently extracted versus blood samples directly extracted, in each case with the extracted DNAs analysed using pathogen-specific PCRs, showed a 10- to 100-fold improvement in detection rate.

Idylla™-Enrich has also been extensively tested with spiked pathogen cells at varying concentrations to compare the enrichment of amplifiable pathogen DNA obtained versus other enrichment or sample preparation methods, including MoYsis (Molzym, Finland), an enzymatic pathogen enrichment offering, and the extraction of whole blood DNA from 200 microliter of blood following detergent lysis of red blood cells from Microbiome, with amplification performed by pathogen-specific PCR. For representative pathogens from the three major pathogen types (gram-negative, gram-positive and fungi), Idylla™-Enrich sample enrichment routinely delivers 10- to 100-fold lower detection thresholds versus the competitive offerings tested.

Idylla™-Enrich has been chosen as the method of choice for sample enrichment in the Dutch Centre for Translational Molecular Medicine (“CTMM”) MARS programme (Molecular Diagnosis and Risk Stratification of Sepsis, a multi-party multi-year grant programme), the largest clinical trial programme for sepsis in the world (7,400 patients with suspected sepsis). To date nearly 8,000 samples have been processed using the Idylla™-Enrich proprietary chemistry.

### Competition

MDx based tests to identify sepsis causing pathogens have so far been commercially unsuccessful because of performance and workflow issues. MDx tests working directly from blood suffer from low sensitivity, as the volume of blood that can be interrogated is limited by the inhibitory effects of human background DNA. In addition, as these tests use labour intensive and complex workflows, their typical six to eight hours turnaround time is much too long to be included in the daily routine. Other MDx tests that work from positive blood cultures accelerate the identification process, but still suffer from the 24-48 hour gap for the blood cultures to turn positive. None of these tests are game changing in the sense that they cannot alter the paradigm of having to choose a treatment for bloodstream infections before any diagnostic information is available.

bioMérieux and Becton Dickinson are the major players in the blood culture market, with product offerings such as the BacTec and BacT/ALERT. Amongst others, bioMérieux (BioFire) and Nanosphere offer positive blood culture identification assays that cover a range of different pathogens. In addition, there are molecular assays specifically for MRSA testing of positive blood cultures currently on the market, and the major player in this market is Cepheid.

The combination of Idylla™-Enrich and the Idylla™ sepsis assay is expected to allow molecular analysis to begin on the Idylla™ platform only 30 minutes after a blood sample has been received, making test results available within a total of approximately two hours. Management believes that this much faster turn-around would offer physicians the potential to change the paradigm of experience-based treatment selection to evidence-based clinical decisions in sepsis. The only direct competitor offering similar performance (three hours turnaround time and 1 colony-forming unit/ml sensitivity) is T2 Biosystems with its T2Dx system. This system uses a nuclear magnetic resonance based method and target-specific capture probes to detect pathogens directly in 2 ml of blood. As of 31 March 2015, a test for fungal infections (specifically, Candida) is

believed to be the only test available on the T2Dx system. Bacterial tests have been announced, but are not yet on the market. In contrast, the new Idylla™-Enrich enrichment technology involves a new proprietary chemistry that is applicable to a wide range of Gram positive/Gram negative bacteria and fungi species, as it is not dependent on the use of target specific capture probes.

Other than the T2Dx system, competitor tests have comparatively long turn around times and market prices for rapid sepsis testing still need to be established. Management believes that the combined use of Idylla™-Enrich and its sepsis assay, as an alternative to current tests, will substantially reduce the time taken from sample-to-result, treatment costs and the length of stay of patients, and thereby create substantial cost savings for care providers. Management believes that these cost savings could, to a certain extent, be reflected in the price of the Idylla™ sepsis assay.

### *Respiratory assays (upper respiratory tract infections)*

#### Medical need

Respiratory viruses are one of the most important causes of morbidity and mortality throughout the world,<sup>(84)</sup> with the influenza virus killing at least 50 million, and possibly as many as 100 million, people in the last century alone.<sup>(85)</sup> The majority of diagnostic tests currently used for this market are rapid immunoassays used at the point-of-care, due to their low-cost as well as convenience. However, one of the key downsides of these rapid immunoassays is their poor performance and that samples typically have to be re-tested with a more sensitive molecular test in a central laboratory. As a result, management believes that there is currently a high unmet need for a test that is designed to provide rapid and reliable results at the point-of-care. In addition, management believes that there is a high unmet need for a respiratory panel assay as, for hospitalised patients, this could lead to the fast triage of patients and targeted treatment and would have a substantial time and workflow benefit compared to performing separate tests.

#### Market potential

The worldwide respiratory diagnostics market was worth around US\$195 million in 2012 and is expected to grow at a CAGR of 8.3% to 2017.<sup>(86)</sup> According to management estimates, influenza tests represent the majority of the market, with the remainder constituting more centralised tests for viruses, such as Respiratory Syncytial Virus (“RSV”), adenovirus, enterovirus and parainfluenza.

#### Description and status

In collaboration with Biocartis, J&J, has developed a first respiratory panel assay, known as Influenza Virus—Respiratory Syncytial Virus (or “IFV-RSV”) for the detection of influenza H1, H1’09, H275Y variant (conveying resistance to Tamiflu), H3, influenza B, RSV A, and RSV B in nasal and nasopharyngeal swabs from patients with influenza-like illness. This assay is in the verification phase and is scheduled for registration trials in the United States in the 2015-2016 flu season. Performance of this assay as a prototype test is superior to existing assays on the market. Clinical performance on 105 previously characterised samples showed 100% concordance with positive, as well as negative, results. In comparison with the FDA cleared Verigene Respiratory Virus Plus Test on the Nanosphere MDx platform, 98/99 samples showed concordant results. One sample showed a negative result in the Verigene test, while showing positive RSV B result on the Idylla™ platform, and the positive result was confirmed by sequencing. In comparison with rapid flu antigen assays, Idylla™ showed 100% sensitivity in a set of 30 RSV samples, while the rapid tests showed an average sensitivity of 40% (ranging from 3% to 70%).

<u>Study/trial</u>	<u>Locations</u>	<u>Number of samples</u>	<u>Discordant samples</u>	<u>Overall concordance</u>	<u>Samples tested with discordance test</u>	<u>Concordance Idylla™ vs 3rd test</u>	<u>Corrected overall concordance</u>
Prototype study . . .	In-house	99	1	99% <sup>(1)</sup>	1	1 <sup>(2)</sup>	100.0%

Notes:

(1) Reference methods: FDA-approved Verigene Respiratory Virus Plus Test.

(2) Sequencing.

Management believes that respiratory assays are generally suitable for Biocartis's US regulatory strategy. Flu-based assays such as the IFV-RSV assay can be the subject of 510(k) clearance based on studies comparing the test with predicate devices in the market. Furthermore, such assays are ideally suited for exploration of CLIA-waived markets. For further information, see "*—Regulation—United States—Biocartis and US regulation*"). Management currently expects that this assay will be launched in 2016.

Biocartis and J&J are also working with the China Centre for Disease Control in Beijing on a second version of this assay for the purpose of pandemic flu surveillance, known as Influenza Virus-Surveillance (or "*IFV-S*"), Biocartis's first research and development collaboration focused on the Chinese market. This assay contains, in addition to the commonly circulating strains, potentially novel pandemic influenza strains that require surveillance. Management currently expects that this assay will be launched in 2016.

Biocartis is also currently planning to develop a third respiratory assay, the Respiratory MP (mixed panel) assay, that is expected to detect a range of over 20 viral and bacterial pathogens commonly found in upper respiratory tract infections. Management currently expects that this assay will be launched in 2017.

### Competition

The main competing CE-marked products for the IFV-RSV are rapid immunoassays used at the point-of-care produced by Focus Diagnostics and a PCR based assay produced by Hologic (Prodesse).

The main competing CE-marked products for the Respiratory MP (mixed panel) assay are respiratory panel assays produced by bioMérieux (BioFire FilmArray), Luminex (xMap) and Autogenomics, but only bioMérieux's FilmArray panel offers a rapid turnaround time (though management believes that it is not as easy to use as the Idylla™ platform).

The FilmArray Respiratory Panel from bioMérieux costs US\$129 and xTAG RVPv1/RVP FAST from the Luminex costs US\$120<sup>(87)</sup> (i.e., excluding any associated laboratory costs, which would not be applicable when using the Idylla™ Respiratory MP (mixed panel) assay).

### *HBV, HCV, and HIV viral load assays*

#### Medical need

Hepatitis C (HCV) is an infectious illness caused by the HCV virus, which infects the liver and causes inflammation. HCV is the most common chronic blood-borne viral infection. According to the US Center for Disease Control and Prevention (the "*CDC*"), there are approximately 3.2 million chronically infected people in the US, or more than 1% of the total population.<sup>(88)</sup> The World Health Organization ("*WHO*") estimates a similarly high prevalence of 5-10 million cases in Europe and approximately 3% of the global population, or more than 170 million chronic carriers, of whom 5-7% may ultimately die of the consequences of HCV infection.<sup>(89)</sup> The infection is often asymptomatic, but chronic infection can progress to scarring of the liver (fibrosis), and advanced scarring (cirrhosis), which is generally apparent after many years. In some cases, those with cirrhosis will go on to develop liver failure or other complications of cirrhosis, including life threatening oesophageal or gastric varices. Left untreated, chronic HCV can lead to liver cancer or liver cirrhosis requiring liver transplantation.

Today, HCV treatment has become almost as straightforward as HIV treatment: the use of direct-acting antiviral agents ("*DAAs*") was introduced for HCV infections and replaced the majority of interferon-alpha-based regimens. Interferon therapy generates considerable and severe side effects requiring monitoring of patients in specialised centres. Today, HCV treatment could be performed by general practitioners. However, such new DAA treatments still require viral load monitoring in order to determine initial response, treatment duration and sustained response. Such viral load assays are currently only performed in laboratories performing batch-based analyses on e.g., Roche cobas® or Abbott m2000® systems. Often an additional week of therapy is administered because of the five-day turnaround time of these batch-based assays.

With a cost of treatment with sofosbuvir (Sovaldi, Gilead), or the new combination therapy with ledipasvir and sofosbuvir (Harvoni, Gilead), of approximately US\$1,000-US\$1,125 per patient a day,<sup>(90)</sup> significant cost savings (approximately US\$7,000-8,000 per patient) could be achieved if HCV viral load could be tested immediately at the time of patient visits.

Like HCV, hepatitis B is an infectious illness caused by the hepatitis B virus (“HBV”), which also infects the liver. Originally known as “serum hepatitis”, the disease is endemic in larger parts of Sub-Saharan Africa and South-East Asia. According to the CDC, about a quarter of the world’s population, more than 2 billion people, have been infected with the hepatitis B virus, including 350 million worldwide who are currently chronic carriers of the virus. In Southeast Asia and China especially, HBV infection represents one of the major health problems, with 10-15% of the population infected, with most infections occurring at birth or early childhood, such patients remaining chronically infected, with cirrhosis and liver cancer as major sequela of this disease. Transmission of hepatitis B virus results from exposure to infectious blood or body fluids, such as semen and vaginal fluids, while viral DNA has been detected in the saliva, tears, and urine of chronic carriers with high titre DNA in serum. Perinatal infection is a major route of infection in endemic (mainly developing) countries. Globally, according to the WHO, more than 780,000 people die every year due to the acute or chronic consequences of hepatitis B, including liver scarring and liver cancer. A vaccine against hepatitis B, available since 1982, is 95% effective in preventing infection.

HIV continues to be a major global public health issue, having claimed more than 39 million lives so far. In 2013, 1.5 million people died from HIV-related causes globally. There were approximately 35 million people living with HIV at the end of 2013 with 2.1 million people becoming newly infected with HIV in 2013 globally. Sub-Saharan Africa is the most affected region, with approximately 24.7 million people living with HIV in 2013.<sup>(91)</sup> Also sub-Saharan Africa accounts for almost 70% of the global total of new HIV infections.<sup>(92)</sup> According to the CDC, 1.15 million HIV infected individuals age 13 and older are living in the United States, including approximately 170,000 undiagnosed individuals, which contributes to the spread of the virus.<sup>(93)</sup> Incidence is still increasing as approximately 50,000 persons are newly infected per year, while approximately 20,000 HIV infected person die per year. HIV prevalence in Europe is slightly lower than in the United States.

HIV targets the immune system and weakens people’s surveillance and defence systems against infections and some types of cancer. As the virus destroys and impairs the function of immune cells, infected individuals gradually become immunodeficient. Immune function is typically measured by CD4 cell count. Immunodeficiency results in increased susceptibility to a wide range of infections and diseases that people with healthy immune systems can fight off. The most advanced stage of HIV infection is Acquired Immunodeficiency Syndrome (“AIDS”), which can take from 2 to 15 years to develop depending on the individual. AIDS is characterised by low CD4 cell count, development of certain cancers, infections, or other severe clinical manifestations. HIV infection is usually diagnosed through blood tests detecting the presence or absence of HIV antibodies. There is no cure for HIV infection. However, effective treatment with antiretroviral drugs can control the virus so that people with HIV can enjoy healthy and productive lives. In 2013, around 12.9 million people living with HIV were receiving antiretroviral therapy globally, of which around 11.7 million were in low- and middle-income countries. Paediatric coverage is still lagging in low- and middle-income countries.

### Market potential

Viral load assays for HBV, HCV, and HIV form one of the cornerstones of the molecular diagnostics for infectious diseases today. According to the research specialist Kalorama Information, HIV molecular tests for diagnostics, genotyping and drug resistance represented a US\$900 million market opportunity in 2012 and the market for HCV and HBV testing (combined), a US\$700 million market opportunity.<sup>(94)</sup> In addition to viral load monitoring, HIV, HBV and HCV assays are used in routine clinical diagnosis for viral infections, and are often used as a confirmatory test after a screening immunoassay-positive result. Management believes that this market could be covered with just one molecular assay, particularly when the quantitative viral load assay is very sensitive with a limit of detection in the range of a qualitative viral detection assay. Furthermore, when used on a high throughput variant of the Idylla™ platform



(see “—Primary other future developments—High volume testing”) the blood bank nucleic acid testing market could be targeted with this viral load menu. Management estimates this blood bank market is worth about €1 billion per year, and believes it to be a potential market opportunity for Biocartis should the high volume testing solution be able to meet the needs of the bloodbanking segment.

Viral load testing is the gold standard in HIV treatment monitoring and is recommended by the WHO.<sup>(95)</sup> The Clinton health access initiative estimates that approximately 37 million HIV viral load tests will be needed by 2020.<sup>(96)</sup> There is currently an urgent need for HIV viral load tests in remote settings, especially in Africa. Tests and systems that can be operated in remote settings will therefore be of particular benefit in fulfilling this demand. UNAIDS reported that an opportunity exists for widespread up-scaling of cost-efficient viral load testing in developing countries.<sup>(97)</sup>

### Description and status

Few integrated MDx systems have the capability to (in addition to plasma and blood sample preparation, RNA and DNA purification, and PCR detection), perform quantitative analysis by means of real-time PCR within a disposable closed cartridge. The prototype of the quantitative HCV-viral load (“HCV-VL”) assay starts directly from plasma or whole blood samples, which management believes is game changing in the field of HCV-VL testing. The HCV-VL prototype assay utilises the same set of pre-dispensed reagents for both sample processing and reverse transcriptase-PCR steps in a closed cartridge format, and demonstrates an equivalent performance in whole blood compared to plasma. The limit of detection for the HCV-VL panels in whole blood and plasma has been determined down to 13 IU/ml. The HCV-VL prototype assay has a large dynamic range, and when compared with an FDA approved molecular assay on 20 paired clinical whole blood and plasma samples, revealed 100% positive agreement (with 96% correlation in plasma and 94% correlation in whole blood).

The fully automated HCV-VL assay design eliminates the hands-on time needed for viral sample preparation and provides results in less than two hours without the need for skilled personnel. Coupled with the multiplexing capability and flexible throughput capacity of the Idylla™ platform, this makes it stand out as a desirable choice when searching for a molecular diagnostic option. Management believes that the HCV-VL assay will offer a convenient aid in patient management for clinicians and public health officials and will aid in-patient compliance in adhering to antiviral therapies.

The HCV-VL assay is currently in the verification phase, and development of the HBV viral load assay is planned to follow after the HCV-VL assay. Management aims to launch the three viral load assays in Europe starting in 2017.

### Competition

Current testing for HIV, HBV, and HCV can generally be divided into two categories: an initial diagnostic test (often performed with immunoassays) and subsequent viral load tests used for monitoring of chronic diseases and response to treatment. HIV, HBV and HCV tests are performed in similar settings and on similar platforms and, as such, can be considered as a joint market. This market has been dominated by Roche, Novartis, and Abbott because of the intellectual property rights they had on PCR and viral markers. With the expiry of these patents, the market is now opening up and management believes there is opportunity for newcomers where competitive elements such as easy of use, cost, and test performance are expected to be important drivers. The main competitors are Roche, Abbott, Novartis, and Siemens, each with high-throughput systems used in specialised laboratories. Several new competitors, such as Cepheid, IQum (Roche) and Quidel have announced that they are developing HIV and/or HCV viral load tests on a sample-to-result system for use in a near-patient setting or in resource-poor settings (developing countries).

The Issuer has not yet obtained any competitor pricing information for fully-integrated, sample-to-result MDx HIV, HBV or HCV tests.

## **Public health initiatives**

Management believes that the Idylla™ platform's unique features put it in a position where it can quickly respond to critical need for a specific type of assay in case of a public health emergency.

### *Ebola assay*

#### Medical need

The most widespread epidemic of the Ebola virus disease (known as “Ebola”) in history is ongoing in several West African countries,<sup>(98)</sup> with 23,781 infections and 9,637 deaths having been recorded in Guinea, Sierra Leone, and Liberia by 24 February 2015.<sup>(99)</sup> Management believes that the 2014 Ebola outbreak is an example of the type of public health emergency where it is important to detect an outbreak and its spread on an urgent basis and to rapidly identify infected patients for subsequent quarantine and supportive medical care.

#### Market potential

Management believes that the ease of use of the Idylla™ platform, combined with a compatible Ebola assay (which is currently under development), will allow Ebola virus testing to occur near the patient, without the need for either specialised laboratory facilities or trained laboratory personnel. In addition, it will, necessarily involve the infectious sample being immediately contained in a fully closed cartridge, preventing the risk of contamination.

Furthermore, management believes that the Ebola outbreak illustrates that the current surveillance and disease control approach is inadequate in terms of timely, high-quality reporting of the spread of diseases throughout larger parts of the world. The Idylla™ platform was designed to significantly lower the barrier for MDx testing in terms of required user experience, infrastructure and capital cost, whilst also providing accurate, high quality, reproducible, standardised and clinically actionable assay data in close proximity to where healthcare workers and patients interact. Management believes the Idylla™ platform could be used for surveillance and disease control purposes in rural settings, airports, ships, etc. Building further on the capabilities of Idylla™ Connect (for further information see, “*Future developments—Idylla™ Connect, a remote connectivity solution for the Idylla™ platform*” below), the Idylla™ consoles and instruments could also function as “local diagnostic sentinel nodes” which (following physician and patient consent) could send anonymised diagnostic results to local, regional and/or international disease data gathering and analysis centres.

While the current Ebola epidemic may fade away during the next one to two years, and with it the need for Ebola testing, management believes a longer term diagnostic opportunity lies in the monitoring of travellers with a fever who have travelled from regions where certain diseases are endemic, and in the support of trials for Ebola vaccine development. Biocartis is therefore currently developing a Rapid Triage Ebola Test for its Idylla™ platform (the “**Ebola assay**”).

#### Description and status

The Ebola assay, which is being developed in collaboration with J&J and the Institute for Tropical Medicine in Antwerp, is intended to be used as an IVD test for near-patient qualitative detection of the Zaire Ebola virus and Sudan Ebola virus (the 2014 outbreak was caused by the Zaire species). The Ebola assay uses RNA liberated from the whole blood of individuals suspected of having the Ebola virus. The assay is a sample-to-result real-time reverse transcriptase PCR test that allows to process whole blood directly in the cartridge without the need for pipetting or centrifuging.

Management believes that the determination in August 2014 that IVDs which detect the Ebola virus may be granted so-called Emergency Use Authorisation (“**EUA**”) in the United States has created a significant opportunity for the Idylla™ platform, which is well suited for near impact testing by non-laboratory trained healthcare professionals. Biocartis therefore sent an EUA interactive review application to the FDA in November 2014, positioning the Idylla™ platform as a class II, 510(k) device (this covers the instrument and its software, the console and

its software as well as the generic cartridge information) and its Ebola assay as suitable for EUA. The FDA's response in December 2014 indicated that the Idylla™ platform and the Ebola assay are suitable for EUA. In order to clear the Ebola assay as an IVD suitable for EUA, Biocartis, or a partner, needs to conduct an analytical validation study. To this end, Biocartis has made prototypes of the Ebola assay available for field testing since December 2014. Studies using these prototypes are ongoing at the NIH in the United States, and management expects to submit the Idylla™ platform and Ebola assay for EUA approval during the second quarter of 2015. In order that Biocartis can continue to market the Ebola assay in the United States after any EUA clearance it may receive has been withdrawn, management intends for Biocartis, or a partner, to proceed with clinical performance testing of the Ebola assay during the second quarter of 2015 in West Africa, and to potentially use this to support a 510(k) clearance application for the Idylla™ platform and a de novo 510(k) clearance application for the Ebola assay in the second half of 2015.

### Competition

Following the 2014 Ebola outbreak, several tests have been granted EUA by the FDA. Most of those tests are molecular tests (developed by US federal laboratories) that rely on manual extraction of the viral RNA from whole blood, plasma or serum. This manual process is not only time consuming, but it also introduces variability and is prone to handling errors. Due to the highly infectious nature of the Ebola virus, these tests require highly contained laboratory environments, which are scarce in the countries primarily affected by the outbreak.

In particular, several MDx assays produced by competitors have received EUA: an assay on the GeneXpert platform from Cepheid, two assays on the FilmArray platform through BioFire Defense; and manual kit assays from Roche, Altona the CDC and the U.S. Department of Defense. In addition, a dipstick immunoassay developed by Corgenix has received EUA. Although a number of the manual steps required by the other EUA MDx assays are automated by the various platforms, the tests still need to be operated by specialised laboratory professionals.

By comparison, management believes that the Ebola assay has significant advantages over the other assays that have received EUA. The Ebola assay eliminates the need for any kind of sample pre-treatment, thereby limiting the exposure of the operator to the infectious material to an absolute minimum. In addition, due to its ease of use, Biocartis expects that healthcare workers with no laboratory training will be able to perform the test, allowing a more widespread use of the test, even in decentralised environments (like mobile diagnostics laboratories and local clinics in West Africa). In addition, once the sample is loaded into the Idylla™ cartridge, there is no risk of contaminating the instrument or the environment. This eliminates the need for regular maintenance of the instrument, or the testing environment.

The kit price (i.e., excluding any associated laboratory costs, which would not be applicable when using the Idylla™ Ebola assay) for the FilmArray Ebola assay of BioFire Defense is quoted as US\$189.<sup>(100)</sup>

### **Other assays**

In line with its strategy to launch at least four to five new assays a year, Biocartis is currently developing a range of other assays which, due to their stage of development, are not described above, but are within its internal product pipeline. In addition, Biocartis intends to further leverage its capabilities via partners that will develop assays compatible with the Idylla™ platform.

Biocartis is also exploring several other Idylla™ assay opportunities in the oncology and infectious diseases field. Due to the stage of research or development, risk profile, or portfolio fit, these have not been included in the current Biocartis pipeline, but nevertheless they could represent considerable business opportunities with further development and de-risking, or with the future establishment of partnerships in non-core fields.

## Partnerships and collaborations

Biocartis has strategic partnerships in place for assay development and commercialisation with key industry players, such as J&J and Abbott Molecular. The partnership with J&J is focused on “complementary”, as well as companion diagnostics, while Abbott Molecular has selected Biocartis as its partner to develop companion diagnostic PCR assays for its customers (pharmaceutical and biotechnology companies). In the context of the Abbott partnership, management envisages closing collaboration agreements with pharmaceutical or biotechnology companies on the joint development of companion diagnostics in the second half of 2015. As part of Biocartis’s collaboration with J&J, a first respiratory panel assay, known as IFV-RSV has been developed to the verification phase. The assay is currently scheduled for registration trials in the 2015-2016 flu season and is planned to be commercialised by J&J.

In addition, to complement its in-house research and development team, Biocartis is in advanced discussions with several “content” or “diagnostic app” developers that will develop assays compatible with the Idylla™ platform. These developers are companies with considerable knowledge of MDx and disease that already offer multiplexed assays as manual kits and have an interest in investing in external development projects through transferring their existing assays onto the Idylla™ platform. This should allow Biocartis to expand the Idylla™ platform assays menu faster and lessen the burden on its in-house research and development resources. Biocartis currently intends to begin to work with such developers in 2015.

Biocartis makes a special assay development toolkit, called the “Developer’s Suite”, available to its strategic partners and external developers to make it possible for them to develop Idylla™ compatible assays. The toolkit includes, among other things, certain Biocartis software which allows partners to set and control all fluidic, temperature, PCR and other physical parameters in the Idylla™ cartridges, which is essential functionality for the development of an Idylla™ compatible assay. Biocartis also makes open Idylla™ cartridges available for internal and external developers so that they are offered flexibility in the choice of existing or new reagents for their various assay development programmes.

## Future developments

### ***Idylla™-Enrich, a product line extension of the Idylla™ platform***

For the sensitive diagnosis of bloodstream infections, it is essential that very low numbers (down to 1 cell per ml) of pathogens can be detected in blood. To reach this sensitivity, large volumes (e.g., 5-10 ml) of whole blood need to be analysed. PCR technology is limited when used on blood samples with a volume larger than 0.2-1.0 ml. This is because blood contains a large number of human white blood cells (typically somewhere between 4 and 11 million per ml), which together contain an amount of DNA which is large enough to inhibit PCR.

To further enhance the menu capability of the Idylla™ platform, Biocartis is developing a product line extension of the Idylla™ platform, internally known as “Idylla™-Enrich”, which is designed to overcome the problems with standard methods of detecting pathogens in blood through selective enrichment of bacterial and fungal DNA from up to 10 ml of whole blood. This selective enrichment process allows for a 50 fold larger sample volume (compared to standard methods) to be interrogated by PCR, and therefore offers a 50-fold higher sensitivity. The human background DNA is efficiently removed in the enrichment process, and the output of the Idylla™-Enrich platform is enriched pathogen DNA in a liquid sample ready for analysis on the Idylla™ platform. Management currently expects that the entire enrichment process will be completed in less than 30 minutes, with only two minutes of hands-on time.

In combination with the Idylla™ platform, the Idylla™-Enrich selective enrichment platform is designed to drastically accelerate, simplify and decentralise diagnostics for bloodstream infections. Biocartis has developed a prototype of the Idylla™-Enrich platform and industrialisation is ongoing, with an expectation of launch in conjunction with the sepsis assay.

As discussed above in “—*Infectious disease assays*” the Idylla™-Enrich platform has been extensively tested with blood samples from critically ill patients through collaborations with laboratories in Amsterdam and Den Bosch (The Netherlands). Idylla™-Enrich has been chosen as

the method of choice for sample enrichment in the CTMM MARS initiative, the largest clinical trial programme for sepsis in the world (with 7,400 patients with suspected sepsis). To date, nearly 8,000 samples have been processed using the Idylla™-Enrich method.

Biocartis is currently planning a staged launch for the Idylla™-Enrich platform. In the first stage, Biocartis intends to launch Idylla™-Enrich with a manual PCR kit for bloodstream infections intended for expert users only, which is currently being developed by Microbiome as part of the CTMM MARS programme. Biocartis has licenced this assay and will move it to the Idylla™ platform. In this initial stage, Biocartis will be focusing on educating key opinion leader users about the benefits of Idylla™-Enrich. Biocartis currently expects that pre-market/key opinion leader studies to support this education may be initiated by mid-2015.

For the second stage of the launch of the Idylla™-Enrich platform, Biocartis plans to develop the sepsis assay, which has already been designed to be compatible with the Idylla™ platform. The manual kit will be withdrawn as a combined offering with Idylla™-Enrich when the sepsis assay for the Idylla™ platform is launched (for further information, see “—*Infectious disease assays—Sepsis assay*” above).

### ***Idylla™ Connect, a remote connectivity solution for the Idylla™ platform***

Biocartis is developing a web-based application intended to offer remote connectivity solutions in support of the Idylla™ platform, internally known as “Idylla™ Connect”. The Idylla™ Connect application is being designed to operate in conjunction with an internet-connected Idylla™ console and will be available to all Idylla™ users who opt to use the application. When fully developed, Idylla™ Connect will be capable of monitoring instrument usage and cartridge consumption and allow users to remotely access their own Idylla™ test results and to send such test results to mobile devices.

As part of a comprehensive customer support function, two-way data communication is expected to allow Biocartis to provide remote assistance for customers requiring help, to monitor sensors and actuators, to verify proper functioning of instrument modules or subassemblies, and make it possible for users to upload new software updates to a console or instrument remotely. Furthermore, under a service contract, Biocartis expects that its customer service team will be able to monitor the performance data of the users’ instruments in order to identify wear and tear of the instrument parts and proactively reach out to customers for preventive maintenance in order to prevent prolonged downtime.

### **Primary other future developments**

#### ***High volume testing***

Biocartis recognises that, particularly in the context of certain infectious diseases, it would be beneficial to develop a high-throughput configuration of the Idylla™ platform. This Idylla™ instrument configuration would be fully automated and would not require manual loading. It would accommodate the high volume needs of large clinical centres and hospitals. Biocartis’s development team is therefore currently in the process of designing such high-throughput configuration of the Idylla™ platform. This configuration is expected to have 24/7 testing capability, with the potential to become an on-demand system for urgent samples. It would use the same cartridges as the current system and would automatically load cartridges into Idylla™ instruments. In case the system runs at full capacity, additional cartridges would be temporarily stored in a climate controlled cartridge hotel to prevent sample degradation. Once the test would be completed, the relevant data would be uploaded automatically to central databases of the laboratory or hospital information systems. Management expects that the timing of launch will be synchronised with availability of a full viral load menu.

#### ***Transfer of genomic material obtained by the Idylla™ platform (Idylla™-Retrieve)***

Biocartis is researching a process that would allow, in appropriate circumstances (for example, if sample material is precious and scarce), to transfer genomic material contained in an Idylla™ cartridge to specialised laboratories for further testing, for example using NGS.

## Facilities

Biocartis is a fully integrated company, with all functions (research and development, manufacturing and engineering) currently on one leased site in Mechelen, Belgium of approximately 5,400 m<sup>2</sup>.

## Production

### *Idylla™ platform*

The manufacture of each component of the Idylla™ platform (the instrument, the console and the cartridge) is currently performed in-house at Biocartis's facilities in Mechelen.

### *Instruments and consoles*

Biocartis's manufacturing capacity for instruments and consoles is currently at 15 instruments and consoles per week. In total, as of 31 March 2015, Biocartis had produced 445 instruments and 210 consoles at its facilities in Mechelen. The components required to manufacture instruments and consoles are supplied by approximately 45 suppliers. Management believes that the current production capacity and required production tooling at suppliers are sufficient to support the initial commercial supply of the Idylla™ platform. Management believes that its manufacturing capacity can easily be expanded further by adding additional operators and installing additional work shifts in response to demand increases. Additionally, it has identified opportunities to expand capacity and reduce costs by outsourcing the production of some components of the Idylla™ platform to specialised contract manufacturing organisations. To this end, Biocartis intends to outsource instrument and console production in the course of 2015. Biocartis expects that, pursuant to that supply contract, the contract manufacturing organisation would undertake material procurement, production and testing of the instruments and consoles at their own facilities, provide value added engineering services to improve cost efficiency and have the capability to provide ongoing servicing and repair of the instruments and consoles.

### *Cartridges*

Biocartis has two production lines for cartridges: an initial pilot production line (which has been in operation since 2010, has produced over 30,000 (development) cartridges and remains available to support assay development activities) and a commercial production line which has been fully operational since the first quarter of 2014 and consists of custom made, semi-automated equipment, which has produced over 70,000 (development and commercial) cartridges. The components required for Idylla™ cartridges are supplied by approximately ten suppliers and management believes that the current production capacity and required production tooling at suppliers is sufficient to support the initial commercial supply of the Idylla™ platform for at least 2015 and 2016.

In order to meet future demand, Biocartis has developed a strategic manufacturing capacity roadmap that management believes will ensure planned capacity is available ahead of demand. This roadmap covers three strategic phases:

- **Scale up current capacity:** Management believes that the current commercial production line provides it with sufficient capacity to meet volume projections for 2015 and 2016. To secure additional capacity for 2017 using the current commercial production line, Biocartis has initiated a project to scale-up the existing production equipment by expanding current machinery capabilities.
- **2015 to 2017:** Biocartis intends to initiate the design and construction of a high volume, automated, production line for Idylla™ cartridges. Biocartis intends the production line to be operated in partnership with a global, top tier contract manufacturing partner. Biocartis intends to enter into a manufacturing partnership and supply contracts with entities which are likely to be located in Western Europe, but with a global presence, a regionalised supply chain network and infrastructure to support further geographical expansion at a later stage. The second production line will be at a separate location to the first production line, thereby providing Biocartis with supply continuity and dual

source capability to reduce the risks associated with a single, localised supply source. Estimated capital expenditure expected to be incurred for this second production line is in the range of €17-27 million. Biocartis is currently considering alternatives to funding this capital expenditure, including securing debt financing and/or having some of the capital expenditure investment covered by the CMO partner.

- **2018 and beyond:** In the third phase of capacity expansion, as demand increases, Biocartis intends, with a manufacturing partner, to enter into production in further geographical locations which fit best with the global markets and territories in which there is a high demand for Biocartis's products.

#### *The Idylla™-Enrich instrument and cartridge*

Biocartis intends to finalise the development of the Idylla™-Enrich instrument in collaboration with a development organisation with the required design expertise. Once the Idylla™-Enrich instrument is ready for commercial use, Biocartis intends to outsource manufacturing to a suitable contract manufacturing organisation.

A fully industrialised Idylla™-Enrich cartridge will be designed and developed by Biocartis and the initial prototype production will be undertaken by Biocartis. Once the Idylla™-Enrich cartridge is ready for commercial use, Biocartis intends to outsource manufacturing to a suitable contract manufacturing organisation.

### **Customers, marketing and sales**

#### **Customers**

Management believes that molecular testing in general will follow the same path that, for example, immunohistochemistry and FISH have followed historically in the pathology market. This path involves moving testing over time from central, highly skilled laboratories towards more non-expert, decentralised settings (such as smaller hospitals, physician office labs and nursing homes) and settings with fully automated solutions. Management believes the Idylla™ platform and accompanying menu of assays offer solutions to both of these market segments. For decentralised settings, they offer an easy to use platform which is designed to provide highly reliable results, while working on-demand in virtually any setting, and, for centralised settings, they offer a number of "first-to-market" assays and improvements to existing tests (offering assays with higher multiplexing, sensitivity, specificity and reproducibility).

As a result, management believes the key target customers for Biocartis's solutions on a global scale are:

- approximately 4,000 pathology laboratories that would be interested in performing Biocartis's oncology assays (out of 16,000 pathology laboratories worldwide);
- approximately 6,000 decentralised rapid response laboratories for Biocartis's infectious disease assays; and
- approximately 4,000 microbiology laboratories for Biocartis's infectious disease assays.

These target customer groups can be clearly identified, with their own conferences, literature and networks, allowing for a targeted communication strategy.

Biocartis's initial commercial focus will be on the large to mid-sized European pathology laboratories (which management estimates to be 950 laboratories in Europe (of which approximately 400 perform MDx in oncology today), as compared to 700-800 in the United States (of which approximately 500 perform MDx in oncology today)) conducting, on average, 600-700 of Biocartis's first wave tests per year, based on management estimates. During the first 12 to 18 months post-launch of the Idylla™ platform, a "seed-expand-grow" campaign is being rolled out with the aim of placing systems at key opinion leader sites throughout Europe. In a second phase, Biocartis will focus on expanding this initial installed base to nearby laboratories, supported by the initial key opinion leader sites, who will act as centres of excellence for training

new users and who will aid in the promotion of the Idylla™ technology by sharing experience and data with their colleagues. In this second phase, Biocartis will be targeting approximately 1,250 laboratories (conducting over 250 Biocartis tests per year) throughout Europe. When market acceptance and understanding of the benefits of the Idylla™ platform are well established, Biocartis will enter a growth phase. Finally as the assay menu expands, management believes that smaller pathology laboratories not performing molecular testing today will also become a commercially attractive customer segment. Management’s target market share for most oncology assays is in the 20-30% range.

Management intends to implement a similar “seed-expand-grow” strategy in respect of the rapid response and microbiology laboratory segments as, to a large extent, these markets also rely on referrals. In the Western European markets that Biocartis will target directly, the rapid response and microbiology laboratory segments are managed under the same public hospital governance structure and, in many cases, are even in the same physical location. Biocartis therefore intends to leverage the same sales force infrastructure of experienced sales people teamed with MDx knowledge experts. In other markets, the structure varies by country. Biocartis will therefore evaluate on a case-by-case basis whether the chosen distribution channel is adequate to also cater for the new target segments, or a new structure should be put in place. Management’s target market share for most infectious disease assays is at least in the 3-7% range.

Biocartis views the following as key stakeholders and has developed key messages relating to the Idylla™ platform’s unique selling proposition accordingly:

<u>Key Stakeholder</u>	<u>Key Messages</u>
Treating clinicians	<ul style="list-style-type: none"> <li>• fast and accurate</li> <li>• understandable and useful information</li> </ul>
Pathologists	<ul style="list-style-type: none"> <li>• ease of use</li> <li>• on-demand access</li> <li>• full automation, walk away</li> <li>• fast and accurate</li> </ul>
Molecular biologist/laboratory manager	<ul style="list-style-type: none"> <li>• ease of use</li> <li>• on-demand access</li> <li>• full automation, walk away</li> <li>• fast and accurate</li> </ul>
Hospital administration	<ul style="list-style-type: none"> <li>• full integration, automation</li> <li>• earning potential</li> </ul>
Patient	<ul style="list-style-type: none"> <li>• accuracy</li> <li>• time to result</li> </ul>



### ***Investment in brand awareness***

As Biocartis is marketing a new MDx platform to a new customer base, management believes it will need to make additional investments in brand awareness and market education.

Biocartis is therefore developing a full palette of market communications, including supporting evidence to cater for the various individual stakeholders. This includes compiling information on health economics and outcomes research for payors (for further information, see "*—Market access strategy—Health economics and outcomes research*"), medical education of physicians on new biomarkers and treatment options, and participating in external quality assessments. In addition, it includes producing marketing materials for Biocartis's sales teams which help justifying investments in Biocartis's products, and the pricing of those products, based on improvements in workflow and standardisation versus alternatives, as well as a reduction in quality control overheads and hands-on-time.

Biocartis's sales team will be supported by other marketing activities, such as Biocartis personnel attending the most relevant industry conferences and conducting post-launch trials ("beta-trials") targeting potential customers.

### ***Market access strategy***

Biocartis will pursue a marketing strategy whereby it will offer customers a number of different financial options for its products and services, from a straight purchase of the Idylla™ platform, on-going service and menu assays, to reagent lease/rental agreements (pursuant to which Biocartis would provide the Idylla™ platform on the basis that the customer must commit to buy a certain number of assays from Biocartis over a set period of time, with the cost of such assays incorporating an additional charge for the use of the Idylla™ platform) and other deal structures.

Biocartis's market access activities will be focused on the following areas: reimbursement, competitive pricing and health economics and outcomes research.

### ***Reimbursement already in place for Biocartis's first wave of assays***

The end users of Biocartis's products will generally rely on third-party payors to cover and reimburse all, or part, of the cost of the products. As a result, sales volumes and prices of Biocartis's products will depend in large part on the availability of coverage and reimbursement from third-party payors. Third-party payors include public funding through governmental programmes, such as the National Health Service in the United Kingdom, private insurance plans and workers' compensation plans. These third-party payors may deny coverage or reimbursement for a product or therapy if they determine that the product or therapy was not medically appropriate or necessary. Third-party payors are also increasingly challenging the prices charged for medical products and services. Some third-party payors must also approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the products or therapies. As a result, even though a new product may have been cleared for commercial distribution, Biocartis may find limited demand for the product until reimbursement approval has been obtained from governmental and private third-party payors.

Public funding is already available in most developed countries for certain established molecular oncology tests. This funding can be categorised into the following three areas:

- specific financing for each test, without detailed specification on technology or biomarkers (i.e., a gene of interest may be specified in contrast to a specific mutation within that gene);
- technology specific reimbursement (molecular test; hybridisation); and
- a hospital's general financing.

Management believes that existing codes or funding can be used in all major markets for Biocartis's BRAF, KRAS NRAS, LCP and MSI assays (although the reimbursement levels for MSI are set at a low value). Management believes that its other oncology assays should be able to benefit from similar funding, or that there is a clear pathway to achieve similar funding.

In contrast, management believes that some of its innovative tests, such as its liquid biopsy tests, will require market access activities to prove their value and to obtain sufficient reimbursement by relevant payors in all key countries.

Most infectious disease assays, such as HCV viral load assays, have established reimbursement amounts. Reimbursement is currently in place in some countries for infectious disease monitoring assays. Infectious disease assays performed in rapid response laboratories, such as assays for sepsis, are typically funded by a hospital's general financing.

### *Competitive pricing*

Biocartis has set the prices for the Idylla™ platform and its first assays based on the total direct and indirect process and process flow cost of competitor products (including shipment costs, savings in sample preparation, DNA amplification and detection and reporting activities, cost for complex infrastructure, utilities, technical staff, costs of accidental contamination, clean-ups and diminished productivity). This is supported by an estimation of the perceived value of Biocartis's products through pricing surveys. Management believes that the superior features of the Idylla™ platform, such as faster turn-around-time, reduced variability and higher sensitivity justify a pricing premium, and Biocartis's list prices and standard discount structure reflect that pricing premium. Biocartis's research on BRAF and KRAS tests confirmed that target prices should be set at least at a similar level to the total cost of ownership of currently marketed manual or semi-automated tests. Management believes that the price of Biocartis's other oncology assays, and most of its infectious disease assays, will be set at competitive levels. Biocartis typically prices below reimbursement levels in the countries where proper reimbursement is in place and stable. Management believes that Biocartis typically matches or does better than its competitors in terms of total cost of ownership of the Idylla™ platform for a laboratory.

Biocartis expects that regulator-approved assays in the European Union will be priced as follows:

- **Oncology assays:** Assays are expected to have prices in the range of €120 to €350, though some may be priced outside this range; and
- **Infectious disease assays:** Initial assays are expected to provide solutions for high unmet needs and are therefore likely to have prices in the range of €100 and €350; Biocartis intends to subsequently add more high volume assays priced in the range of €30 to €100, though some may be priced outside this range.

Management believes that its sepsis assay is a particularly high value assay and will be attractive compared to current blood culture and blood culture based pathogen identification assays as its sample-enrichment-to-result solution offers a major improvement in patient management. It is expected that the rapid turnaround time of the sepsis assay will allow an earlier initiation of active, targeted antimicrobial therapy, informed by more rapid identification and susceptibility test results, and thereby improve patient health outcomes and provide significant reductions in length of hospital stay, length of ICU stay and number of blood culture samples taken.

Biocartis undertook a pricing survey using the Van Westendorp methodology where it asked potential customers from four countries (Italy, Germany, France and Spain) what they would consider to be a cheap and expensive price for an instrument combining the features of the Idylla™ platform and a reagent rental deal. Based on the results of that price survey, Biocartis believes that a €30,000 – €60,000 range will be acceptable to its customers.

The traditional business model for medical instrument service consists of installation by a specialist, extensive training, reactive on-site repair and call centres for first and second line support. The established service prices are therefore relatively high (usually 10% of instrument

list price per year, or half of the installation list price over a five-year period). Services on the Idylla™ platform will be priced at these market prices, with additional incentives offered for customers to connect to Idylla™ Connect. However, management believes it will be able to provide these services in a more efficient and tailored way than its competitors, through centralised online monitoring of the installed base through Idylla™ Connect, once this has been launched. This should allow Biocartis to proactively approach customers to prevent breakdowns (for example by replacing worn instrument modules prior to failure) and to understand the cause of any system failure even before the customer contacts Biocartis. In addition, the user-friendly design of the Idylla™ platform will allow for its self-installation by the customer.

### *Health economics and outcomes research*

Management believes that health economics and outcomes research proving the economic value of the Idylla™ platform and its assays will strongly support the commercial sales and the sales price of its assays, particularly in the case of newly offered assays where no reimbursement is currently available. Biocartis is therefore building a strong health economic case, including savings in drug and hospitalisation costs, to defend a higher price than some of the currently available tests and to ensure long term market access for its rapid PCR-based assays. As part of its sales and marketing strategy, it intends to:

- assist prospective laboratories in making the decision to invest in Biocartis's Idylla™ platform by conducting an analysis of the total cost of ownership of the Idylla™ platform compared to that customer's current manual systems;
- conduct hospital economic studies that include all relevant cost savings resulting from the implementation of the Idylla™ platform and associated assays (i.e., length of stay, drug use, patient management and outcomes);
- conduct health economic and health technology assessments for third party payors to assess the budget impact, cost effectiveness and patient outcomes associated with the Idylla™ platform and assays; and
- conduct outcomes research to support the clinical and social value of the Idylla™ platform and assays to third party payors, practitioners and patients, using "real world evidence" studies and mapping patient journeys.

### **Channels to market**

With the CE-mark in place for its Idylla™ platform and the Idylla™ BRAF Mutation Test, Biocartis is building a direct presence in Western Europe (with direct sales representation already in place in 13 European countries (Austria, Belgium, Denmark, France, Germany, Iceland, Italy, Luxembourg, Netherlands, Norway, Sweden, Switzerland, United Kingdom) and in planning for Portugal and Spain) and, in parallel, a strong and dedicated distributor network in the key countries where the CE-mark is accepted. For further on the CE-mark, see "*—Regulation—European Union*".

In countries where additional regulations apply, Biocartis will opt for a direct sales model, a distributor model or a partnership model. Biocartis currently expects that its products will be registered for launch in Canada (with a distributor model), Australia (distributor model) and South Korea (distributor model) in 2015, in the United States (with a partnership model, whereby distributors will be supported by a limited number of Biocartis employees supporting them), Brazil (distributor model) in 2016, and in Japan (through a distributor or partnership) and China (through a direct presence, or otherwise) in 2016-2017. In the meantime, Biocartis is actively exploring the possibility of entering the US market on a shorter timescale. This would allow it to maximise early revenue potential, as well as assisting in building evidence for later product registrations in the United States.

Biocartis intends to group the markets it directly approaches based on language, cultural and/or geographical fit. For Europe, Biocartis has defined the following countries or country clusters: DACH (Germany, Austria and Switzerland), the UK and Ireland, Italy, France, the Benelux countries (Belgium, The Netherlands and Luxembourg) and the Nordic countries (Denmark, Finland, Iceland, Norway and Sweden). For most of these country clusters, Biocartis has already

hired an experienced sales manager, who, in line with Biocartis's strategy, has a strong background and network in pathology and MDx. Biocartis intends to expand its current sales force of 15 people in Europe gradually in 2015 and significantly in 2016 (when the core assay menu is expected to be available). Given the foregoing, on an assay-by-assay basis, roll-out in the United States is expected to be approximately one to two years following roll-out in the European Union (depending on regulatory class). In certain cases, management may choose to accelerate launch via an RUO route. China and Japan are expected to be synced in time with United States, after initial launch in those countries has taken place.

For the markets which will be targeted using distributors, Biocartis has hired an experienced export director and a distributor manager. Biocartis expects that other distributor managers will join this team. Biocartis will carefully select its distributors and all distributors should be local and able to ensure that local regulatory formalities are complied with. Management believes that Biocartis will be able to include certain terms in its distributor contracts, including a minimum and yearly increasing purchase obligation and several possibilities for Biocartis to terminate the contract (such as in respect of a change of control, or for a breach of purchase obligations). Management believes that the inclusion of these terms will provide it with upfront sales and a reliable and flexible distributor network.

Twelve distributor agreements have been signed covering 17 markets to date, including Australia, Belarus, Czech Republic, Estonia, Greece, Kuwait, Latvia, Lithuania, Mexico, New Zealand, Oman, Qatar, Russia, Slovakia, South Korea, Turkey and United Arab Emirates. These distributor agreements typically contain volume commitments. Biocartis has sold 98 instruments and has secured commitments from distributors to buy at least 130 instruments over the next three years since it launched the Idylla™ platform in September 2014.

## **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 requirements and labelling requirements. A summary of the most important regulations is set out below.

### ***European Union***

In the European Union, Biocartis is currently required to comply with the local rules and regulations which implement the IVD Directive. The IVD Directive provides the regulatory framework for manufacturers who place IVD devices on the EU market. Each member state of the European Union (each, a "**Member State**") is required to implement the IVD Directive into its national legislation.

### ***CE conformity mark***

In order to demonstrate compliance with the essential requirements of the IVD Directive and to obtain the right to affix the CE-conformity mark (without which Biocartis's products could not be marketed as IVDs in Europe), each of Biocartis's products must undergo a conformity assessment procedure, which procedure varies according to the type of device and its classification. For moderate-risk IVD devices ("general IVDs"), the conformity procedure involves the manufacturer issuing an EC Declaration of Conformity (a "**Conformity Declaration**") based on a self-assessment of the conformity of its products with the relevant essential requirements of the IVD Directive and registering such Conformity Declaration with the governmental or regulatory body that is responsible for regulating medical devices in the relevant Member State (the "**Competent Authority**"). The relevant Member State is usually the manufacturer's place of incorporation. For all other classifications of IVD devices, a conformity assessment procedure requires notification to a notified body in the relevant Member State (a notified body is an organisation accredited by the relevant Member State to conduct conformity assessments) who would typically audit and examine the quality system for the manufacture, design and final inspection of a device before issuing a certification demonstrating compliance with the relevant essential requirements of the IVD Directive.

Biocartis's Idylla™ platform and the Idylla™ BRAF Mutation Test are classified as "general" IVDs. Based on a self-assessment of the conformity of these products with the relevant essential requirements of the IVD Directive, Biocartis issued a Conformity Declaration and registered these products with the Belgian Competent Authority (the Federal Agency for Medicinal and Health Products) as CE-marked IVDs for distribution in the European Union on 29 August 2014. Biocartis is therefore entitled to affix the CE-conformity mark to the Idylla™ platform and the Idylla™ BRAF Mutation Test, which allows Biocartis to market these products in European Union, as well as in countries recognising CE-marked IVD devices (for further information, see "*—Customers, marketing and sales—Channels to market*" above). As part of its strategy, Biocartis intends, in general, to seek CE-mark status for each of its assays so that they can be marketed in European Union and the key countries where the CE-mark is accepted first.

The IVD Directive is due to be replaced by a new European Regulation governing the safety and performance of IVD Regulation which is currently expected to come into force in 2016, with a transitional period of compliance of between three and five years. Changes that are expected to be introduced by the IVD Regulation can be divided into two areas: technical, IVD-specific areas which cover the essential requirements, the classification system, the conformity assessment procedures and clinical evidence requirements; and features, such as the designation and monitoring of notified bodies, as well as vigilance and market surveillance systems. The IVD Regulation is currently being considered by the European Council and thereafter its text will be subject to debate between the Council and the European Parliament. However, the changes that are anticipated to be brought into effect are expected to impact all key IVD stakeholders operating in Europe.

For manufacturers involved in the type of products developed and manufactured by Biocartis, this may involve complying with a more stringent, time-intensive and costly set of requirements impacting the design and manufacturing of devices. Both new and pre-existing devices will need to comply with the requirements of the IVD Regulation. New clinical evidence requirements specific to the IVD sector are also expected with respect to the way a device works to provide a diagnosis. Biocartis's quality management system (for further information, see "*—Quality management system*") has already taken these requirements into account in its development process, and Biocartis therefore believes it is unlikely that the additional requirements for clinical evidence would significantly impact the Idylla™ platform or Biocartis's assays which are currently on the market or under development. Manufacturers of CE-marked assays that are currently on the market and which would not meet the new requirements may have to provide additional information to their relevant Competent Authority.

The change that will likely have the most significant impact on Biocartis is the new classification system for IVDs. Under the current IVD Directive, Biocartis's Idylla™ platform and the Idylla™ BRAF Mutation Test are moderate-risk IVD devices which do not require the involvement of a notified body in the certification process. However, the new classification system defined in the IVD Regulation will upgrade the oncology assays to a higher class of risk that would require the services of a notified body to enable them to be CE-marked. It can therefore be expected that the time to market for such assays, once the new IVD Regulation is in force, would be delayed by one to two quarters (on average) when compared to the current self-certification process. As the new IVD Regulation is unlikely to become effective earlier than the first quarter of 2016, Biocartis intends to apply the self-certification process to CE-mark for its KRAS and NRAS assays. For assays that are currently expected to be launched in, or after, the first quarter of 2016, Biocartis's current development timelines take into account the additional time needed for obtaining CE-mark status associated with complying with the requirements of the new IVD Regulation.

The IVD Regulation also includes new labelling requirements, such as the development of a unique device identification (UDI) system, to make devices more traceable. Management believes that these new labelling requirements will have minimal impact on Biocartis's products, as Biocartis's quality management system has already integrated these new requirements into Biocartis's products in order to help ensure a smooth transition upon the implementation of the IVD Regulation.

It is not clear how the IVD Directive applies to LDTs offered by both healthcare institutions and other third parties (which are not healthcare institutions). Management believes that, as a

result, many such healthcare institutions and other third parties do not currently comply with the requirements of the IVD Directive and therefore benefit from a competitive advantage, as compared to companies that comply with the IVD Directive, when bringing new LDTs onto the market. However, if the IVD Regulation comes into force as currently drafted, management believes that both healthcare institutions and other third parties offering LDTs will need to comply with some (in the case of healthcare institutions) or all (in the case of other third parties) of the requirements of the IVD Regulation, thereby reducing, or eliminating, their current competitive advantage.

As a manufacturer of CE-marked medical devices sold on the European market, Biocartis must also maintain a vigilance system that enables it to notify relevant regulatory authorities of incidents which may lead to (or may have led to) death or serious injury/health consequences for individuals, or a recall of the relevant product. This includes obligations to submit reports to the relevant national Competent Authority (or Authorities) for recording and evaluation when incidents (comprising any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health) occur, for the dissemination of information which could be used to prevent a recurrence of the incident or to alleviate the consequences of such incidents, and where appropriate, by the implementation of a "Field Safety Corrective Action" to reduce the risk of death or serious injury associated with the use of the device (such as a product recall).

#### *Research use and clinical investigations*

In the European Union, subject to certain restrictions set out in the Active Implantable Medical Devices Directive (Directive 90/385/EEC), the Medical Devices Directive (Directive 93/42/EEC) and the local laws and regulations implementing these Directives in each member state, devices without the CE-conformity mark may be used for clinical investigations, for example for the purposes of determining whether the particular device will meet the requirements of the IVD Directive and the Medical Devices Directive.

#### **United States**

In the United States, IVDs are medical devices as defined in section 210(h) of the Federal Food, Drug, and Cosmetic Act 1938, as amended (the "FD&C Act"), and may also be biological products subject to section 351 of the Public Health Service Act 1944. Like other medical devices, IVDs are subject to premarket and post market controls as defined in the USA Code of Federal Regulations, 21CFR820, Quality System Regulation. Clinical laboratories running IVDs are also subject to the CLIA.

#### *Requirement for premarket notification or approval*

IVDs are classified in one of three classes (Class I, II or III) depending on risk and the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy. The classification of an IVD determines the appropriate premarket process.

- Class I: general controls, such as registration, listing, labelling and adherence to quality system regulations;
- Class II: general controls, premarket notification (510(k)) and special controls such as performance standards, patient registries and post-market surveillance; and
- Class III: general controls and PMA.

Pursuant to the 510(k) process, a person who wants to market a Class I or II (or some Class III) device intended for human use in the United States must submit a 510(k) premarket notification to the FDA at least 90 days before marketing the device (unless the device is exempt from the 510(k) requirements). The FDA will then review the 510(k) premarket notification and determine whether the proposed device is "substantially equivalent" to a previously cleared 510(k) device or a device that was in commercial distribution before 28 May 1976, for which the FDA has not yet

called for the submission of PMA applications, referred to as a “predicate” device. The type of studies required to demonstrate substantial equivalence include the following:

- in the majority of cases, analytical studies using clinical samples (sometimes supplemented by carefully selected artificial samples) will suffice;
- for some IVDs, the link between analytical performance and clinical performance is not well defined. In these circumstances, clinical information may be required. Where clinical information is required, the producer must (unless a relevant exemption applies) apply for an investigational device exemption (“IDE”), which would allow the investigational device to be used in a clinical study in order to collect safety and effectiveness data; and
- the FDA rarely requires prospective clinical studies for IVDs, but regularly requests clinical samples with sufficient laboratory and/or clinical characterisation to allow an assessment of the clinical validity of a new device. This is usually expressed in terms of clinical sensitivity and clinical specificity or agreement.

In making its determination, the FDA compares the proposed device to the predicate device. If the two devices are comparable in intended use and safety and effectiveness, the device may be cleared for marketing. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labelling, medical devices to which the device is substantially equivalent, safety and biocompatibility information and the results of performance testing. Marketing may commence only when the FDA issues a clearance letter finding the proposed device to be substantially equivalent to the predicate. After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or any product modification that would constitute a significant change in intended use, requires a new 510(k) clearance. If the device would no longer be substantially equivalent, it would require a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, then the relevant person who wants to market the device in the United States must submit, and the FDA must approve, a PMA before marketing can begin.

The FDA has implemented more stringent clinical investigation and PMA requirements for devices that are classified as Class III. Pursuant to the PMA process, the relevant person who wants to market the device in the United States would be required to provide clinical and laboratory data that establishes that the new device is safe and effective in an absolute sense as opposed to in a comparative sense as with a 510(k). Information about the device and its components, device design, manufacturing and labelling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will typically inspect the device manufacturer’s facilities for compliance with quality system regulation, or QSR, requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The PMA can include post-approval conditions including, among other things, restrictions on labelling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorise certain modifications to the device, its labelling or its manufacturing process.

After a device is cleared, or approved for marketing by the FDA, numerous and pervasive regulatory requirements continue to apply. These include, but are not limited to:

- Regulation on registration of the manufacturer and listing of the IVD devices in the FDA database when starting commercial distribution;
- the QSR regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over and document manufacturing of their products;
- Part 11 compliance with FDA required e-records of documents in the manufacturer’s quality system defined as “in scope”;
- labelling and claims regulations, which prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labelling;
- FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;

- the Medical Device Reporting regulation, which requires reporting to the FDA certain adverse experiences associated with the use of the product;
- complaint handling regulations designed to track, monitor and resolve complaints related to our products;
- in some cases, ongoing monitoring of our products' performance and periodic reporting to the FDA of such performance results; and
- the federal Physician Sunshine Payment Act and various state laws on reporting remunerative relationships with healthcare customers.

If a relevant person wants to market a device in the United States and wants to test it in a clinical study in the United States prior to obtaining 510(k) or PMA approval, that person will have to apply for an IDE. An IDE allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data to support a PMA or 510(k) clearance application.

#### *Research use only in the United States ("RUO")*

In the United States, certain IVD products may be sold (subject to certain restrictions) as RUO diagnostic products, without 510(k) clearance or PMA approval. Many producers introduce such products as RUO products first, and then only later obtain 510(k) clearance or PMA approval. Producers selling RUO IVD products must comply with certain rules, including the following:

- they cannot make clinical or analytical performance claims for an RUO assay;
- they cannot promote an RUO assay's use with additional laboratory equipment; and
- they may only sell an RUO assay to those clinical laboratories that are qualified to run high complexity tests under the CLIA (the CLIA sets forth the conditions that all US laboratories must meet in order to be certified to perform testing on human specimens).

#### *Investigational use only (IUO)*

In the United States, certain IVD products may also be sold (subject to certain restrictions) as IUO diagnostic products, without 510(k) clearance or PMA approval. Producers selling IUO IVD products must comply with very restrictive clinical study rules.

#### *Emergency use authorisation (EUA)*

Under section 564 of the FD&C Act, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological and nuclear (CBRN) threat agents when there are no adequate, approved, and available alternatives.

On 22 September 2006, the then-Secretary of the US Department of Homeland Security, Michael Chertoff, determined, pursuant to section 319F-2 of the Public Health Service Act, that the Ebola virus presents a material threat against the US population sufficient to affect national security. Pursuant to section 564(b)(1) of the Public Health Service Act, and on the basis of such determination, the US Secretary of Health and Human Services declared, on 5 August 2014, that circumstances existed justifying the authorisation of the emergency use of IVDs for the detection of the Ebola virus, subject to the terms of any such authorisation.

#### *Clinical Laboratory Improvement Amendments of 1988 (CLIA)*

The CLIA establishes quality standards for laboratory testing and an accreditation programme for clinical laboratories in the United States. The CLIA requirements vary according to the technical complexity in the testing process and risk of harm in reporting erroneous results. The regulations established three categories of testing on the basis of the complexity of the testing methodology:

- waived tests (these are tests that can be operated outside of specialised, dedicated laboratory environments and without the need for technically specialised and highly trained staff);



- tests of moderate complexity, and
- tests of high complexity.

Producers apply for CLIA categorisation during the premarket process. Under the CLIA, laboratories performing only waived tests are subject to minimal regulation, whereas laboratories performing moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

#### *Biocartis and US regulation*

Management believes that the Idylla™ platform and most of Biocartis's other assays will fall into FDA classifications that require the submission of a premarket notification (510(k)) or an application for PMA approval to the FDA. Currently, none of Biocartis's products have received 510(k) clearance or PMA approval. Biocartis assumes that it will require clinical data to support a 510(k) clearance application for the Idylla™ platform and consequently submitted a first pre-IDE notification file to the FDA for the Idylla™ platform in November 2011. The product concepts were well received by the FDA in January 2012 and the FDA encouraged Biocartis to explore the CLIA-waived low risk route with a first assay. A second pre-IDE notification was submitted by Biocartis's partner, J&J, for their respiratory virus assay, which Biocartis currently expects will become the first test on the Idylla™ platform to receive 510(k) clearance. Once Biocartis receives FDA clearance, or exemption, for the Idylla™ platform, Biocartis and its partners intend to submit individual 510(k) or PMA files to the FDA for the clearance/approval of their individual assays.

For the US market in general, Biocartis intends to introduce assays first as RUO or IUO assays, after which it will seek 510(k) clearance or PMA approval for such assays. However, it will also seek to market suitable assays in the United States on a shorter timescale by applying for EUA, where possible.

Management believes that the determination in August 2014 that IVDs which detect the Ebola virus may be granted EUA in the United States has created a significant opportunity for the Idylla™ platform, which is well suited for near impact testing by non-laboratory trained healthcare professionals. Biocartis therefore sent an EUA interactive review application to the FDA in November 2014, positioning the Idylla™ platform as a Class II, 510(k) device (this covers the instrument and its software, the console and its software as well as the generic cartridge information) and its Ebola assay as suitable for EUA. The FDA's response in December 2014 indicated that the Idylla™ platform and the Ebola assay are suitable for EUA. In order to clear the Ebola assay as an IVD suitable for EUA, Biocartis, or a partner, need to conduct an analytical validation study. To this end, Biocartis has made prototypes of the Ebola assay available for field testing since December 2014. Studies using these prototypes are ongoing at the NIH in the United States, and management expects to submit the Idylla™ platform and Ebola assay for EUA approval during the first half of 2015. In order that Biocartis can continue to market the Ebola assay in the United States after any EUA clearance it may receive has been withdrawn, management intends for Biocartis, or a partner, to proceed with clinical performance testing of the Ebola assay during the second quarter of 2015 in West Africa, and to potentially use this to support a 510(k) clearance application for the Idylla™ platform and a de novo 510(k) clearance application for the Ebola assay in the second half of 2015.

#### ***Other territories***

In accordance with Biocartis's commercialisation strategy, Biocartis will develop a country specific regulatory strategy for countries outside of the European Union and the United States (including China, Japan, Brazil, Mexico, Canada, Russia, Turkey and Australia). Some of these target countries require samples from their local population to be included in clinical studies used to support product registration applications. Biocartis therefore intends to conduct multinational clinical studies (which look at samples from each of the target countries, where possible) and multi-country regulatory auditing to gain maximum efficiency in product registrations in countries outside of the European Union and the United States.

## Regulation of end users

In general, users of any diagnostic platform are required to respect local laws and regulations when providing healthcare services, including performing diagnostic activities. For example, in a number of jurisdictions an ISO15189 accreditation needs to be obtained on a test-by-test basis to qualify for reimbursement. The norm requires laboratories to have a Quality Management System. As most laboratories have a Quality Management System in place, the amount of work to obtain ISO15189 accreditation for Idylla™ is considered limited given the sample-to-result nature of the platform.

## Intellectual property

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 assays or cartridges that operate on the Idylla™ system. Biocartis's intellectual property is held by Biocartis N.V.

## Patents

Biocartis's patent portfolio consists of 56 patent families, of which:

- 30 are proprietary families comprising issued and pending patents worldwide whose patent life will expire between 2020 and 2034; and
- 26 are in-licensed families.

The value of the unique Idylla™ platform is protected by a group of 49 patent families and six invention disclosures, comprising issued patents and pending patent applications worldwide, covering the platform technology (basic system, fluidics, ultra-sonification, thermal control, downstream analysis and signal processing) and its associated biochemistry (assay design, reagent storage, sample intake, etc.).

Biocartis continues to strengthen and extend the lifetime of its patent portfolio by documenting and patenting improvements to its Idylla™ platform.

The following table describes of Biocartis's patents.

<u>Platform</u>	<u>Number of patents</u>	<u>Summary status in main jurisdictions</u>	<u>Expiry dates</u>	<u>Description</u>	<u>Type of right</u>
The Idylla™ platform . . . . .	23 patent families. 6 invention disclosures	8 granted in the European Union, 7 granted in the United States, 23 granted in other; 10 pending in the European Union, 9 pending in the United States, 60 pending in other jurisdictions	from 2020 to 2034	Technologies related to sample preparation, reagent storage and sample intake, optics and signalling processing systems, downstream analysis, fluidics, assay design and bio methods, thermal control and ultra-sonification	Owned

<b>The Idylla™ platform</b> . . . . .	26 patent families.	13 granted in the European Union, 16 granted in the United States, more than 45 granted in other; 12 pending in the European Union, 17 pending in the United States; more than 75 pending in other jurisdictions	from 2016 to 2033	Technologies related to sample preparation, optical systems, fluidics, thermal control, assay design and bio methods and ultra-sonification	Licence
<b>Idylla™-Enrich</b> . . .	7 patent families	1 granted in the European Union, 8 granted in other; 7 pending in the European Union, 7 pending in the United States, 36 pending in other jurisdictions	from 2030 to 2033	Technologies covering the hardware aspects of the platform, as well as the assay aspects of the sepsis assay	Owned

### *Oppositions*

Despite the expansive patent protection granted and applied for, described above, Biocartis's patents have only received two oppositions to date, both relating to European patents; with respect to one opposition, Biocartis has filed an appeal to a decision by the European Patent Office, while with respect to the other, which is in its early stages, Biocartis has filed its response to the notice of opposition. Regardless of the outcome of the proceedings, Biocartis does not view the outcome of these opposition proceedings to be material to its ability to conduct its business or the level of its overall intellectual property protection.

### *Intellectual property agreements*

Biocartis's patent portfolio notably includes proprietary patents, patent applications and licensed rights pursuant to a number of agreements as detailed in "*—Material contracts*" below.

### *Freedom to operate (FTO) assessments*

Since 2010 and on an on-going basis external US and EU patent attorneys and agents have conducted freedom to operate ("**FTO**") assessments in the US and EU regarding the Idylla™ platform and are conducting FTO assessments in relation to screenings regarding assays and platform extensions (including Idylla™-Enrich) in order to minimise the risk of Biocartis infringing valid intellectual property rights of third parties by commercialising technology and products.

As part of its stage-gated platform development process, Biocartis is continuing to keep this information up-to-date with additional assessments.

A multidisciplinary team at Biocartis also closely monitors the patent landscape with respect to assay-associated biochemistry and biomarkers in the jurisdictions of interest to Biocartis. During the early ideation and product definition phases of each assay, as well as at the end of the feasibility phase, when all product components are defined, FTO assessments are conducted by external patent attorneys who provide their advice regarding particular jurisdictions.

While management believes that these independent patent attorneys and agents undertake good faith efforts to conduct thorough searches, no guarantee can be given that all relevant documents have been uncovered. In addition, several of the patent applications identified are still under prosecution and the granted claims may differ significantly from the filed claims. It is also possible that pending filed patent applications do exist but are not yet published. For further information, see "*Risk-Factors—Risks related to Biocartis's business—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's business could suffer*".

### *Trademarks, domain names and designs*

Biocartis currently has three international designs in seven countries, three international trademarks, one Benelux trademark and 204 domain names.

The design rights concern the Idylla™ system components:

- contour line and position of the actuators on the cartridge;
- instrument progress bar; and
- look and feel of the console.

Biocartis uses its corporate name, Biocartis, and associated logo in creating awareness of its expertise and in marketing its platform technology. Biocartis obtained Switzerland, Australia, China, European Union, Japan, South Korea, Norway and US registration for the Biocartis name; Switzerland and European Union registration for the Biocartis logo; the name and logo is pending in further jurisdictions. The name is also the subject of a number of domain name registrations.

Biocartis uses the trademark Idylla™ to identify its Idylla™ platform. The trademark Idylla™ has been registered in China and Japan and is pending in further jurisdictions.

204 domain names have been registered for nine families of domains: biocartis, idylla, hyperplexing, assaydeveloperkit, idyllaconnect, idyllaportal, idyllasurveillance, idyllastudio and diagnosticgrid.

## Employees

Management believes that one of Biocartis's key strengths is its employee base, which has grown significantly to support and execute Biocartis's business plan.

As at 31 December 2014, Biocartis had a total headcount of 194, representing 189 full time equivalents.

The following table shows the evolution of Biocartis's headcount for the last three financial years:

	As at 31 December		
	2014	2013	2012
Operations staff . . . . .	65	63	28
Research and development . . . . .	85	71	61
Marketing and distribution . . . . .	20	6	3
General and administrative . . . . .	24	21	19
<b>Total headcount</b> . . . . .	<b>194</b>	<b>161</b>	<b>111</b>
<b>Average full time equivalents</b> . . . . .	<b>189</b>	<b>157</b>	<b>109</b>

According to Biocartis's current business plan, the headcount at the end of 2015 is expected to increase to approximately 230.

As at 31 December 2014, 16% of Biocartis's staff were qualified to Ph.D. level and 36% held a Master's degree. At least 80% of staff held at least a first degree. The employee base has all of the necessary key skills to operate in a fully, vertically integrated manner (innovative research, early and late stage assay development, industrialisation, solution driven engineering, manufacturing, maintenance and support teams, Quality Assurance and Quality Control, regulatory, sales and marketing and programme management).

The Group currently employs staff of 18 different nationalities and has a high level of gender diversity (approximately 50/50 male to female representation).

## Material contracts

### *Abbott Molecular*

On 21 May 2014, Biocartis and Abbott Molecular entered into a framework collaboration agreement establishing a framework for potential collaborations with respect to the

development and commercialisation of companion diagnostic assays for use on the Idylla™ platform.

Both parties will submit all of their companion diagnostic leads with pharma clients relating to PCR assays to a joint steering committee for joint development on the Idylla™ platform. Upon mutual agreement to pursue a companion diagnostic programme with a pharma client, the standard business model for companion diagnostics will be followed, where pharma clients will fund the development of the companion diagnostic assays. The rights and obligations of the parties, including the further financial arrangements, in relation to commercialisation of the companion diagnostic assays will be detailed in individual project agreements. Each of Biocartis and Abbott Molecular will receive a proportion of the upfront and development fees associated with an executed companion diagnostics agreement with a pharma client commensurate with the percentage of the development work performed by each of them, respectively. Any profits built into the upfront and development fees will be split between the parties.

### ***Janssen Pharmaceutica NV***

In December 2010, Biocartis and JPNV entered into a strategic partnership setting out the parties' aims to co-develop assays for the Idylla™ platform and pursuant to which JPNV obtained the worldwide commercialisation rights for assays for neurodegenerative disease and certain viral infectious diseases. On 9 October 2014, parties restated their licence and development agreement to be aligned with the current needs of both parties.

The agreement has been entered into for a renewable term of 20 years beginning from 2010. It provides several early termination provisions. In the event of a change of control in Biocartis or other certain events, JPNV can terminate the agreement if no adequate assurances are provided that performance under the agreement will not be diminished.

Under this restated agreement, the parties agreed to collaborate in the development of assays in accordance with a mutually agreed roadmap. In particular, the restated agreement provides Biocartis with greater flexibility in respect of the development of its assay menu and enables JPNV to collaborate with Biocartis on complementary and companion diagnostic assays for its pharmaceutical compounds. JPNV now has the right to propose development of a limited number of assays per year and, upon receiving such proposals, Biocartis will elect to add the assay to its own roadmap, allow JPNV to develop it, or agree to jointly develop it. For assays commercialised by JPNV, Biocartis is entitled to receive low double digit royalties on net sales. Exclusive field rights granted to JPNV in 2010 reverted to Biocartis. An example of an assay being developed under this agreement is the IFV-RSV assay.

Biocartis and JPNV agreed to negotiate in good faith a separate non-exclusive distribution agreement for distribution of Idylla™ instruments and consoles in connection with assays sold by JPNV under the agreement. Also, it has been agreed that Biocartis will be engaged to manufacture the assays developed and commercialised by JPNV (provided it is able to do so) subject to a separate manufacturing and supply agreement to be negotiated in good faith. JPNV has been granted an option to acquire the right to manufacture or to have any of the various components of the Idylla™ platform manufactured, and to acquire access to all plans, know-how and IP rights required, against payment of a manufacturing transfer fee. This option can be exercised in certain circumstances such as inability of supply by Biocartis, expiration and certain cases of termination of the agreement.

In addition, Biocartis and JPNV entered into a co-promotion agreement on 1 October 2014 relating to the co-promotion of Idylla™ and the Idylla™ BRAF Mutation Test in Austria, France, Germany, Italy, Ireland, Switzerland and the UK. The co-promotion agreement has been entered into for a term expiring on 31 December 2016. It can be terminated at any time by giving three months notice or with immediate effect upon change of control in Biocartis.

### ***bioMérieux***

On 27 November 2013, Biocartis and bioMérieux entered into an agreement on an early termination of a restated and amended joint development and licence agreement entered into in

July 2011 (originally dated October 2010). The termination agreement provides for a full discharge of obligations of each party under the terminated agreement, with some limited exceptions, as well as for the grant by bioMérieux of a fully paid-up, non-exclusive, non-transferable, non-sublicensable and perpetual licence to bioMérieux's existing intellectual property rights related to a particular assay which is not in Biocartis's current pipeline of assays.

### ***Philips***

On 14 January 2010, Biocartis and Philips entered into an intellectual property assignment and intellectual property licence agreement pursuant to which Philips assigned certain patents and patent applications and (subject to low single digit royalty payments by Biocartis on instrument revenues), granted licences on certain patents and patent applications to Biocartis.

Under the agreement, Biocartis acquired all rights, title and interest in a number of patents describing the Idylla™ platform. In addition, Philips granted Biocartis a licence to an additional set of patents with a broader scope than the Idylla™ platform. This licence was exclusive and sublicensable in the field of human sample testing on the Idylla™ platform and successors thereof and non-exclusive in other fields. Biocartis granted Philips a licence on assigned patents and related know-how for research and development purposes only (i.e., not commercial rights) outside the field of human sample testing and use on non-Idylla™ platforms in the field of human sample testing. Biocartis also agreed to grant Philips, its affiliates or its customers, upon Philips' request and subject to certain conditions and limitations, a non-exclusive licence for commercial use under the assigned patents and know-how for use outside the field of human sample testing and for use on non-Idylla™ platforms in the field of human sample testing.

The agreement remains in force for the longer of, (i) 12 years from the date of its signature; or (ii) an expiration of all licenced patents. Philips can terminate the agreement in case of material breach by Biocartis, an insolvency of Biocartis, an infringement claim related to any of the licensed patents brought by Biocartis or any of its affiliates against Philips or any of its affiliates, or a refusal of Biocartis or any of its affiliate to license such patents to Philips on reasonable conditions, none of which are considered by management to be likely to occur.

### ***Idylla™-Enrich acquisition***

On 15 August 2011, Biocartis and Philips entered into an intellectual property assignment and intellectual property licence agreement pursuant to which Philips assigned certain patents and patent applications and know-how in relation to the Idylla™-Enrich technology to Biocartis. Biocartis licenced back such assigned patents, patent applications and know-how to Philips for internal research and development purposes and, to a certain extent, for commercial purposes in the field of circulating tumour cells, nucleotide sequencing technology and non-biological/non-healthcare applications.

In consideration of the assignment, Biocartis agreed to pay Philips a consideration consisting amongst others of milestone payments, revenue sharing payments and royalties, it being understood that Biocartis has the option to make a lump sum payment in lieu of all further revenue sharing payments and royalties.

The agreement will remain in force for the longer of 15 August 2026 or the lifetime of the last to expire assigned patents. Philips can terminate the agreement in case of material breach by Biocartis, in case of insolvency events and in case Biocartis fails to perform its best efforts to achieve the commercialization milestones as set out in the agreement. In case of termination by Philips, Biocartis must immediately cease the manufacture and sales of products in which one or more of the assigned patents are used.

### ***Grants and subsidies***

Biocartis has received numerous grants from a variety of institutions, including the Flemish Government's Institute for the Promotion of Innovation by Science and Technology in Flanders ("IWT"), and the Flemish Agency of Entrepreneurship (Hermes), a number of which are subject to ongoing obligations. Through 31 December 2014, Biocartis had received an aggregate of

€13.2 million in grants, including €2.6 million in 2012, €3.5 million in 2013 and €1.9 million in 2014. Under currently existing grant programmes, as of 31 December 2014 Biocartis stood to receive a further € 0.6 million provided grant milestones or other conditions are achieved.

The grant programmes under which Biocartis received grant monies during the last three years are as follows:

<u>Project</u>	<u>Value of grant to Biocartis<sup>(1)</sup></u>	<u>Start date and duration</u>	<u>Biocartis's role</u>
<b>Flemish Agency of Entrepreneurship (Hermes):</b>		January 2011 5 years	Training investment in the Flanders region of Belgium
Training Support . . . . .	€2,000,000		
<b>CTMM (MARS)</b>	Contribution from Biocartis:	April 2010 57 months	Development of rapid integrated MDx tests
Molecular Diagnosis and Risk Stratification of Sepsis . . . . .	<ul style="list-style-type: none"> <li>• €445,000 in kind; and</li> <li>• €607,000 in cash</li> </ul> Contribution to Biocartis: <ul style="list-style-type: none"> <li>• €445,000 in cash; and</li> <li>• €283,000 in kind</li> </ul>		
<b>IWT</b>			
Idylla™ Platform Development . . . . .	€2,071,000	February 2011 2 years	Development of the Idylla™ platform to its fullest capabilities related to sample types and applications (quantitative and qualitative)
<b>IWT</b>			
Oncology assay development on the Idylla™ platform . . . . .	€1,907,000	July 2012 2 years	Development of oncology assays directed towards fast and accessible molecular diagnostics for personalised treatment decisions in oncology
<b>IWT Innovation Mandate</b>			
<b>Part 1</b> . . . . .	€97,000 and exclusive licence option	Completed June 2014	Fertility test development on Idylla™ platform
<b>Part 2</b> . . . . .	€131,000 and exclusive licence option	June 2014, 2 years	

<b>PREPARE IMI</b> . . . . .	€450,000	January 2014 5 years	Fast route for Idylla™ industrialisation and manufacturing for pandemic strains (previously also included DMAT Respiratory panel)
<b>IWT</b> Grouped Feasibilities . . . . .	€300,000	October 2013 2 years	Establishment of an efficient process for the front-end innovation funnel and connection with the formal portfolio management development
<b>IWT</b> Hyperplexing . . . . .	€1,354,000	July 2013 – June 2014	Develop technologies on liquid biopsy, sequencing, gene amplification, and RNA extraction

**Note:**

(1) A number of grants have other parties; grant amounts in table represent only the Biocartis portion of the grant.

Biocartis continues to apply for grant support from various sources. Biocartis has not received any indication yet as to whether other current submissions will be approved.

**Insurance**

Biocartis maintains insurance to cover its potential exposure for a number of claims and losses, including public liability insurance and product liability insurance.

In addition, Biocartis has obtained directors and officers liability insurance, which covers expenses, capped at a certain amount, that Biocartis’s board members and senior management may incur in connection with their conduct as members of Biocartis’s board of directors or senior management. Management believes that the insurance coverage Biocartis has is adequate in light of the risks Biocartis faces.

**Environmental and health and safety issues**

Biocartis is committed to providing a safe and healthy work environment for all of its employees, contractors and visitors. This commitment also extends to ensuring that its operations do not place local communities or the environment at risk of injury, illness or damage. To this end, Biocartis has in place a risk management system which, among other things, is designed to identify, monitor and manage all environmental, health and safety aspects of its operations, products and services. Biocartis’s prevention and protection steering team, which consists of representatives of each of Biocartis’s different departments, is responsible for implementing and overseeing Biocartis’s risk management system and meets on a monthly basis to discuss, among other things, any health and safety or environmental issues that have arisen, and any steps that need to be taken to address these. The prevention and protection steering team is advised by Biocartis’s internal prevention advisor, an environmental coordinator and a biosafety adviser.



None of Biocartis's sites have been the subject of any significant environmental prosecutions for violating environmental regulations, licences or other requirements during the past five financial years.

### **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, as set out below. The quality system covers all of Biocartis's products and assays. In the future, Biocartis intends to further develop the quality system to cover the regulatory requirements of other major territories, including China, 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 has implemented 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's 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 Programme 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's Quality Manual and Quality Policy.

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

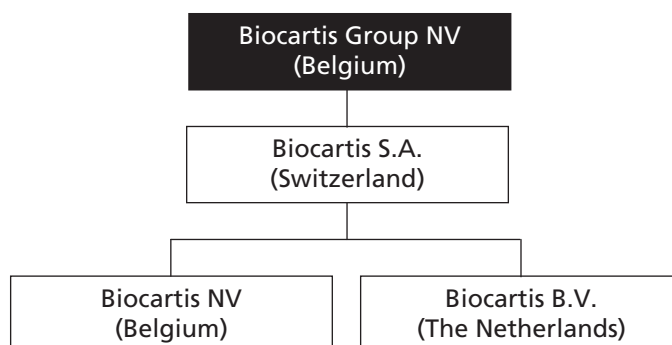
### **Legal proceedings**

There are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which Biocartis is aware), during the previous 12 months which may have, or have had in the recent past, significant effects on Biocartis and/or Biocartis's financial position or profitability.

### **Group structure**

The group consists of the holding company, Biocartis Group NV, and three wholly owned subsidiaries. In addition, Biocartis currently holds approximately 13% of the share capital in MyCartis NV.

The following chart represents the structure of Biocartis as of 31 December 2014:



#### **Additional information**

Biocartis's headquarters are located in Mechelen, Belgium. Biocartis's registered address is: Generaal De Wittelaan 11 B, 2800 Mechelen, Belgium, and its telephone number is: + 32 (0)15 632 600. It was incorporated on 24 November 2014 and registered in Belgium for an unlimited duration under registration number 0505.640.808 (RLP Antwerp, division Mechelen).

## MANAGEMENT AND CORPORATE GOVERNANCE

### Overview

The Issuer has the legal form of a corporation with limited liability (*naamloze vennootschap/ société anonyme*) organised under the laws of Belgium. The Issuer was formed on 24 November 2014. This section summarises the rules and principles by which the Issuer's corporate governance will be organised, and which are contained in the Belgian Companies Code, other relevant legislation and the Issuer's articles of association and corporate governance charter effective as of the closing of the Offering.

### Corporate governance

The Issuer has adopted a corporate governance charter that is in line with the Belgian Code on Corporate Governance of 12 March 2009 and that will enter into force upon the closing of the Offering. The Issuer's board of directors approved the charter on 13 April 2015, subject to and with effect as of the closing of the Offering. The corporate governance charter describes the main aspects of the corporate governance of the Issuer, 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 Issuer's articles of association. The Issuer will apply the nine corporate governance principles contained in the Belgian Code on Corporate Governance and will comply with the corporate governance provisions set forth in the Belgian Code on Corporate Governance, except in relation to the following two matters. Although at the date of this Prospectus, no options have been granted to independent directors, the Issuer intends to award stock based incentives to the independent directors, upon advice of the remuneration and nomination committee. This is contrary to provision 7.7 of the Belgian Code on Corporate Governance 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 Issuer 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. Furthermore, 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 chairman of the audit committee, however, will be an independent director and will have a casting vote. The Issuer justifies this as it allows the audit committee to draw on the additional expertise of current members of the board of directors that have financial and auditing expertise.

What constitutes good corporate governance will evolve with the changing circumstances of a company and with the standards of corporate governance globally, and must be tailored to meet those changing circumstances. The board of directors intends to update the corporate governance charter as often as required to reflect changes to the Issuer's corporate governance.

The articles of association and the corporate governance charter will be made available on the Issuer's website ([www.biocartis.com](http://www.biocartis.com)) and can be obtained free of charge at the Issuer's registered office after closing of the Offering.

### Board of directors

#### ***Powers and responsibilities of the board of directors***

The Issuer has opted for a "one tier" governance structure whereby the board of directors is the ultimate decision making body, with the overall responsibility for the management and control of the Issuer, and is authorised to carry out all actions that are considered necessary or useful to achieve the Issuer's purpose. The board of directors has all powers except for those reserved to the general shareholders' meeting by law or the Issuer's articles of association.

Pursuant to the Issuer's corporate governance charter, the role of the board of directors is to pursue the long term success of the Issuer by providing entrepreneurial leadership and enabling risks to be assessed and managed. The board of directors decides on the Issuer's values and strategy, its risk appetite and key policies.

The board of directors is assisted by a number of committees in relation to specific matters. The committees advise the board of directors on these matters, but the decision making remains with the board of directors as a whole (see also "*—Committees of the board of directors*" below).

The board of directors appoints and removes the chief executive officer. The role of the chief executive officer is to implement the mission, strategy and targets set by the board of directors and to assume responsibility for the day-to-day management of the Issuer. The chief executive officer reports directly to the board of directors.

Pursuant to the Belgian Companies Code and the Issuer's articles of association, the board of directors must consist of at least three directors. The Issuer's corporate governance charter provides that the composition of the board of directors should ensure that decisions are made in the corporate interest. It should be determined on the basis of diversity, as well as complementary skills, experience and knowledge. Pursuant to the Belgian Code on Corporate Governance, at least half of the directors must be non-executive and at least three directors must be independent in accordance with the criteria set out in the Belgian Companies Code and in the Belgian Code on Corporate Governance. By 1 January 2021, at least one third of the members of the board of directors must be of the opposite gender.

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. Proposals by the board of directors for the appointment or re-election of any director must be based on a recommendation by the remuneration and nomination committee. 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.

The board of directors elects a chairman from among its non-executive members on the basis of his knowledge, skills, experience and mediation strength. On the date of this Prospectus, Dr. Pauwels is chairman of the board of directors and chief executive officer. With effect as of the closing of the Offering, Rudi Mariën, acting through Gengest BVBA, will be chairman of the board of directors. If the board of directors envisages appointing a former chief executive officer as chairman, it should carefully consider the positive and negative aspects in favour of such a decision and disclose why such appointment is in the best interest of the Issuer. The chairman is responsible for the leadership and the proper and efficient functioning of the board of directors.

The board of directors meets whenever the interests of the Issuer so require or at the request of one or more directors. In principle, the board of directors will meet sufficiently regularly and at least five times per year. The decisions of the board of directors are made by a simple majority of the votes cast. The chairman of the board of directors has a casting vote.

### **Pre-Offering composition of the board of directors**

As of the date of this Prospectus, the board of directors is composed of 11 directors. The table below gives an overview of the members of the Issuer's board of directors and their term of office as at the date of this Prospectus:

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Start of Term</u>	<u>End of Term</u>
Rudi Pauwels .....	55	Chairman, Chief executive officer	2014	2017
Rudi Mariën .....	69	Non-Executive Director	2014	2017
Domenico Valerio .....	58	Non-Executive Director	2014	2017
Rajesh Parekh .....	54	Non-Executive Director	2014	2017
Thomas Gibbs .....	51	Non-Executive Director	2014	2017
Christine Deuschel Cornioley ....	55	Non-Executive Director	2014	2017
Ruth Devenyns .....	50	Non-Executive Director	2014	2017
Gustaaf Van Reet .....	69	Non-Executive Director	2014	2017
Jeanne Bolger .....	55	Non-Executive Director	2014	2017
Roald Borré .....	42	Non-Executive Director	2014	2017
Hugh Sturley .....	59	Non-Executive Director	2014	2017

**Rudi Pauwels** is the chairman and chief executive officer of the Issuer and 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 personalized HIV treatment. He is (co)-author of 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. Pursuant to the Shareholders' Agreement, Mr. Pauwels was appointed to the board upon the proposal by Coöperatieve AESCAP Venture I U.A., RMM S.A., Advent Private Equity Fund IV, Benaruca and BIOSPV Limited.

**Rudi Mariën** is a non-executive director of the Issuer. He is also 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 centralized 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. Pursuant to the Shareholders' Agreement, Mr. Mariën was appointed to the board upon the proposal by Coöperatieve AESCAP Venture I U.A., RMM S.A., Advent Private Equity Fund IV, Benaruca and BIOSPV Limited.

**Domenico (Dinko) Valerio** is a non-executive director of the Issuer. He is also co-founder and a General Partner of Aescap Venture, which focuses on investments in European biomedical companies. Mr. Valerio founded biotech company Crucell N.V. and co-founded Galapagos Genomics N.V. as a joint venture of Crucell and Tibotec/Virco. Since 2014 he serves as the Chairman of the Board of ProQR Therapeutics N.V., a company he co-founded. Mr. Valerio's career started in academia. He holds a Masters of Science in Biology & Physics from the University of Amsterdam, the Netherlands and a PhD in Molecular Genetics with Honors from Leiden University, the Netherlands. He was visiting scientific specialist at Genentech Inc. and a post-doctoral fellow at the Salk Institute in San Diego and in 1992, Mr. Valerio was appointed Professor in Gene Therapy at Leiden University. He has published over 100 papers in peer-reviewed journals and is an inventor with 11 patent families. Pursuant to the Shareholders' Agreement, Mr. Valerio was appointed to the board upon the proposal by Coöperatieve AESCAP Venture I U.A., RMM S.A., Advent Private Equity Fund IV, Benaruca and BIOSPV Limited.

**Rajesh Parekh** is a non-executive director of the Issuer. He has over 20 years of experience as an entrepreneur and investor in the life sciences. Following an academic career in molecular

medicine at Oxford University, Mr. Parekh co-founded Oxford GlycoSciences which became listed on the London Stock Exchange and NASDAQ. He was also Chairman of Chroma Therapeutics and a Director of Celldex Therapeutics. Mr. Parekh currently is the Chairman of Galapagos and a General Partner at Advent Venture Partners and at Advent Life Sciences. He also serves on the boards of several biotechnology companies. Mr. Parekh holds an MA degree from Oxford University, the United Kingdom and a D.Phil degree from Oxford University, the United Kingdom. Pursuant to the Shareholders' Agreement, Mr. Parekh was appointed to the board upon the proposal by Coöperatieve AESCAP Venture I U.A., RMM S.A., Advent Private Equity Fund IV, Benaruca and BIOSPV Limited.

**Thomas Gibbs** is a non-executive director of the Issuer. He is also Director of Business Development and Licensing at Debiopharm International and Director at Debiopharm Diagnostics. Mr. Gibbs has spent more than two decades in the commercialization of life science technologies, split equally between the pharmaceutical industry and scientific tool developers. He has broad experience in both start-ups and more established companies in Europe and the USA. Mr. Gibbs has been responsible for a wide range of activities including quality assurance, late stage product development and marketing, operations and business development. He holds a BSc in Applied Biology from the University of Wales Institute of Science and Technology, the United Kingdom and a PhD in Biological Sciences from the University of Warwick, the United Kingdom. Pursuant to the Shareholders' Agreement, Mr. Gibbs was appointed to the board upon the proposal by Debiopharm Diagnostics S.A.

**Christine Deuschel Cornioley** is a non-executive director of the Issuer. She is also Vice President of Portfolio and Project Management at Debiopharm International SA where since 2008 she has been responsible for a portfolio of drug development projects in the fields of oncology, pain and autoimmune and infectious diseases. Between 1995 and 2003 Mrs. Deuschel Cornioley has held various managerial positions in Business Development and Project Management at Debiopharm. Between 2003 and 2007 she spent three years in several biotech startups and was, until its merger with Merlion Pharmaceuticals Singapore, the CEO of Athelas SA, a startup company specialized in antibacterial drug discovery. Mrs. Deuschel Cornioley has also worked in academia, in the field of bioinorganic and organometallic chemistry. She holds a PhD of Nat. science from the University of Fribourg, Switzerland, an MBA from HEC, Lausanne, Switzerland and from EPFL, Lausanne, Switzerland. She also completed post-doctoral studies at the University of California at Berkeley. Pursuant to the Shareholders' Agreement, Mrs. Deuschel Cornioley was appointed to the board upon the proposal by Debiopharm Diagnostics S.A.

**Ruth Devenyns** is a non-executive director of the Issuer. Mrs. Devenyns has a long standing experience in the biotechnology sector. A former analyst and investment banker, Mrs. Devenyns was in charge of the venture capital activities in the sector at KBC Private Equity until end of March 2012. She was involved in several IPO's, private placements and M&A-transactions and held various directorships including Ablynx, Applied Maths and Pronota. At KBC Private Equity she also managed various investments in agro-biotech and seed companies such as CropDesign and Ceres. In June 2012 she joined Korys, the investment structure of the Colruyt family, and became an independent director of Euronext-listed DevGen until its acquisition by Syngenta in December 2012. Mrs. Devenyns is also a director of MDxHealth and FlandersBio, the biotech sector organization in Flanders. She holds a degree in Applied Economics from Ghent University, Belgium. Pursuant to the Shareholders' Agreement, Mrs. Devenyns was appointed to the board upon the proposal by QRS NV, Koninklijke Philips N.V., Dham NV, Topbio1 LP, Petercam NV/SA, Mr. Luc Verelst, The Wellcome Trust Limited as trustee of the Wellcome Trust and Mrs. Hilde Windels.

**Gustaaf Van Reet** is a non-executive director of the Issuer. He is also Managing Director of Viziphar Biosciences and a European and Belgian patent agent. Mr. Van Reet started his professional career as a theoretical medicinal chemist for Janssen Pharmaceuticals in 1972 and in 1973 joined its Patents Department which he managed until 1989. In 1987, Mr. Van Reet was appointed Managing Director of Janssen Biotech and Head of General Research Coordination at Janssen Pharmaceuticals. From 1989 to 1999, he was President of the Janssen Research Foundation, which combined all research activities of the Janssen Group worldwide, Managing Director of Janssen Pharmaceutica and a member of the J&J Pharmaceutical Group Operating Committee. From 2000 to 2004, Mr. Van Reet was Vice President of J&J Development Corporation and in this capacity responsible for the multinational's investments in life sciences companies in

Europe. Mr. Van Reet was also co-founder and Chairman of Movetis, a spin-out of Johnson & Johnson which was later acquired by Shire plc as well as Chairman of Octopus, Okapi Sciences and Actogenix. He currently serves on the boards of TheraSolve and DoseVue and is Chairman of ThromboGenics. Mr. Van Reet holds a MSc in Bioengineering from Katholieke Universiteit Leuven, Belgium and a PhD in Bioengineering from Katholieke Universiteit, Leuven. Pursuant to the Shareholders' Agreement, Mr. Van Reet was appointed to the board upon the proposal by JJDC.

**Jeanne Bolger** is a non-executive director of the Issuer. Over the course of her career, Mrs. Bolger has held a wide range of roles spanning marketing, sales, medical and regulatory affairs, global licensing and acquisition, global alliance management and venture investment. She currently is Vice President, Venture Investment, Johnson & Johnson Innovation – JJDC where she leads the identification and evaluation of investment opportunities in the UK and Europe, predominantly in pharmaceuticals and biotechnology but also in diagnostics and personalized medicine. Mrs. Bolger participates as an investor and board member in managing investments on behalf of Johnson & Johnson Innovation – JJDC. She is also a lecturer in the MSc in Pharmaceutical Medicine at Trinity College, Dublin. Mrs. Bolger holds a MB BCh BAO NUI degree from University College Dublin Medical School and a Dip Fin Acc (ACCA) degree, Ireland. Pursuant to the Shareholders' Agreement, Mrs. Bolger was appointed to the board upon the proposal by JJDC.

**Roald Borré** is a non-executive director of the Issuer. Mr. Borré started his professional career at the Financieel Economische Tijds newspaper as a financial analyst specialized 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 Puilaecto 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. Pursuant to the Shareholders' Agreement, Mr. Borré was appointed to the board upon the proposal by ParticipatieMaatschappij Vlaanderen and PMV-TINA Comm.VA.

**Hugh Sturley** is a non-executive director of the Issuer. He is also General Manager for Europe, Africa and the Middle East of Hitachi Chemical Diagnostics, Inc. Mr. Sturley has spent his entire career in clinical diagnostics, holding managerial positions in R&D, product development and business development. Prior to joining Hitachi in 2002, he worked for a number of major diagnostic companies including Amersham International, Ortho Clinical Diagnostics and DPC (now Siemens Healthcare) in the UK and US developing commercially successful products. Mr. Sturley holds a BSc (Hons.) in Biophysics from the University of Leeds, the United Kingdom and a PhD in Analytical Chemistry from the University of Loughborough, the United Kingdom. Pursuant to the Shareholders' Agreement, Mr. Sturley was appointed to the board upon the proposal by Hitachi Chemical Co. Ltd.

Prior to the closing of the Offering the Issuer does not have independent directors.

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

### **Post-Offering composition of the board of directors**

With effect as of the closing of the Offering, the board of directors will be composed of 7 directors. The table below gives an overview of the members of the Issuer's board of directors and their terms as at the closing of the Offering:

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Start of Term</u>	<u>End of Term</u>
Rudi Mariën <sup>(1)</sup> . . . . .	69	Chairman, Non-Executive Director	2015	2016
Rudi Pauwels <sup>(2)</sup> . . . . .	55	Chief Executive Officer, Director	2015	2018
Hilde Windels <sup>(3)</sup> . . . . .	49	Chief Financial Officer, Managing Director	2015	2018
Roald Borré . . . . .	42	Non-Executive Director	2015	2016
Peter Piot . . . . .	66	Non-Executive Director, Independent Director	2015	2018
Renaat Berckmoes . . . . .	49	Non-Executive Director, Independent Director	2015	2018
Mark Shaffar . . . . .	59	Non-Executive Director, Independent Director	2015	2018

Note:

- (1) Acting through Gengest BVBA.
- (2) Acting through Valetusan Ltd.
- (3) Acting through Hilde Windels BVBA.

**Rudi Mariën** will be the chairman and a non-executive director of the Issuer. See his biography under "*—Pre-Offering composition of the board of directors*".

**Rudi Pauwels** is the chief executive officer and a director of the Issuer. See his biography under "*—Pre-Offering composition of the board of directors*".

**Hilde Windels** is the chief financial officer and managing director of the Issuer. She 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. 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. Mrs. Windels holds a Masters in Economics from the University of Leuven, Belgium.

**Roald Borré** is a non-executive director of the Issuer. See his biography under "*—Pre-Offering composition of the board of directors*".

**Peter Piot** will be an independent director of the Issuer. He is also 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 organizations. In 1976 he co-discovered the Ebola virus in Zaïre. 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** will be an independent director of the Issuer. He is also a non-executive director at Primacom AG and FPIM-SFPI and a partner at Fortino CVA. Mr. Berckmoes also has held finance positions at Telenet, 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** will be an independent director of the Issuer. He 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 will be Generaal De Wittelaan 11 bus B, 2800 Mechelen, Belgium.

### ***Share ownership and intention of the directors to participate in the Offering***

Immediately prior to the closing of the Offering, none of the non-executive directors (based on the post-Offering composition of the board of directors) own shares or stock options. The Issuer has not received any indication that any of its non-executive directors (based on the post-Offering composition of the board of directors) intends to purchase Offered Shares.

Although at the date of this Prospectus, no options have been granted to independent directors, the Issuer intends to award stock based incentives to the independent directors, upon advice of the remuneration and nomination committee.

For an overview of the share and stock option ownership of the chief executive director and chief financial officer, see "*—Executive management—Share ownership and intention of the members of the executive management to participate in the Offering*".

### ***Committees of the board of directors***

The board of directors has established two board committees subject to and with effect as of the closing of the Offering, 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.

#### ***Audit committee***

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. Subject to and with effect as of the closing of the Offering, the following directors will be the members of the audit committee Renaat Berckmoes (chairperson), 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, will be an independent director and will have a casting vote. The Issuer justifies this as it allows the audit committee to draw on the additional expertise of current members of the board of directors that have financial and auditing expertise.

The members of the audit committee must 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. According to the board of directors, 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 (see also "*—Other mandates*" below).

The role of the audit committee is to supervise and review the financial reporting process, the internal control and risk management systems and the internal audit process of the Issuer. The audit committee monitors the audit of the statutory and consolidated financial statements, including the follow-up questions and recommendations by the statutory auditor. The audit committee also makes recommendations to the board of directors on the selection, appointment and remuneration of the external auditor and monitors the independence of the external auditor.

In principle, the audit committee meets as frequently as necessary for the efficiency of the operation of the audit committee, but at least four times a year. The members of the audit committee have full access to the executive management and to any other employee to whom they may require access in order to carry out their responsibilities.

#### *Remuneration and nomination committee*

The remuneration and nomination committee consists of at least three directors. 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. The remuneration and nomination committee is chaired by the chairperson of the board of directors or another non-executive director appointed by the committee. Subject to and with effect as of the closing of the Offering, the following directors will be the members of the remuneration and nomination committee: Rudi Mariën (chairperson), Renaat Berckmoes and Mark Shaffar. 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 participates 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 role of the remuneration and nomination committee is to make recommendations to the board of directors with regard to the appointment of directors, make proposals to the board of directors on the remuneration policy and individual remuneration for directors and members of the executive management, and to submit a remuneration report to the board of directors. In addition, the remuneration and nomination committee each year submits the remuneration report to the annual general shareholders' meeting.

In principle, the remuneration and nomination committee meets as frequently as necessary for the efficiency of the operation of the committee, but at least three times a year.

#### *Independent directors*

A director will only qualify as an independent director if he meets at least the criteria set out in article 526ter of the Belgian Companies Code, which can be summarised as follows:

- Not being an executive member of the board of directors, exercising a function as a member of the executive management or as a person entrusted with daily management of the Issuer or a company or person affiliated with the Issuer, and not having been in such a position during the previous five years before his nomination.
- Not having served for more than three terms as a non-executive director of the board of directors, without exceeding a total term of more than twelve years.
- Not being an employee of the senior management (as defined in article 19, 2° of the Belgian Act of 20 September 1948 regarding the organisation of the business industry) of the Issuer or a company or person affiliated with the Issuer and not having been in such a position for the previous three years before his nomination.
- Not receiving, or having received, any significant remuneration or other significant advantage of a financial nature from the Issuer or a company or person affiliated with the Issuer, other than any bonus or fee (*tantièmes*) he receives or has received as a non-executive member of the board of directors.
- Not holding (directly or via one or more companies under his control) any shareholder rights representing 10% or more of the Issuer's shares or of a class of the Issuer's shares (as the case may be), and not representing a shareholder meeting this condition.
- If the shareholder rights held by the director (directly or via one or more companies under his control) represent less than 10%, the disposal of such shares or the exercise of the rights attached thereto may not be subject to contracts or unilateral undertakings entered into by the director. The director may also not represent a shareholder meeting this condition.

- Not having, or having had within the previous financial year, a significant business relationship with the Issuer or a company or person affiliated with the Issuer, either directly or as partner, shareholder, member of the board of directors, member of the senior management (as defined in article 19, 2° of the aforementioned Belgian Act of 20 September 1948) of a company or person who maintains such a relationship.
- Not being or having been within the last three years, a partner or employee of the current or former statutory auditor of the Issuer or a company or person affiliated with the current or former statutory auditor of the Issuer.
- Not being an executive director of another company in which an executive director of the Issuer is a non-executive member of the board, and not having other significant links with executive directors of the Issuer through involvement in other companies or bodies.
- Not being a spouse, legal partner or close family member (by marriage or birth) to the second degree of a member of the board of directors, a member of the executive management, a person charged with the daily management, or a member of the senior management (as defined in article 19, 2° of the aforementioned Belgian Act of 20 September 1948) of the Issuer or a company or person affiliated with the Issuer, or of a person who finds him or herself in one or more of the circumstances described in the previous bullets.

The resolution appointing the director must mention the reasons on the basis of which the capacity of independent director is granted.

In the absence of guidance in the law or case law, the board of directors has not further quantified or specified the aforementioned criteria set out in article 526ter of the Belgian Companies Code. Furthermore, in considering a director's independence, the criteria set out in the Belgian Code on Corporate Governance will also be taken into consideration. The Issuer is of the view that the independent directors that will enter into office at the closing of the Offering comply with each of the relevant criteria of the Belgian Companies Code and Belgian Code on Corporate Governance. The board of directors will also disclose in its annual report which directors it considers to be independent directors. An independent director who ceases to satisfy the requirements of independence must immediately inform the board of directors.

As of the closing of the Offering, Peter Piot, Renaat Berckmoes and Mark Shaffar will be independent directors.

### ***Performance review of the board of directors***

The board of directors evaluates its own size, composition, performance and interaction with executive management and that of its committees on a continuous basis.

The evaluation assesses how the board of directors and its committees operate, checks that important issues are effectively prepared and discussed, evaluates each director's contribution and constructive involvement, and assesses the present composition of the board of directors and its committees against the desired composition. This evaluation takes into account the members' general role as director, and specific roles as chairperson, chairperson or member of a committee of the board of directors, as well as their relevant responsibilities and time commitment.

Non-executive directors assess their interaction with the executive management on a continuous basis.

### **Executive management**

The Issuer's executive management is composed of the chief executive officer and the other members of the executive management.

### ***Chief executive officer***

The chief executive officer is responsible for the day-to-day management of the Issuer. He may be granted additional well-defined powers by the board of directors. He has direct

operational responsibility for the Issuer and oversees the organisation and day-to-day management of subsidiaries, affiliates and joint ventures. The chief executive officer is responsible for the execution and management of the outcome of all decisions of the board of directors.

The chief executive officer leads the executive management within the framework established by the board of directors and under its ultimate supervision. The chief executive officer is appointed and removed by the board of directors and reports directly to it.

#### ***Other members of the executive management***

The executive management is composed of four members and includes the chief executive officer and chief financial officer. Its members are appointed by the board of directors on the basis of a recommendation by the remuneration and nomination committee. The Issuer's executive management does not constitute a *directiecomité/comité de direction* within the meaning of article 524bis of the Belgian Companies Code. The executive management is responsible and accountable to the board of directors for the discharge of its responsibilities.

The board of directors has delegated the day-to-day management of the Issuer as well as certain management and operational powers to the chief executive officer. The chief executive officer is assisted by the chief financial officer and other members of the executive management.

The board of directors has also delegated powers of day-to-day management to the chief financial officer. The chief financial officer is responsible for financial, accounting, audit, risk and legal matters, as well as day-to-day and operational matters. The other members of the executive management (other than the chief executive officer) report to the chief financial officer.

The executive management is responsible for:

- operating Biocartis;
- implementing the policy and plans of the Issuer as defined by the board of directors and in accordance with its instructions;
- executing the decisions made by the board of directors;
- assessing the achievement of the targets for the business of the Issuer and its subsidiaries;
- preparing corporate policies, strategies and strategic plans for the attention of and approval by the board of directors or its committees;
- promoting an active internal and external communications policy;
- ensuring that management capacity, financial and other resources are provided and used efficiently;
- for submitting to the board of directors or to one of its committees for approval or advice in accordance with such regulations and standards as are promulgated by the board of directors from time to time: (a) capital investment, financial measures and acquisition or divestiture of companies, participations and businesses of material significance, and (b) material agreements with third parties and engagement in new business activities;
- preparing the Issuer's yearly business plan and yearly budget to be submitted to the board of directors;
- establishing an independent internal audit function with resources and skills adapted to the company's nature, size and complexity. If the Issuer does not have an internal audit function, the need for one should be reviewed at least annually;
- setting up the Issuer's internal control and risk management systems and submit them for approval to the board of directors;
- promulgating guidelines, including guidelines for planning, controlling, reporting, finance, personnel, information and other technologies; and

- dealing with such other matters as are delegated by the board of directors from time to time.

### **Composition of the executive management**

The executive management consists of the following members:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Rudi Pauwels <sup>(1)</sup> .....	55	Chief executive officer
Hilde Windels <sup>(2)</sup> .....	49	Chief financial officer, managing director
Ulrik Cordes .....	44	Chief commercial officer
Joris Schuurmans <sup>(3)</sup> .....	41	Chief operating officer

Notes:

- (1) Acting through Valetusan Ltd.
- (2) Acting through Hilde Windels BVBA.
- (3) Acting through Ismedrix Life Sciences B.V.

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

**Hilde Windels** is the chief financial officer and managing director of the Issuer. See her biography under “—Board of directors—Post-Offering composition of the board of directors”.

**Ulrik Cordes** is the chief commercial officer of the Issuer. 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, Mr. Cordes 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. Mr. Cordes holds a Master of Science in Biochemistry from the University of Copenhagen, Denmark and a Bachelor of Commerce from Copenhagen Business School, Denmark.

**Joris Schuurmans** is the chief operating officer of the Issuer. Mr. Schuurmans has broad industry experience in Operations, R&D, Project Management and product development. Prior to joining Biocartis, Mr. Schuurmans was responsible for Project Management at MDxHealth. In this capacity, he was responsible for the development and launch of MDxHealth’s ConfirmMDx for Prostate Cancer. He was a director at Crucell and worked in various positions within Janssen Biologics. Mr. Schuurmans holds a Master of Science in Chemical Engineering from Delft University of Technology, the Netherlands.

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.

### **Share ownership and intention of the members of the executive management to participate in the Offering**

The table below provides an overview of the number of shares held by each member of the executive management upon the date of this Prospectus:

<u>Name</u>	<u>Number of shares held</u>
Rudi Pauwels <sup>(1)(3)</sup> .....	3,081,518
Hilde Windels <sup>(2)(3)</sup> .....	20,545
Ulrik Cordes .....	—
Joris Schuurmans <sup>(4)</sup> .....	—

Notes:

- (1) Acting through Valetusan Ltd. The shares are held by Benaruca (which holds 2,541,684 shares on the date of this Prospectus) and BIOSPV Limited (which holds 539,834 shares on the date of this Prospectus), which are controlled by Rudi Pauwels. For further information on the shareholding of Benaruca and BIOSPV Limited, see also “Principal Shareholders”.

- (2) Acting through Hilde Windels BVBA. The shares held by Hilde Windels are held in her own name.
- (3) Benaruca and Hilde Windels are Participating Shareholders who committed to subscribe for new shares in the Offering pursuant to the Investment Agreement.
- (4) Acting through Ismedrix Life Sciences B.V.

The table below provides an overview of the number of options under the 2013 Plan that are held by each member of the executive management upon closing of the Offering. At the date of this Prospectus none of the members of the executive management hold stock options under the 2008 Plan and 2015 Plan:

Name	2013 Plan		
	Vested options	Unvested options	Total options
Rudi Pauwels <sup>(1)</sup> .....	—	—	—
Hilde Windels <sup>(2)</sup> .....	97,916	2,084	100,000
Ulrik Cordes .....	26,041	36,459	62,500
Joris Schuurmans <sup>(3)</sup> .....	5,625	9,375	15,000

Notes:

- (1) Acting through Valetusan Ltd.
- (2) Acting through Hilde Windels BVBA.
- (3) Acting through Ismedrix Life Sciences B.V.

For an overview of the features of the stock options, see also “—Description of share plans”.

Other than in relation to Benaruca and Hilde Windels, the Issuer has not received any indication that the members of the executive committee intend to purchase Offered Shares.

## Remuneration and benefits

### Remuneration policy

Biocartis’s remuneration policy is designed to:

- enable Biocartis to attract and retain talented employees,
- promote continuous improvement in the business, and
- link remuneration and performance, motivating employees to deliver increased shareholder value through superior business results.

The remuneration of the directors and members of the executive management is further described below in “—Directors” and “—Executive management” respectively.

### Directors

#### General

Upon recommendation and proposal of the remuneration and nomination committee, the board of directors determines the remuneration of the directors to be proposed to the general shareholders’ meeting.

Pursuant to Belgian law, the general shareholders’ meeting approves the remuneration of the directors, including inter alia, each time as relevant, (i) in relation to the remuneration of executive and non-executive directors, the 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 executive directors, the 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, (iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration and (iv) any provisions of service agreements to be entered into with executive

directors providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen months' remuneration).

#### *Remuneration and compensation in 2014*

During 2014, no remuneration or compensation was paid to the directors (excluding the chief executive officer), other than €25,000 that was paid to Viziphar Biosciences BVBA, the management company of Mr. Van Reet, in its capacity as member of the formerly existing IP steering committee, and the reimbursement of travel and hotel expenses incurred by the directors in connection with their attendance of meetings of the board of directors.

#### *Remuneration and compensation as of the closing of the Offering*

The remuneration and compensation of the non-executive directors for the current financial year, which has been determined by the general shareholders' meeting and will become effective upon the closing of the Offering, is as follows:

- Annual fixed fees:
  - The chairman of the board of directors will receive an annual fixed fee of €14,000.
  - The chairperson of the audit committee will receive an annual fixed fee of €12,000.
  - The chairperson of the remuneration and nomination committee will receive an annual fixed fee of €10,000.
  - The other non-executive directors will receive an annual fixed fee of €8,500.
- Attendance fees: In addition to their annual fixed fees, as aforementioned, each non-executive director will receive an attendance fee of €2,000 per meeting of the board of directors attended in person (of €1,000 if the meeting is attended per conference call), €1,000 per meeting of the audit committee of which the director is a member, €500 per meeting of the remuneration and nomination committee of which the director is a member.
- Share based awards: Each independent director will receive options or warrants in relation to 5,000 shares on an annual basis. Part of the stock options under the 2015 Plan will be used for this purpose.

There are currently no plans to change the remuneration policy or remuneration of non-executive directors. However, the Issuer will permanently review the remuneration of non-executive directors against market practice. The Issuer also reimburses reasonable out of pocket expenses of directors (including travel expenses) incurred in performing the mandate of director.

The directors who will also be a member of the executive management will be remunerated for the executive management mandate, but not for their director mandate.

#### ***Executive management***

##### *General*

The remuneration of the chief executive officer and the other members of the executive management is based on recommendations made by the remuneration and nomination committee. The chief executive officer participates 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).

An appropriate proportion of the remuneration package will be structured so as to link rewards to corporate and individual performance, thereby aligning the interest of the executive management with the interests of the Issuer and its shareholders. The chief executive officer will determine whether the targets for the variable remuneration of the members of the executive management, as set by the board of directors are met. 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)
- Participation in stock option plans

The members of the executive management do not have a variable remuneration (i.e., remuneration linked to performance criteria), unless this would be decided by the board of directors and except that the remuneration of the member of the executive management that has an employee contract also includes a variable remuneration component. The variable remuneration of the executive management member with an employee contract 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 2014 has not yet been determined. Furthermore, the chief executive officer and chief financial officer are entitled to a one-time bonus consisting of six months of salary in case of the closing of the Offering.

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

#### *Remuneration and compensation in 2014*

The following remuneration and compensation was paid to the chief executive officer and other members of the executive management in 2014:

	<u>Chief executive officer (€)</u>	<u>Members of the executive management other than the chief executive officer (on an aggregate basis) (€)<sup>(1)</sup></u>
Annual base salary .....	388,983.29	654,946.04
Group insurance .....	—	6,923.52
Representation allowance .....	—	3,000.00
Car lease/transport allowance .....	—	14,671.56
Meal tickets .....	—	1,300.20
Medical plan .....	—	180.00
Expat expenses .....	—	65,138.00
Bonus plan <sup>(2)</sup> .....	—	2,600.00
<b>Total .....</b>	<b>388,983.29</b>	<b>748,759.32</b>

#### Notes:

- (1) The remuneration of the member of the executive management that has an employee contract also includes a variable remuneration component. The eligibility for the variable remuneration for performance year 2014 has not yet been determined (see "*—Executive management—General*").



- (2) The overview does not include a one-time performance bonus in cash that is due in relation to 2014 and which amounts to EUR 34,950 for the chief executive officer, and in the aggregate EUR 49,860 for the other members of the executive management.

#### *Payments upon termination*

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

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

The employment agreement of Ulrik Cordes was entered into for an indefinite period of time in 2013, and can be terminated by either Ulrik Cordes 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 Biocartis in case of serious cause. In certain circumstances, in case of termination, Ulrik Cordes will also benefit of a relocation fee.

The services contract of Joris Schuurmans (acting through Ismedrix Life Sciences B.V.) was entered into for an indefinite period of time, and can be terminated by either Joris Schuurmans or Biocartis at any time subject to a prior notice of three months (or the payment of an indemnity equal to three months of fixed monthly fees). In certain cases, the contract can be terminated by either Joris Schuurmans or Biocartis with immediate effect.

#### ***Indemnification and insurance of directors and executive management***

As permitted by the Issuer's articles of association, the Issuer has entered into indemnification arrangements with the directors and relevant members of the executive management and has implemented directors' and officers' insurance coverage.

#### **Description of share plans**

The Issuer 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**").

#### ***2008 Plan***

On 2 July 2008, the board of directors of Biocartis S.A. 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 S.A. amended and restated certain clauses of the 2008 Plan. On November 25, 2014, the 2008 Plan was rolled up in order to relate to the shares of the Issuer instead of the shares of Biocartis S.A.

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 Issuer is able to require certain shareholders of the Issuer (namely Benaruca, (which is controlled by Rudi Pauwels, the chief executive office), 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.

As at the date of this Prospectus, a total number of 94,362 stock options are still outstanding under the 2008 Plan, entitling the holders to acquire 94,362 shares of the Issuer. All stock options are vested as at the date of this Prospectus.

### **2013 Plan**

On 25 August 2011, the general shareholders' meeting of Biocartis S.A. approved the 2013 Plan, enabling Biocartis S.A. 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 November 25, 2014, the 2013 Plan was rolled up in order to relate to the shares of the Issuer instead of the shares of Biocartis S.A.

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 Issuer 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. The exercise price of the stock options that have not been granted at the date of this Prospectus will be determined by the board of directors 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.

As at the date of this Prospectus, 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 Issuer. As at the date of this Prospectus, a total of 597,736 stock options are vested. As at the date of this Prospectus, a total number of 279,660 stock options can still be granted under the 2013 Plan.

### **2015 Plan**

On 15 January 2015, Biocartis established an option plan, pursuant to which 217,934 options were issued. This plan was cancelled by the general shareholders' meeting of the Issuer on 13 April 2015 and replaced on the same date by a new stock option plan (the "**2015 Plan**"), enabling the Issuer 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 Issuer 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.

As at the date of this Prospectus, no stock options have been granted under the 2015 Plan.

## **Other Information**

### ***Conflicts of interest***

Directors are expected to arrange their personal and business affairs so as to avoid conflicts of interest with the Issuer. 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 chief financial officer).

To the knowledge of the Issuer, there are, on the date of this Prospectus, no potential conflicts of interests between any duties to the Issuer of the persons mentioned in "*—Board of directors and executive management—Board of directors—Post-Offering composition of the board of directors*" and in "*—Board of directors and executive management—Executive management*" and their private interests and/or other duties.

There are no outstanding loans granted by the Issuer to any of the persons mentioned in "*—Board of directors and executive management—Board of directors—Post-Offering composition of the board of directors*" and in "*—Board of directors and executive management—Executive management*", nor are there any guarantees provided by the Issuer for the benefit of any of the persons mentioned in "*—Board of directors and executive management—Board of directors—Post-Offering composition of the board of directors*" and in "*—Board of directors and executive management—Executive management*".

None of the persons mentioned in "*—Board of directors and executive management—Board of directors—Post-Offering composition of the board of directors*" and in "*—Board of directors and executive management—Executive management*" has a family relationship with any other of the persons mentioned in "*—Board of directors and executive management—Board of directors—Post-Offering composition of the board of directors*" and in "*—Board of directors and executive management—Executive management*".

### ***Dealing code***

With a view to preventing market abuse (insider dealing and market manipulation), the board of directors has established a dealing code subject to and with effect as of the closing of the Offering. The dealing code describes 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 Issuer. The dealing code sets limits on carrying out transactions in shares of the Issuer and allows dealing by the above mentioned persons only during certain windows. The dealing code is attached to the Issuer's corporate governance charter.

### ***Disclosure policy***

As a Belgian listed company and with a view to ensuring investors in shares of the Issuer have available all information necessary to ensure the transparency, integrity and good functioning of the market, the board of directors has established an information disclosure policy. The information disclosure policy is aimed at ensuring that inside information of which the Issuer is aware is immediately disclosed to the public. In addition, the information disclosure policy is aimed at ensuring information that is disclosed is fair, precise and sincere, and will enable the holders of shares in the Issuer and the public to assess the influence of the information on the Issuer's position, business and results.

## Other

In relation to each of the directors (based on the post-Offering composition of the board of directors) and each of the members of executive management, the Issuer is not aware of (i) any convictions in relation to fraudulent offenses during the past five years or (ii) any official public incrimination and/or sanctions of such members by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer during the past five years. Mr. Rudi Mariën, through his management company Gengest BVBA, was a director of Pharmaneuroboost which was declared bankrupt in 2013. Mr. Roald Borré was a director of Pro Bike BVBA and BikeSport BVBA, which were both declared bankrupt in 2011 and 2012, respectively. Mr. Rajesh Parekh was a director of Luxfold and chairman of CoCo Therapeutics Ltd, both of which were put into voluntary liquidation during the past five years. Other than as described, the Issuer is not aware of any bankruptcies, receiverships or liquidations of any entities in which the members of the board of directors (based on the post-Offering composition of the board of directors) held any office, directorships, or partner or senior management positions during the past five years.

## Other mandates

In the five years preceding the date of this Prospectus, the directors (based on the membership before and after the closing of the Offering) and members of the executive management have held the following directorships (apart from their functions within Biocartis) and memberships of administrative, management or supervisory bodies and/or partnerships:

<u>Name</u>	<u>Current</u>	<u>Past</u>
Rudi Pauwels <sup>(1)</sup> . . . . .	MDxHealth <sup>(2)</sup> MyCartis NV Valetusan Ltd. Benaruca Cambenes SA Riverwells Investments SA Calimontes SL Caruso Inversiones SL	N/A
Rudi Mariën <sup>(3)</sup> . . . . .	Gengest BVBA Biovest Comm.VA DSJ Bruxelles NV LMA BVBA Immo St-Michel NV MyCartis NV <sup>(4)</sup> MDxHealth <sup>(4)</sup> myoscience <sup>(4)</sup> Quest For Growth <sup>(4)</sup> Oystershell <sup>(4)</sup> Bio-Incubator Gent II <sup>(4)</sup>	Cerba European Lab DevGen <sup>(4)</sup> Multiplicom NV <sup>(4)</sup> Pharmaneuroboost <sup>(4)</sup> ActoGeniX <sup>(4)</sup>
Domenico Valerio . . . . .	Ocinemod BV Stichting Vitenda Stichting Endavit Aescap Venture Management BV <sup>(11)</sup> ProQR Therapeutics NV	Vivendy Therapeutics Ltd Affectis Pharmaceuticals AG ActoGenix NV EOS SpA
Rajesh Parekh . . . . .	Advent Venture Partners Advent Life Sciences Advent Management IV Advent management Life Sciences Advent Life Sciences Services Cellnovo Galapagos PE F2G Levicept Novartis Venture Fund	Avila Inc EUSA Inc Celldex Therapeutics CoCo Therapeutics Ltd. Luxfold NeRRe Therapeutics

<u>Name</u>	<u>Current</u>	<u>Past</u>
Thomas Gibbs	Debiopharm Diagnostics Debiopharm International Immunexpress Diagnoplex	Spinomix Parker Hannifin Med Discovery
Christine Deuschel Cornioley	Debiopharm International	N/A
Ruth Devenyns	MDxHealth FlandersBio Hasseltberg	DevGen
Gustaaf Van Reet	Viziphar Biosciences ThromboGenics TheraSolve DoseVue	Octopus Okapi Sciences Actogenix Movetis
Jeanne Bolger	Johnson & Johnson Innovation – JJDC Merus Pulmocide TopiVert Inivata	Janssens Alzheimer Immunotherapy Janssen Sciences Ireland
Roald Borré	High Wind NV <sup>(5)</sup> Laboratoria Smeets NV Capricorn Cleantech Fund NV <sup>(6)</sup> MyCartis NV <sup>(6)</sup> PMV-TINA Comm.VA <sup>(6)</sup>	BikeSport BVBA Pro Bike BVBA
Hugh Sturley	Hitachi Chemical Diagnostics	N/A
Hilde Windels <sup>(7)</sup>	Hilde Windels BVBA Erytech VIB	MDxHealth <sup>(8)</sup> FlandersBio
Peter Piot	N/A	N/A
Renaat Berkmoes	Primacom AG FPIM-SFPI Fortino	Telenet
Mark Shaffar	Shaffar LLC	Abbott Laboratories
Ulrik Cordes	N/A	The Management Consulting Company Sakura Finetic Nordic Dako Polska Sp. Zo.o 3D-PharmXchange BV <sup>(10)</sup>
Joris Schuurmans <sup>(9)</sup>	Ismedrix Life Sciences BV Stichting Knowledge Explosion Network Prospexis Holding BV <sup>(10)</sup>	

Notes:

- (1) Acting at the Issuer through Valetusan Ltd. post-Offering.
- (2) Acting as representative of Valetusan Ltd.
- (3) Acting at the Issuer through Gengest BVBA post-Offering.
- (4) Acting through Gengest BVBA.
- (5) Acting as permanent representative of ParticipatieMaatschappij Vlaanderen and of PMV-TINA.
- (6) Acting as permanent representative of ParticipatieMaatschappij Vlaanderen.
- (7) Acting at the Issuer through Hilde Windels BVBA.
- (8) Acting through Hilde Windels BVBA.
- (9) Acting at the Issuer through Ismedrix Life Sciences B.V.
- (10) Acting through Ismedrix Life Sciences B.V.
- (11) Aescap Venture Management acts as a Director for: Aescap Venture I Seed BV, Aescap Venture I Pooling BV, Aescap Venture I BV, Aescap Venture I Beheer BV, Coöperatieve Aescap Venture I, Aescap Venture I Pooling II BV, Stichting Administratie Kantoor Aescap Venture I, Aescap Venture I Co-Investment BV, Coöperatieve Aescap Venture I, Aescap Venture I Holding BV, i-Optics Pooling BV

## PRINCIPAL SHAREHOLDERS

The following table presents the ownership of the shares immediately prior to the closing of the Offering; immediately after the closing of the Offering assuming a full placement of the New Shares; and immediately after the closing of the Offering assuming a full placement of the Offered Shares. An assumption has been made that the existing shareholders will not participate in the Offering in addition to pre-commitments by the Participating Shareholders (see also “*The Offering—Pre-commitment by the Participating shareholders*”). The natural persons holding less than 1% of the outstanding shares prior to the closing of the Offering have been presented under “other”.

Shareholder	Shares owned before the closing of the Offering		Shares owned assuming full placement of the New Shares		Shares owned assuming full placement of the Offered Shares		Shares owned on a fully diluted basis assuming full placement of the Offered Shares <sup>(6)</sup>	
	(Number)	(%)	(Number)	(%)	(Number)	(%)	(Number)	(%)
Johnson & Johnson Innovation – JJDC, Inc. <sup>(1)</sup> .....	4,948,098	16.25	6,188,408	15.81	6,188,408	15.30	6,188,408	13.46
Debiopharm Diagnostics S.A. ...	4,749,707	15.60	4,749,707	12.13	4,749,707	11.74	4,749,707	10.33
RMM S.A. <sup>(2)</sup> .....	3,989,058	13.10	3,989,058	10.19	3,989,058	9.86	3,989,058	8.67
Benaruca S.A. <sup>(1)(3)(4)</sup> .....	2,541,684	8.35	2,542,459	6.50	2,542,459	6.29	2,542,459	5.53
BIOSPV Limited <sup>(3)</sup> .....	539,834	1.77	539,834	1.38	539,834	1.33	539,834	1.17
Topbio1 LP .....	1,804,644	5.93	1,804,644	4.61	1,804,644	4.46	1,804,644	3.92
PMV-TINA Comm.VA <sup>(1)</sup> .....	1,768,398	5.81	1,845,917	4.72	1,845,917	4.56	1,845,917	4.01
ParticipatieMaatschappij Vlaanderen NV .....	428,000	1.41	428,000	1.09	428,000	1.06	428,000	0.93
Coöperatieve AESCAP Venture I U.A. ....	1,440,850	4.73	1,440,850	3.68	1,440,850	3.56	1,440,850	3.13
Dham NV .....	1,283,990	4.22	1,283,990	3.28	1,283,990	3.17	1,283,990	2.79
Koninklijke Philips N.V. <sup>(5)</sup> .....	1,149,947	3.78	1,149,947	2.94	1,149,947	2.84	5,331,076	11.59
Hitachi Chemical Co. Ltd <sup>(1)</sup> .....	1,040,535	3.42	1,443,635	3.69	1,443,635	3.57	1,443,635	3.14
bioMérieux SA .....	963,000	3.16	963,000	2.46	963,000	2.38	963,000	2.09
Padoki civil law partnership <sup>(1)</sup> ..	953,790	3.13	1,017,719	2.60	1,017,719	2.52	1,017,719	2.21
Advent Private Equity Fund IV Limited Partnership .....	758,317	2.49	758,317	1.94	758,317	1.87	758,317	1.65
Lucien Verelst .....	387,415	1.27	387,415	0.99	387,415	0.96	387,415	0.84
Philippe Renaud <sup>(4)</sup> .....	379,004	1.24	379,004	0.97	379,004	0.94	379,004	0.82
The Wellcome Trust Limited ...	310,233	1.02	310,233	0.79	310,233	0.77	310,233	0.67
Other .....	1,011,857	3.32	1,227,410	3.14	1,227,410	3.03	2,590,344	5.63
Free float .....			6,694,466	17.10	7,998,813	19.78	7,998,813	17.39
<b>Total .....</b>	<b>30,448,361</b>	<b>100</b>	<b>39,144,013</b>	<b>100</b>	<b>40,448,360</b>	<b>100</b>	<b>45,992,423</b>	<b>100</b>
Total of Benaruca S.A. and BIOSPV Limited <sup>(3)</sup> .....	3,081,518	10.12	3,082,293	7.87	3,082,293	7.62	3,082,293	6.70
Total of PMV-TINA Comm.VA and ParticipatieMaatschappij Vlaanderen NV .....	2,196,398	7.21	2,273,917	5.81	2,273,917	5.62	2,273,917	4.94

### Notes:

- (1) This shareholder is one of the Participating Shareholders who committed to subscribe for new shares in the Offering. The Participating Shareholders are Johnson & Johnson Innovation – JJDC, Inc., Benaruca S.A., Ferdinand Verdonck, Padoki civil law partnership, PMV-TINA Comm.VA, Petercam NV/SA as nominee on behalf of certain of its clients, Hilde Windels, Biover II BVBA, Hitachi Chemical Co. Ltd and Kokopilau civil law partnership. For the purpose of the overview, it is assumed that 2,001,186 new shares are issued to the Participating Shareholders at an Offer Price that is at the mid-point of the Price Range. See also “*The Offering—Pre-commitment by the Participating Shareholders*”.
- (2) This shareholder is controlled by Rudi Mariën, a director of the Issuer.
- (3) This shareholder is controlled by Rudi Pauwels, a director of the Issuer.

- (4) This shareholder has entered into a shadow option agreement in relation to the 2008 Plan.
- (5) This shareholder has entered into a conversion option agreement with the Issuer. See also *"Share capital and articles of Association—Outstanding warrants—Philips conversion option agreement"*
- (6) Assuming the exercise of all outstanding warrants (entailing the issue of up to 1,362,934 new shares) and the exercise of the conversion option by Philips for the maximum number of shares covered (entailing the issue of up to 4,181,129 in the event 41,811,294 shares are outstanding following the closing of the Offering and all outstanding warrants have been exercised it being understood that the actual number of shares issuable will depend on a number of factors—see *"Shares capital and articles of association—Outstanding warrants"*).

All of the shares have the same voting rights. For further details of the Issuer's share capital as well as outstanding warrants that can be exercised into the Issuer's shares, see *"Share capital and articles of association"*.

On 25 November 2014, the Issuer and all existing shareholders of the Issuer have entered into the Shareholders' Agreement, which sets out certain arrangements regarding the operation of, the management of and the shareholding in the Issuer. The Issuer and all existing shareholders of the Issuer are expected to enter into a termination agreement, pursuant to which the Shareholders' Agreement will, subject to and effective as of the closing of the Offering, be terminated.

## RELATED PARTY TRANSACTIONS

As part of its business, Biocartis has entered into several transactions with related parties, including its principal shareholders. The following is a summary of Biocartis's most significant transactions with related parties for the year ended 31 December 2014 and as of the date hereof. For further detail on related party transactions, see note 3.32 to the Financial Statements.

On 25 August 2014, Biocartis entered into an investment agreement (the "**Investment Agreement**"), pursuant to which it raised commitments for €64.5 million pursuant to the F-round financing (with three equal tranches, of which two tranches have been contributed and the third is, in relevant part, contingent on either the closing of the Offering or the meeting of a certain milestone) backed by the Participating Shareholders.

Currently, the existing shareholders have entered into the Shareholders' Agreement, containing amongst others terms regarding the Issuer's business and governance, as well as pre-emptive rights and other transfer restrictions regarding the Issuer's shares. The Issuer is a party to this Shareholders' Agreement. The Shareholders' Agreement will be terminated effective as of the closing of the Offering.

Biocartis also entered into an amended and restated license and development agreement with J&J, while one of its shareholders, JJDC, is also a Johnson & Johnson company.

In November 2014, Biocartis spun out its former Evaluation™ business into MyCartis NV for a gain on disposal of €26.6 million, distributing the shares to Biocartis's shareholders. Following the exercise by Debiopharm Diagnostics of a put option in December 2014 Biocartis reacquired in January 2015 and continues to hold approximately 13% of the share capital in MyCartis NV. For further information on the disposal of MyCartis NV, see Note 3.12 to the Financial Statements.

Other than these agreements, Biocartis has not undertaken any related party transactions except the compensation paid to its board of directors and executive management (see also "*Management and corporate governance—Remuneration and benefits—Directors*" and "*Management and corporate governance—Remuneration and benefits—Executive management*").

See also "*Principal shareholders*".



## SHARE CAPITAL AND ARTICLES OF ASSOCIATION

### General

The Issuer has the legal form of a corporation with limited liability (*naamloze vennootschap/ société anonyme*) organised under the laws of Belgium. The Issuer was formed on 24 November 2014. Pursuant to the provisions of the Belgian Companies Code, the liability of the shareholders of the Issuer is in principle limited to the amount of their respective committed contribution to the capital of the Issuer. The Issuer is registered with the legal entities register of Antwerp, division Mechelen under number 0505.640.808. The Issuer's registered office is located at Generaal De Wittelaan 11 B, 2800 Mechelen, Belgium.

This section summarises information relating to the Issuer's share capital, the articles of association, certain material rights of its shareholders under Belgian law and the Issuer's articles of association. The contents of this section are derived primarily from the Issuer's articles of association, which were adopted by the general shareholders' meeting of 13 April 2015, and which will enter into force subject to and effective as of the closing of the Offering.

The description provided hereafter is only a summary and does not purport to provide a complete overview of the articles of association or the relevant provisions of Belgian law. Neither should it be considered as legal advice regarding these matters.

### Corporate purpose

The corporate purpose of the Issuer is set forth in article 4 of its articles of association. The corporate purpose reads (in translation from the Dutch original text) as follows:

The purpose of the Issuer is, as well in Belgium as abroad, as well in its own name and for its own account as in the name or for the account of third parties, alone or in co-operation with third parties:

1. to acquire by means of subscription, contribution, merger, co-operation, financial intervention or in any other way, an interest or a participation in all companies, businesses, enterprises, institutions or associations, whether already existing or still to be incorporated, without any distinction, both in Belgium and abroad.
2. to manage, increase the value of, and liquidate such participations or interests or rights and the researching of investment and disinvestment opportunities, as well as to directly or indirectly participate in the management, the administration, supervision and liquidation of the enterprises, companies, business activities, institutions and associations in which the Issuer holds a participation or an interest or any other right.
3. to advise and assist, in any field of the conduct of business, the management and the administration of the enterprises, companies, business activities, institutions and associations in which it holds an interest or a participation or any other right, and, in general, to undertake all actions that wholly or partially, directly or indirectly, fall under the activities of a parent company.
4. to purchase, trade or otherwise acquire, to sell, rent, lease, parcel out, have constructed, have altered, have built on, all real estate or rights pertaining to real estate in Belgium and abroad, as well as to undertake all actions that are necessary, advantageous or useful for the managing and running of a realty patrimony of the Issuer.
5. to purchase, sell, transfer, manage, liquidate and valorise all securities, shares, bonds, government securities, instruments and rights, as well as to undertake all actions that are necessary or useful for the managing of such assets of the Issuer.
6. to research and develop equipment, products, tests, expertise and all products or services, directly or indirectly, wholly or partly, associated or affiliated therewith, for the medical and health sector, including but not limited to human and animal healthcare, pharmaceutical and para-pharmaceutical or biomedical industries, diagnostics and therapeutics, in vitro diagnostic activity, the more general life science activity, genetics, micro- and nanotechnology, and all this in the broadest sense, as well as the

development and execution of research, systems, test systems, test equipment, products and services directly or indirectly, wholly or partly, associated or affiliated with the foregoing.

7. to produce, manufacture, industrialise and market in any manner, exploit and distribute all of the above mentioned products, appliances, tests, expertise and services and this in a direct or indirect manner.
8. to purchase, acquire, sell, transfer, exploit, take a licence or give a licence, realise, monetise, market and manage all types of intellectual properties, property and usage rights, patents, trademarks, drawings, licences or other intellectual properties or other rights attached to all the aforementioned activities and this in the broadest sense.

The Issuer can:

- perform all so-called financial, movable and immovable transactions that, directly or indirectly, relate to the Issuer's corporate purpose or which may benefit this corporate purpose;
- grant guarantees, act as agent or representative, and grant advances, credit facilities or securities, including mortgages, to any company, enterprise, association or person.

### Share capital and shares

On the date of this Prospectus, the share capital of the Issuer amounts to €304,483.61 and is fully paid-up. It is represented by 30,448,361 shares, of which 25,282,638 shares constitute common shares, and 5,165,723 shares constitute preferred F shares without nominal value (*nominale waarde/valeur nominale*) representing the same pro rata fraction of the share capital.

The changes in the Issuer's share capital since its incorporation can be summarised as follows:

Date	Transaction	Increase/ (Reduction) of share capital (€)	Number of shares issued	Number of common shares issued	Number of preferred F shares issued	Issue price per share (€)	Resulting share capital (€)	Outstanding shares
24 November 2014	Incorporation <sup>(1)</sup>	152,955.00	18,812	16,992	1,820	8.1307	152,955.00	18,812
25 November 2014	Capital increase through contribution in kind <sup>(2)</sup>	222,114,578.00	27,317,920	24,673,872	2,644,048	8.1307	222,267,533.00	27,336,732
15 January 2015	Capital increase through contribution in cash <sup>(3)</sup>	20,488,255.67	2,519,855	—	2,519,855	8.5373	242,755,788.67	29,856,587
15 January 2015	Capital increase through contribution in kind <sup>(4)</sup>	4,811,553.45	591,774	591,774	—	8.5373	247,567,342.12	30,448,361
15 January 2015	Capital increase through incorporation of issue premium <sup>(5)</sup>	8,281.18	—	—	—	—	247,575,623.30	30,448,361
13 April 2015	Cancellation of classes of shares and capital reduction <sup>(6)</sup>	(247,271,139.69)	—	—	—	—	304,483.61	30,448,361

Notes:

- (1) At the occasion of the incorporation of the Issuer on 24 November 2014, its share capital amounted to €152,955.00, represented by 18,812 shares without nominal value, of which 16,992 shares constituted common shares, and 1,820 shares constituted preferred F shares. The shares were issued with an issue value of (rounded) €8.1307 per new share in consideration of a contribution in kind of 18,812 shares in Biocartis S.A.

- (2) By resolution of the Issuer's extraordinary general shareholders' meeting held on 25 November 2014, the Issuer's share capital was increased to €222,267,533.00, through the contribution in kind of the remaining shares in Biocartis S.A., against issuance of 27,317,920 new shares without nominal value and with an issue value of (rounded) €8.1307 per new share, of which 24,673,872 shares constituted common shares, and 2,644,048 shares constituted preferred F shares.
- (3) By resolution of the Issuer's extraordinary general shareholders' meeting held on 15 January 2015, the Issuer's share capital was increased through the contribution in cash of an aggregate amount of €21,512,795.00 in implementation of the second tranche of the F-round financing agreed upon in the Investment Agreement, against issuance of 2,519,855 new preferred F shares without nominal value at an issue price of (rounded) €8.5373 per new share. An amount of €20,488,255.67 was booked as capital increase and an amount of €1,024,539.33 was booked as issue premium.
- (4) By resolution of the Issuer's extraordinary general shareholders' meeting held on 15 January 2015, the Issuer's share capital was increased through the contribution in kind of 2,253,262,501 shares in MyCartis NV for an aggregate value of €5,052,158.00, against issuance of new 591,774 common shares without nominal value at an issue value of (rounded) €8.5373 per new share. An amount of €4,811,553.45 was booked as capital increase and an amount of €240,604.55 was booked as issue premium.
- (5) By resolution of the Issuer's extraordinary general shareholders' meeting held on 15 January 2015, the Issuer's share capital was increased with an amount of €8,281.18 through the incorporation of an amount of issue premium, without the issuance of new shares.
- (6) By resolution of the Issuer's extraordinary general shareholders' meeting held on 13 April 2015, the Issuer's share capital was reduced with an amount of €247,271,139.69, whereby such amount was booked as issue premium. No distribution was made to the shareholders and no shares were cancelled. As a result of the capital reduction, the Issuer's shares have a fractional value of €0.01 per share.

On 13 April 2015, an extraordinary general shareholders' meeting of the Issuer also resolved the following, subject to and with effect as of the closing of the Offering:

- to convert all 5,165,723 preferred F shares into common shares of the Issuer one for one basis;
- to increase the Issuer's share capital by a contribution in cash through the issuance of new shares to be placed in the Offering for a maximum of €100 million (including issue premium);
- to issue a warrant, called "**Over-allotment Warrant**", which the Issuer may offer to the Stabilisation Manager (see also "*—Outstanding warrants—Over-allotment Warrant*").

The Issuer's shares currently have a fractional value of €0.01. The fractional value of a share is calculated as a fraction of which the numerator is the amount of the Issuer's subscribed share capital and of which the denominator is the total number of issued and outstanding Shares. The current fractional value reflects a capital reduction with allocation of the amount of the share capital reduction to the issue premium account, which was approved by the extraordinary general shareholders' meeting of the Issuer held on 13 April 2015. Pursuant to Belgian company law, the board of directors cannot use its powers under the authorised capital to issue new shares at an issue price that is lower than the fractional value of the existing shares. Likewise, the board of directors is not authorised to use the authorised capital to issue warrants or convertible bonds that are exercisable or convertible into new shares at an exercise price or conversion price (on a per share basis) that is lower than the fractional value of the existing Shares. When issuing shares under the authorised capital, the board of directors will take into account the applicable price at which the Issuer's shares will then be trading on the stock exchange. It is not uncommon that in the event of a capital increase, the new shares are issued at a discount to the prevailing trading price of the existing shares at that time. Therefore, in order to permit the board of directors to make effective use of its powers under the authorised capital following the closing of the Offering, the fractional value of the Issuer's shares was reduced to €0.01 per share.

The resolution to reduce the share capital triggered a creditors' protection procedure under the Belgian Companies Code. Creditors of the Issuer whose receivables came into existence prior to, and that have not yet matured at the date of publication of the shareholders' resolution in respect of the aforementioned transaction in the annexes to the Belgian Official Gazette (*Belgisch Staatsblad/Moniteur Belge*) (which publication is still pending on the date of this Prospectus) or for which proceedings have been initiated in a court of law or an arbitral tribunal before 13 April 2015 (being the date of the general shareholders' meeting resolving upon the capital reduction), may request that the Issuer provides (additional) collateral in respect of such receivables. Such creditors are entitled to request (additional) collateral for a period of two months following the publication of the resolution in the Belgian Official Gazette (*Belgisch*

*Staatsblad/Moniteur Belge*). The Issuer may also discharge any such creditor's request by paying the receivable at its value less a discount for early payment. While a distribution of the proceeds of the capital reduction has not been foreseen, if a creditor exercises its rights under the creditors' protection procedure and requests (additional) collateral, the Issuer may not make use of the proceeds of the capital reduction for distribution to its shareholders until such creditor has obtained (additional) collateral or payment from the Issuer, unless a court, ruling in the form of summary proceedings, has denied the creditor's request for collateral on the ground that the creditor benefits from sufficient existing collateral or that the solvency profile of the Issuer does not justify a request for collateral. As of the date of this Prospectus, no request for collateral has been filed with the Issuer.

Assuming a full placement of the New Shares, the Issuer's share capital will amount to €391,440.13 as of the closing of the Offering, represented by 39,144,013 shares, each with a fractional value of €0.01 and each representing the same pro rata fraction of the share capital. Assuming a full placement of the Offered Shares, the Issuer's share capital will amount to €404,483.60 as of the closing of the Offering, represented by 40,448,360 shares, each with a fractional value of €0.01 and each representing the same pro rata fraction of the share capital.

As of the date of this Prospectus, neither the Issuer nor any of its subsidiaries held any of the Issuer's own shares.

## **Outstanding warrants**

### ***Stock based incentive plans***

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

- the 2008 Plan (for further information, see "*Management and corporate governance—Description of share plans—2008 Plan*");
- the 2013 Plan (for further information, see "*Management and corporate governance—Description of share plans—2013 Plan*");
- the 2015 Plan (for further information, see "*Management and corporate governance—Description of share plans—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.

### ***Philips conversion option agreement***

On 15 August 2011, Biocartis S.A. and 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's 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 Issuer 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 Issuer 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 (see also "*Business—Material contracts—Idylla™-Enrich acquisition*").

On 25 November 2014, the conversion option agreement was rolled up in order to relate to the Issuer and the Issuer's shares. As at the date of this Prospectus, 4,181,129 shares are covered by this agreement. This conversion right can only be exercised by Philips upon acceptance of the exercise by the Issuer. The price to be paid in relation to the shares upon conversion shall be the underlying stock price of the Issuer's shares.

### ***Whitemarsh capital warrants***

In execution of a decision of the board of directors of Biocartis S.A. of 24 April 2014, 100,000 options on shares of the Issuer were granted by Biocartis S.A. 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 Issuer and the Issuer's shares instead of shares in Biocartis S.A. 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 €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 \$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 \$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 it is expected that the first 33,000 WHC Warrants will not vest. As at the date of this Prospectus, 100,000 shares are covered by this agreement.

### ***Over-allotment Warrant***

On 13 April 2015, an extraordinary general shareholders' meeting of the Issuer resolved to issue the Over-allotment Warrant. The Over-allotment Warrant can only be exercised by the Stabilisation Manager, acting on behalf of the Underwriters, to subscribe to additional new shares in an aggregate amount equal to up to 15% of the new shares subscribed for in the Offering (the "**New Shares**") at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering. The Over-allotment Warrant will only be exercisable for a period of 35 days following the Listing Date, after which they will automatically expire. See "*Underwriting—Price stabilisation and short positions*".

### **Form and transferability of the shares**

Upon closing of the Offering, all of the shares will belong to the same class of securities and will be in registered or dematerialised form. A register of registered shares (which may be held in electronic form) is maintained at the Issuer's registered address. It may be consulted by any holder of shares. A dematerialised share will be represented by an entry on a personal account of the owner or holder, with a recognised account holder or clearing and settlement institution. Holders of shares may elect, at any time, to have their registered shares converted into dematerialised shares, and vice versa, at their own expense. Upon closing of the Offering, the Offered Shares will be delivered in dematerialised form.

The shares are freely transferable. This is without prejudice to certain restrictions that may apply pursuant to applicable securities laws requirements which are further described in "*Transfer restrictions*". In addition, certain existing shareholders and warrant holders have, however, entered into contractual restrictions. See "*Plan of distribution—Lock-up arrangements*".

## Currency

The Issuer's shares do not have a nominal value, but reflect the same fraction of the Issuer's share capital, which is denominated in euro.

## Rights attached to the shares

### *Voting rights attached to the shares*

Each shareholder of the Issuer is entitled to one vote per share. Shareholders may vote by proxy, subject to the rules described below in "*—Right to attend and vote at general shareholders' meetings—Voting by proxy or remote voting*".

Voting rights can be mainly suspended in relation to shares:

- which are not fully paid up, notwithstanding the request thereto of the board of directors of the Issuer;
- to which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Issuer on the date of the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified the Issuer and the FSMA at least 20 days prior to the date of the general shareholders' meeting in accordance with the applicable rules on disclosure of major shareholdings; and
- of which the voting right was suspended by a competent court or the FSMA.

Pursuant to the Belgian Companies Code, the voting rights attached to shares owned by the Issuer, as the case may be, are suspended.

Generally, the general shareholders' meeting has sole authority with respect to:

- the approval of the annual financial statements of the Issuer;
- the distribution of profits (except interim dividends (see "*—Rights attached to the shares—Dividends*"));
- the appointment and dismissal of directors and the statutory auditor of the Issuer;
- the granting of release from liability to the directors and the statutory auditor of the Issuer;
- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate;
- the approval of the remuneration report included in the annual report of the board of directors and the determination of the following features of the remuneration or compensation of directors, members of the executive management and certain other executives (as the case may be): (i) in relation to the remuneration of executive and non-executive directors, 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 executive directors, 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, (iii) in relation to the remuneration of independent directors, any variable part of the remuneration, and (iv) any provisions of service agreements to be entered into with executive directors, members of the executive management and other executives providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, 18 months' remuneration);

- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other reorganisations of the Issuer; and
- the approval of amendments to the articles of association.

### ***Right to attend and vote at general shareholders' meetings***

#### *Annual meetings of shareholders*

The annual general shareholders' meeting is held at the registered office of the Issuer or at the place determined in the notice convening the general shareholders' meeting. The meeting is held every year on the second Friday of the month May at 2 p.m. (Brussels time). If this date is a legal holiday the meeting is held the next business day at the same time. At the annual general shareholders' meeting, the board of directors submits the audited non-consolidated and consolidated annual financial statements and the reports of the board of directors and of the statutory auditor with respect thereto to the shareholders.

The general shareholders' meeting then decides on the approval of the statutory non-consolidated annual financial statements, the proposed allocation of the Issuer's profit or loss, the release from liability of the directors and the statutory auditor, the approval of the remuneration report included in the annual report of the board of directors and, when applicable, the (re-)appointment or dismissal of the statutory auditor and/or of all or certain directors. In addition, as relevant, the general shareholders' meeting must also decide on the approval of the remuneration of the directors and statutory auditor for the exercise of their mandate, and on the approval of provisions of service agreements to be entered into with executive directors, members of the executive management and other executives providing (as the case may be) for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, 18 months' remuneration) (see also "*—Rights attached to the shares—Voting rights attached to the shares*").

#### *Special and extraordinary general shareholders' meetings*

The board of directors or the statutory auditor (or the liquidators, if appropriate) may, whenever the interest of the Issuer so requires, convene a special or extraordinary general shareholders' meeting. Such general shareholders' meeting must also be convened every time one or more shareholders holding, alone or together, at least 20% of the Issuer's share capital so request. Shareholders that do not hold at least 20% of the Issuer's share capital do not have the right to have the general shareholders' meeting convened.

#### *Right to put items on the agenda of the general shareholders' meeting and to table draft resolutions*

Shareholders who hold alone or together with other shareholders at least 3% of the Issuer's share capital have the right to put additional items on the agenda of a general shareholders' meeting that has been convened and to table draft resolutions in relation to items that have been or are to be included in the agenda. This right does not apply to general shareholders' meetings that are being convened on the grounds that the quorum was not met at the first duly convened meeting (see "*—Quorum and majorities*"). Shareholders wishing to exercise this right must prove on the date of their request that they own at least 3% of the outstanding share capital. The ownership must be based, for dematerialised shares, on a certificate issued by the applicable settlement institution for the shares concerned, or by a certified account holder, confirming the number of shares that have been registered in the name of the relevant shareholders and, for registered shares, on a certificate of registration of the relevant shares in the share register book of the Issuer. In addition, the shareholder concerned must register for the meeting concerned with at least 3% of the outstanding share capital (see also "*—Formalities to attend the general shareholders' meeting*"). A request to put additional items on the agenda and/or to table draft resolutions must be submitted in writing, and must contain, in the event of an additional agenda item, the text of the agenda item concerned and, in the event of a new draft resolution, the text of the draft resolution. The request must reach the Issuer at the latest

on the twenty second day preceding the date of the general shareholders' meeting concerned. If the Issuer receives a request, it will have to publish at the latest on the fifteenth day preceding the general shareholders' meeting an update of the agenda of the meeting with the additional agenda items and draft resolutions.

#### *Notices convening the general shareholders' meeting*

The notice convening the general shareholders' meeting must state the place, date and hour of the meeting and must include an agenda indicating the items to be discussed. The notice needs to contain a description of the formalities that shareholders must fulfil in order to be admitted to the general shareholders' meeting and exercise their voting right, information on the manner in which shareholders can put additional items on the agenda and table draft resolutions, information on the manner in which shareholders can ask questions during the general shareholders' meeting, information on the procedure to participate to the general shareholders' meeting by means of a proxy or to vote by means of a remote vote, and, as applicable, the registration date for the general shareholders' meeting. The notice must also mention where shareholders can obtain a copy of the documentation that will be submitted to the general shareholders' meeting, the agenda with the proposed resolutions or, if no resolutions are proposed, a commentary by the board of directors, updates of the agenda if shareholders have put additional items or draft resolutions on the agenda, the forms to vote by proxy or by means of a remote vote, and the address of the webpage on which the documentation and information relating to the general shareholders' meeting will be made available. This documentation and information, together with the notice and the total number of outstanding voting rights, must also be made available on the Issuer's website at the same time as the publication of the notice convening the meeting, for a period of five years after the relevant general shareholders' meeting.

The notice convening the general shareholders' meeting has to be published at least 30 days prior to the general shareholders' meeting in the Belgian Official Gazette (*Belgisch Staatsblad/ Moniteur Belge*) and in a newspaper that is published nation-wide in Belgium and in media that can be reasonably relied upon for the dissemination of information within the EEA in a manner ensuring fast access to such information on a non-discriminatory basis. A publication in a nation-wide newspaper is not needed for annual general shareholders' meetings taking place on the date, hour and place indicated in the articles of association of the Issuer if the agenda is limited to the treatment of the financial statements, the annual report of the board of directors, the remuneration report and the report of the statutory auditor, the discharge from liability of the directors and statutory auditor, and the remuneration of directors. See also "*—Rights attached to the shares—Voting Rights attached to the shares*". In addition to this publication, the notice has to be distributed at least 30 days prior to the meeting via the normal publication means that the Issuer uses for the publication of press releases and regulated information. The term of 30 days prior to the general shareholders' meeting for the publication and distribution of the convening notice can be reduced to 17 days for a second meeting if, as the case may be, the applicable quorum for the meeting is not reached at the first meeting, the date of the second meeting was mentioned in the notice for the first meeting and no new item is put on the agenda of the second meeting. See also further below under "*—Quorum and majorities*".

At the same time as its publication, the convening notice must also be sent to the holders of registered shares, holders of registered bonds, holders of registered warrants, holders of registered certificates issued with the co-operation of the Issuer (if any), and, as the case may be, to the directors and statutory auditor of the Issuer. This communication needs to be made by letter unless the addressees have individually and expressly accepted in writing to receive the notice by another form of communication.

#### *Formalities to attend the general shareholders' meeting*

All holders of shares, warrants, profit-sharing certificates, non-voting shares, bonds, subscription rights or other securities issued by the Issuer, as the case may be, and all holders of certificates issued with the co-operation of the Issuer (if any) can attend the general shareholders' meetings insofar as the law or the articles of association entitles them to do so and, as the case may be, gives them the right to participate in voting.



In order to be able to attend a general shareholders' meeting, a holder of securities issued by the Issuer must satisfy two criteria: being registered as holder of securities on the registration date for the meeting, and notify the Issuer:

- Firstly, the right to attend general shareholders' meetings applies only to persons who are registered as owning securities on the fourteenth day prior to the general shareholders' meeting at midnight (Central European Time) via registration, in the applicable register book for the securities concerned (for registered securities) or in the accounts of a certified account holder or relevant settlement institution for the securities concerned (for dematerialised securities or securities in book-entry form).
- Secondly, in order to be admitted to the general shareholders' meeting, securities holders must notify the Issuer at the latest on the sixth day prior to the general shareholders' meeting whether they intend to attend the meeting and indicate the number of shares in respect of which they intend to do so. For the holders of dematerialised securities or securities in book-entry form, the notice should include a certificate confirming the number of securities that have been registered in their name on the record date. The certificate can be obtained by the holder of the dematerialised securities or securities in book-entry form with the certified account holder or the applicable settlement institution for the securities concerned.

The formalities for the registration of securities holders, and the notification of the Issuer must be further described in the notice convening the general shareholders' meeting.

#### *Voting by proxy or remote voting*

Each shareholder has, subject to compliance with the requirements set forth above under "*Formalities to attend the general shareholders' meeting*", the right to attend a general shareholders' meeting and to vote at the general shareholders' meeting in person or through a proxy holder, who need not be a shareholder. A shareholder may designate, for a given meeting, only one person as proxy holder, except in circumstances where Belgian law allows the designation of multiple proxy holders. The appointment of a proxy holder may take place in paper form or electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law), through a form which shall be made available by the Issuer. The signed original paper or electronic form must be received by the Issuer at the latest on the sixth calendar day preceding the meeting. The appointment of a proxy holder must be made in accordance with the applicable rules of Belgian law, including in relation to conflicts of interest and the keeping of a register.

The notice convening the meeting may allow shareholders to vote remotely in relation to the general shareholders' meeting, by sending a paper form or, if specifically allowed in the notice convening the meeting, by sending a form electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law). These forms shall be made available by the Issuer. The original signed paper form must be received by the Issuer at the latest on the sixth calendar day preceding the date of the meeting. Voting through the signed electronic form may occur until the last calendar day before the meeting.

The Issuer may also organise a remote vote in relation to the general shareholders' meeting through other electronic communication methods, such as, among others, through one or several websites. The Issuer shall specify the practical terms of any such remote vote in the convening notice.

Holders of securities who wish to be represented by proxy or vote remotely must, in any case comply with the formalities to attend the meeting, as explained under "*Formalities to attend the general shareholders' meeting*".

#### *Quorum and majorities*

In general, there is no attendance quorum requirement for a general shareholders' meeting and decisions are generally passed with a simple majority of the votes of the shares present or represented. However, capital increases (other than those decided by the board of directors

pursuant to the authorised capital), decisions with respect to the Issuer's dissolution, mergers, de-mergers and certain other reorganisations of the Issuer, amendments to the articles of association (other than an amendment of the corporate purpose), and certain other matters referred to in the Belgian Companies Code do not only require the presence or representation of at least 50% of the share capital of the Issuer but also a majority of at least 75% of the votes cast. An amendment of the Issuer'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 Issuer 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.

#### *Right to ask questions*

Within the limits of article 540 of the Belgian Companies Code, shareholders have a right to ask questions to the directors in connection with the report of the board of directors or the items on the agenda of such general shareholders' meeting. Shareholders can also ask questions to the statutory auditor in connection with its report. Such questions can be submitted in writing prior to the meeting or can be asked at the meeting. Written questions must be received by the Issuer no later than the sixth day prior to the meeting. Written and oral questions will be answered during the meeting concerned in accordance with applicable law. In addition, in order for written questions to be considered, the shareholders who submitted the written questions concerned must comply with the formalities to attend the meeting, as explained under "*Formalities to attend the general shareholders' meeting*".

#### **Dividends**

All shares, including the shares offered in the Offering, entitle the holder thereof to an equal right to participate in the Issuer's profits (if any). Pursuant to the Belgian Companies Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with the generally accepted accounting principles in Belgium and based on a (non-binding) proposal of the Issuer's board of directors. The Issuer's articles of association also authorise the board of directors to declare interim dividends without shareholder approval subject to the terms and conditions of the Belgian Companies Code.

The Issuer's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Issuer's statutory unconsolidated financial statements rather than its consolidated financial statements. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Issuer's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e., summarised, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), decreased with the non-amortised costs of incorporation and extension and the non-amortised costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves. In addition, prior to distributing dividends, 5% of the net profits must be allotted to a legal reserve, until the legal reserve amounts to 10% of the Issuer's share capital. The Issuer's legal reserve currently does not meet this requirement nor will it do so at the closing of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during the next years will have to be allocated to the legal reserve, limiting the Issuer's ability to pay out dividends to its shareholders. For further information in relation to the Issuer's dividend policy, see "*Dividends and dividend policy*".

#### **Rights regarding liquidation**

The Issuer can only be dissolved by a shareholders' resolution passed with a majority of at least 75% of the votes cast at an extraordinary general shareholders' meeting where at least 50% of the share capital is present or represented.

If, as a result of losses incurred, the ratio of the Issuer's net assets (determined in accordance with Belgian legal and accounting rules for non-consolidated financial statements) to share capital is less than 50%, the board of directors must convene an extraordinary general shareholders' meeting within two months as of the date upon which the board of directors discovered or should have discovered this undercapitalisation. At this general shareholders' meeting the board of directors needs to propose either the dissolution of the Issuer or the continuation of the Issuer, in which case the board of directors must propose measures to redress the Issuer's financial situation. The board of directors must justify its proposals in a special report to the shareholders. Shareholders representing at least 75% of the votes validly cast at this meeting have the right to dissolve the Issuer, provided that at least 50% of the Issuer's share capital is present or represented at the meeting.

If, as a result of losses incurred, the ratio of the Issuer's net assets to share capital is less than 25%, the same procedure must be followed, it being understood, however, that in that event shareholders representing 25% of the votes validly cast at the meeting can decide to dissolve the Issuer. If the amount of the Issuer's net assets has dropped below €61,500 (the minimum amount of share capital of a corporation with limited liability organised under the laws of Belgium (*naamloze vennootschap/société anonyme*)), any interested party is entitled to request the competent court to dissolve the Issuer. The court can order the dissolution of the Issuer or grant a grace period within which the Issuer is to remedy the situation.

If the Issuer is dissolved for any reason, the liquidation must be carried out by one or more liquidators appointed by the general shareholders' meeting and whose appointment has been ratified by the commercial court. Any balance remaining after discharging all debts, liabilities and liquidation costs must first be applied to reimburse, in cash or in kind, the paid-up capital of the shares not yet reimbursed. Any remaining balance shall be equally distributed amongst all the shareholders.

### ***Changes to the share capital***

#### *Changes to the share capital decided by the shareholders*

In principle, changes to the share capital are decided by the shareholders. The general shareholders' meeting may at any time decide to increase or reduce the share capital of the Issuer. Such resolution must satisfy the quorum and majority requirements that apply to an amendment of the articles of association, as described above under "*—Right to attend and vote at general shareholders' meetings—Quorum and majorities*".

#### *Capital increases decided by the board of directors*

Subject to the same quorum and majority requirements, the general shareholders' meeting may authorise the board of directors, within certain limits, to increase the Issuer's share capital without any further approval of the shareholders. This is the so-called authorised capital. This authorisation needs to be limited in time (i.e., it can only be granted for a renewable period of maximum five years) and in scope (i.e., the authorised capital may not exceed the amount of the registered capital at the time of the authorisation).

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

The Issuer's general shareholders' meeting decided that the board of directors, when exercising its powers under the authorised capital, will be 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). See also "*—Preferential subscription right*" below. 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 Issuer or its subsidiaries). See "*—Legislation and jurisdiction—Public takeover bids*". 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*).

### *Preferential subscription right*

In the event of a capital increase for cash with the issue of new shares, or in the event of an issue of convertible bonds or warrants, the existing shareholders have a preferential right to subscribe, pro rata, to the new shares, convertible bonds or warrants. These preferential subscription rights are transferable during the subscription period.

The general shareholders' meeting may decide to limit or cancel this preferential subscription right, subject to special reporting requirements. Such decision by the general shareholders' meeting needs to satisfy the same quorum and majority requirements as the decision to increase the Issuer's share capital.

The shareholders may also decide to authorise the board of directors to limit or cancel the preferential subscription right within the framework of the authorised capital, subject to the terms and conditions set forth in the Belgian Companies Code. On 13 April 2015, the Issuer's general shareholders' meeting decided that, when exercising its powers under the authorised capital, the board of directors will be 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) (see also "*—Capital increases decided by the board of directors*" above).

Generally, unless expressly authorised in advance by the general shareholders' meeting, the authorisation of the board of directors to increase the share capital of the Issuer through contributions in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Issuer by the FSMA of a public takeover bid on the financial instruments of the Issuer. The Issuer's general shareholders' meeting did not grant such express authorisation to the board of directors.

### *Purchase and sale of own shares*

In accordance with the Issuer's articles of association and the Belgian Companies Code, the Issuer can, on or outside the stock market, purchase and sell its own shares, profit certificates or associated certificates by virtue of a special shareholders' resolution approved by at least 80% of the votes validly cast at a general shareholders' meeting where at least 50% of the share capital and at least 50% of the profit certificates, if any, are present or represented. The prior approval by the shareholders is not required if the Issuer purchases the shares to offer them to the Issuer's personnel.

In accordance with the Belgian Companies Code, an offer to purchase shares must be made by way of an offer to all shareholders under the same conditions. Shares can also be acquired by the Issuer without offer to all shareholders under the same conditions, provided that the acquisition of the shares is effected in the central order book of the regulated market of Euronext Brussels or, if the transaction is not effected via the central order book, provided that the price offered for the shares is lower than or equal to the highest independent bid price in the central order book of the regulated market of Euronext Brussels at that time. Shares can only be acquired with funds that would otherwise be available for distribution as a dividend to the shareholders. The total amount of shares held by the Issuer can at no time be more than 20% of its share capital. Voting rights attached to shares held by the Issuer as treasury shares are suspended.

Generally, the general shareholders' meeting can authorise the board of directors to acquire on or outside the stock exchange a number of the Issuer's shares representing a maximum of 20% of the subscribed capital, determining the minimum and maximum price that the board of directors can pay for the shares. This authorisation can also cover the acquisition on or outside the stock exchange by a direct subsidiary of the Issuer and can be valid for a term of up to five years as of the date of the approval of the proposed resolution. The Issuer's general shareholders' meeting did not grant such authorisation to the board of directors.

The board of directors may, without prior authorisation by the general shareholders' meeting, in accordance with article 622, §2 of the Belgian Companies Code, dispose of the Issuer's own shares, profit certificates or associated certificates at a price it determines, on or

outside the stock market or in the framework of its remuneration policy to employees, directors or consultants of the Issuer. This authorisation is valid without any restriction in time. This authorisation can also cover the disposal of the Issuer's shares on or outside the stock market by a direct subsidiary of the Issuer within the meaning of article 627 of the Belgian Companies Code.

## **Legislation and jurisdiction**

### ***Notification of significant shareholdings***

Pursuant to the Belgian Act of 2 May 2007 on the disclosure of significant shareholdings in issuers whose securities are admitted to trading on a regulated market and containing various provisions, a notification to the Issuer and to the FSMA is required by all natural and legal persons in the following circumstances:

- an acquisition or disposal of voting securities, voting rights or financial instruments that are treated as voting securities;
- the holding of voting securities upon first admission thereof to trading on a regulated market;
- the passive reaching of a threshold;
- the reaching of a threshold by persons acting in concert or a change in the nature of an agreement to act in concert;
- where a previous notification concerning the voting securities is to be updated;
- the acquisition or disposal of the control of an entity that holds the voting securities; and
- where the Issuer introduces additional notification thresholds in the articles of association,

in each case where the percentage of voting rights attached to the securities held by such persons reaches, exceeds or falls below the legal threshold, set at 5% of the total voting rights, and 10%, 15%, 20% and further multiples of 5% or, as the case may be, the additional thresholds provided in the articles of association. The Issuer has provided for an additional threshold of 3% in the articles of association.

The notification must be made as soon as possible and at the latest within four trading days following the acquisition or disposal of the voting rights triggering the reaching of the threshold. Where the Issuer receives a notification of information regarding the reaching of a threshold, it has to publish such information within three trading days following receipt of the notification.

The forms on which such notifications must be made, as well as further explanations, can be found on the website of the FSMA ([www.fsma.be](http://www.fsma.be)). Violation of the disclosure requirements may result in the suspension of voting rights, a court order to sell the securities to a third party and/or criminal liability. The FSMA may also impose administrative sanctions.

The Issuer is required to publicly disclose any notifications received regarding increases or decreases in a shareholder's ownership of the Issuer's securities, and must mention these notifications in the notes to its financial statements. A list as well as a copy of such notifications will be accessible on the Issuer's website ([www.biocartis.com](http://www.biocartis.com)).

### ***Public takeover bids***

Public takeover bids for the Issuer's shares and other securities giving access to voting rights (such as warrants or convertible bonds, if any) are subject to supervision by the FSMA. Any public takeover bid must be extended to all of the Issuer'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.

Belgium implemented the Thirteenth Issuer Law Directive (European Directive 2004/25/EC of 21 April 2004) by the Belgian Takeover Act and the Belgian Takeover Decree. 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 Issuer'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 (see "*Notification of significant shareholdings*" above) and merger control, that may apply towards the Issuer and which 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 Issuer's shares. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their shares at a premium.

In addition, 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 Issuer 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 Issuer by the FSMA of a public takeover bid on the securities of the Issuer. The general shareholders' meeting can, however, under certain conditions, expressly authorise the board of directors to increase the capital of the Issuer in such case by issuing shares in an amount of not more than 10% of the existing shares of the Issuer at the time of such a public takeover bid. Such authorisation has not been granted to the board of directors of the Issuer (see also "*Changes to the share capital—Preferential subscription right*").

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

The Issuer is a party to the following significant agreements or instruments which, upon a change of control of the Issuer or following a takeover bid can either be terminated 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):

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

- the development services and delivery agreement dated 18 November 2010 entered into between Grohmann Engineering GmbH and Biocartis NV;
- the co-promotion agreement dated 1 October 2014 entered into between Janssen Pharmaceutica NV and Biocartis NV; and
- the development agreement dated 21 September 2011 entered into between Philips Medisize BV and Biocartis NV.

In addition, the Issuer's 2013 Plan and 2015 Plan also contain take over protection provisions. The 2013 Plan and 2015 Plan are described in more detail in the section "*Management and corporate governance—Description of share plans*".

### ***Squeeze-outs***

Pursuant to article 513 of the Belgian Companies Code or the regulations promulgated thereunder, a person or legal entity, or different persons or legal entities acting alone or in concert, who own together with the relevant company 95% of the securities with voting rights in such public company are entitled to acquire the totality of the securities with voting rights in that company following a squeeze-out offer. The securities that are not voluntarily tendered in response to such an offer are deemed to be automatically transferred to the bidder at the end of the procedure. At the end of the squeeze-out procedure, the company is no longer deemed a public company, unless bonds issued by the company are still spread among the public. The consideration for the securities must be in cash and must represent the fair value (verified by an independent expert) as to safeguard the interests of the transferring shareholders. When the squeeze-out offer is made with a view to a merger through absorption by a corporation with limited liability (*naamloze vennootschap/société anonyme*) that holds at least 90% of the shares and other securities with voting rights, the threshold to carry out a squeeze-out offer is reduced from 95% to 90% of the securities conferring voting rights.

A squeeze-out offer is also possible upon completion of a public takeover, provided that the bidder holds 95% of the voting capital and 95% of the voting securities of the public company. In such a case, the bidder may require that all remaining shareholders sell their securities to the bidder at the offer price of the takeover bid, provided that, in case of a voluntary takeover offer, the bidder has also acquired 90% of the voting capital to which the offer relates. The shares that are not voluntarily tendered in response to any such offer are deemed to be automatically transferred to the bidder at the end of the procedure. The bidder needs to reopen his/her public takeover offer within three months following the expiration of the offer period.

### ***Sell-out right***

Within three months following the expiration of an offer period related to a public takeover bid, holders of voting securities or of securities giving access to voting rights may require the offeror, acting alone or in concert, who owns at least 95% of the voting capital and 95% of the voting securities in a public company following a takeover bid, to buy its securities from it at the price of the bid, on the condition that, in case of a voluntary takeover offer, the offeror has acquired, through the acceptance of the bid, securities representing at least 90% of the voting capital subject to the takeover bid.

## THE OFFERING

Certain key dates in connection with the Offering are summarised in the following table. These are all anticipated dates, which are subject to any unforeseen circumstance, withdrawal, or to an early closing or extension of the Offering Period.

15 April 2015 .....	Expected start of the Offering Period
29 April 2015 .....	Expected end of the Offering Period <sup>(1)</sup>
30 April 2015 .....	Pricing and allocation
30 April 2015 .....	Publication of the Offer Price and results of the Offering
4 May 2015 .....	Expected Listing Date (listing and start of trading)
5 May 2015 .....	Expected Closing Date (payment, settlement and delivery of the Offered Shares)

Note:

(1) In the event of an early closing or extension of the Offering Period, these dates will be amended and published in the same manner as the announcement of the start of the Offering Period.

### Conditions and nature of the Offering

The Offering consists of: (i) the Belgian Offering (i.e., an initial public offering to retail and institutional investors in Belgium); (ii) a private placement in the United States to persons who are reasonably believed to be QIBs as defined in Rule 144A under the US Securities Act, in reliance on Rule 144A; and (iii) private placements to certain qualified and/or institutional investors in the rest of the world (those qualified and/or institutional investors together with the QIBs are collectively being referred to as the “**Institutional Investors**”). The Offering outside the United States will be made in compliance with Regulation S.

The Offering is an offering of up to 8,695,652 new shares in the Issuer.

The Stabilisation Manager, acting on behalf of the Underwriters, is expected to be granted by the Issuer the Over-allotment Option, in the form of the Over-allotment Warrant which entitles the Stabilisation Manager, acting on behalf of the Underwriters, to subscribe to additional new shares in an aggregate amount equal to up to 15% of the New Shares at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering.

The Global Coordinator is KBC Securities NV/SA. The Underwriters are KBC Securities NV/SA, Kempen & Co N.V. and Petercam NV/SA. See “*Plan of distribution*”.

The actual number of New Shares issued by the Issuer in the Offering will only be determined after the Offering Period and will be published in the Belgian financial press, simultaneously with the publication of the Offer Price and the allocation of shares to Retail Investors (i.e., an individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a “qualified investor” as defined in article 10, §1 of the Belgian Prospectus Act). Such publication is currently expected to be made on or about 30 April 2015 and in any event no later than the first or second business day after the end of the Offering Period.

The Issuer reserves the right to withdraw the Offering or to reduce the maximum number of Offered Shares at any time prior to the allocation of the Offered Shares. Any withdrawal of the Offering will be published in the Belgian financial press, through electronic information services such as Reuters or Bloomberg, and a supplement will be published. A reduction in the number of Offered Shares prior to expiry of the Offering Period will be published in the Belgian financial press, through electronic information services such as Reuters or Bloomberg, and in a supplement to the Prospectus. In the event of a publication of a supplement to the Prospectus, investors will have the right to withdraw their orders made prior to the publication of the supplement.



## **Pre-commitment by the Participating Shareholders**

The Participating Shareholders have committed to subscribe for an aggregate amount of €21,512,800.00 subject to the closing of the Offering. The subscription by the Participating Shareholders in the Offering will satisfy their commitment to complete the third tranche of the F-round financing that was agreed in the Investment Agreement, and of which the first and second tranche were completed on 25 November 2014 and 15 January 2015, respectively.

## **Offer Price**

The Offer Price will be a single price in euro, exclusive of the Belgian tax on stock exchange transactions, if applicable (see "*Taxation—Belgian tax on stock exchange transactions*"), and costs, if any, charged by financial intermediaries for the submission of applications, and will apply to all investors, whether Retail Investors or Institutional Investors.

The Offer Price will be determined within the Price Range on the basis of a book-building process in which only Institutional Investors can participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time.

The Price Range has been determined by the Issuer in common agreement with the Global Coordinator, taking into account market conditions and factors including but not limited to:

- the condition of the financial markets;
- the Issuer's financial position;
- qualitative assessment of the demand for the Offered Shares; and
- all other factors deemed relevant.

The Issuer reserves the right to increase or decrease the lower limit of the Price Range or to decrease the upper limit of the Price Range. If the Price Range is narrowed through an increase of the lower limit and/or a decrease of the upper limit, the change will be published in the Belgian financial press and by means of an announcement through electronic information services such as Reuters or Bloomberg. Other changes to the Price Range will also be published in the Belgian financial press and by means of an announcement through electronic information services, as well as in a supplement to the Prospectus. Investors who have submitted subscription orders will not be notified individually. The Offer Price for investors shall not, however, exceed the higher end of the Price Range. In the event of a publication of a supplement to the Prospectus, investors will have the right to withdraw their orders made prior to the publication of the supplement.

Retail Investors in Belgium can only acquire the Offered Shares at the Offer Price and are legally bound to acquire the number of Offered Shares indicated in their subscription order at the Offer Price, unless the Offering has been withdrawn in which case the subscription orders will become null and void.

## **Dilution resulting from the Offering**

See table, "*Principal shareholders*".

## **Offering Period**

The Offering Period will begin on 15 April 2015 and is expected to close no later than 4:00 pm (CEST) on 29 April 2015, subject to the possibility of an early closing or extension, provided that the Offering Period will in any event be open for at least six business days from the availability of this Prospectus. The Prospectus will be made available as of the first day of the Offering Period. The Offering Period for Retail Investors and Institutional Investors will be the same. Any early closing of the Offering Period will be published in the Belgian financial press,

and the dates for each of pricing, allocation, publication of the Offer Price and the results of the Offering, conditional trading and closing of the Offering will in such case be adjusted accordingly. The Offering Period can only be closed earlier in case of a coordinated action between the Underwriters. In the event the Offering Period is extended, this will be published in the Belgian financial press. Prospective investors can submit their subscription orders during the Offering Period. Taking into account the fact that the Offering Period may be closed early, investors are invited to submit their applications as promptly as possible.

Subscription orders by Retail Investors may be submitted at the counters of KBC Bank, KBC Securities and Petercam and their affiliates at no cost to the investor. Applications are not binding upon the Issuer or the Underwriters as long as they have not been accepted in accordance with the allocation rules described below under "*—Allocation*".

Subscription orders by Retail Investors may be submitted through intermediaries other than KBC Bank, KBC Securities, and Petercam and their affiliates but Retail Investors are advised to request details of the costs which these intermediaries may charge, which they will have to pay themselves.

To be valid, the subscription orders must be submitted no later than 4:00 pm (CEST) on 29 April 2015, unless the Offering Period is closed earlier or extended, in which case the subscription orders must be submitted no later than 4:00 pm (CEST) at such earlier or extended closing date of the Offering Period.

### **Retail Investors**

Retail Investors must indicate in their subscription orders the number of Offered Shares they are committing to subscribe for. Only one application per Retail Investor will be accepted. If the Underwriters determine, or have reason to believe, that a single Retail Investor has submitted several subscription orders, through one or more intermediaries, they may disregard such subscription orders. There is no minimum or maximum amount of Offered Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described in "*—Allocation*".

### **Institutional Investors**

Institutional Investors must indicate in their subscription orders the number of Offered Shares or an amount (in euro) they are committing to subscribe for, and the prices at which they are making such subscription orders during the book-building period. Only Institutional Investors can participate in the book-building process during the Offering Period.

### **Right to withdraw**

In accordance with the Belgian Prospectus Act, every significant new factor, material mistake or inaccuracy relating to the information included in this Prospectus that is capable of affecting the assessment of the Offered Shares and that arises or is noted between the time when this Prospectus is approved and the closing of the Offering, or as the case may be, the time when trading of the Offered Shares on the relevant market begins, whichever occurs later, will be mentioned in a supplement to this Prospectus. Investors who have already agreed to subscribe for the Offered Shares before the supplement is published will have the right, exercisable within at least two business days after the publication of the supplement, to withdraw their subscription orders, provided that the new factor, mistake or inaccuracy referred to above arose before the closing of the Offering and the delivery of the Offered Shares. The supplement is subject to approval by the FSMA and will, following such approval, be made public in the same manner as this Prospectus. A supplement will be published in the event the Offer Price is set below the lower end of the Price Range, if the Price Range is changed (other than in the event of a narrowing of the Price Range through an increase of the lower limit and/or a decrease of the upper limit of the Price Range), if the maximum number of Offered Shares is reduced prior to the allocation of the Offered Shares, or if the Offering is withdrawn.

## **Allocation**

The number of Offered Shares allotted to investors will be determined at the end of the Offering Period by the Issuer in common agreement with the Global Coordinator on the basis of the respective demand of both Retail Investors and Institutional Investors and on the quantitative, and, for Institutional Investors only, the qualitative analysis of the order book, in accordance with Belgian regulations relating to allocation to Retail Investors and Institutional Investors as set forth below, and taking into account the Offered Shares that must be allocated to the Participating Shareholders in consideration of their subscription commitment pursuant to the Investment Agreement.

In accordance with Belgian regulations, a minimum of 10% of the Offered Shares shall be allocated to Retail Investors, subject to sufficient retail demand. However, the proportion of Offered Shares allocated to Retail Investors may be increased or decreased if subscription orders received from them exceed or do not reach, respectively, 10% of the Offered Shares effectively allocated.

In case of over-subscription of the Offered Shares reserved for Retail Investors, the allocation to Retail Investors will be made on the basis of objective allocation criteria. The criteria that may be used for this purpose are the preferential treatment of applications submitted by Retail Investors at the counters of KBC Securities, KBC Bank, or Petercam and their affiliates, and the number of shares for which applications are submitted by Retail Investors.

The results of the Offering, the allocation for Retail Investors and the Offer Price will be published in the Belgian financial press, which is currently expected to take place on or about 30 April 2015 and in any event no later than the first or second business day after the end of the Offering Period.

In the event of the over-allotment of Offered Shares, the Underwriters will use reasonable efforts to deliver the newly issued shares to individual persons residing in Belgium and to investors subject to Belgian income tax on legal entities (*rechtspersonenbelasting/impôt des personnes morales*), in this order of priority. No tax on stock exchange transactions is due on the subscription for newly issued shares (see "*Taxation—Belgian tax on stock exchange transactions*").

Notwithstanding the foregoing, the Participating Shareholders will be allocated all of the Offered Shares (representing a maximum of 2,151,280 Offered Shares based on the low end of the Price Range), that he or she committed to subscribe for pursuant to the Investment Agreement. See also "*—Pre-commitment by the Participating Shareholders*". In the event of over-subscription, therefore, the number of new shares that will be allocated to the Participating Shareholders in consideration of their subscription commitment pursuant to the Investment Agreement will not be reduced.

## **Payment and taxes**

The Offer Price must be paid by the investors in full, in euro, together with any applicable stock exchange taxes and costs. For further information about applicable taxes, see "*Taxation—Belgian taxation*".

The Closing Date is expected to be 5 May 2015 unless the Offering Period is closed earlier or extended. The Offer Price must be paid by investors upon submission of the subscription orders or, alternatively, by authorising their financial institutions to debit their bank accounts with such amount for value on the Closing Date.

## **Form of the Offered Shares and delivery**

From their issue date, the Offered Shares will be subject to all provisions of the articles of association of the Issuer. The Offered Shares shall be of the same class as existing shares, including as to voting and dividend rights, and will be profit sharing as from any distribution in respect of which the relevant record date or due date falls on or after the date of the issue of

such Offered Shares, including any distributions in relation to the financial year that started on 1 January 2015, as the case may be. The rights attached to the shares are described in *"Share capital and articles of association—Rights attached to the shares"*.

All Offered Shares will be delivered in dematerialised (book-entry) form only, and will be credited on or around the Closing Date to investors' securities accounts via Euroclear Belgium, the Belgian central securities depository.

Investors who, after delivery, wish to have their shares registered, should request that the Issuer record the shares in the Issuer's share register.

Holders of registered shares may request that their registered shares be converted into dematerialised shares and vice versa. Any costs incurred in connection with the conversion of shares into another form will be borne by the shareholders.

All Offered Shares will be fully paid-up upon their delivery and freely transferable, subject to what is set forth under *"Plan of Distribution"*.

### **Trading and listing on the regulated market of Euronext Brussels**

An application has been made for the listing and admission to trading on the regulated market of Euronext Brussels of all shares, including the Offered Shares. The shares are expected to be listed under the symbol "BCART" with an ISIN code of BE0974281132.

Trading is expected to commence on or about 4 May 2015 (unless in case of early closing or extension of the Offering Period) and will start at the latest on the Closing Date, when the Offered Shares are delivered to investors.

As of the Listing Date until the Closing Date and delivery of the Offered Shares, the shares will be traded on the regulated market of Euronext Brussels on an "as-if-and-when issued and/or delivered" basis. Investors who wish to effect transactions in shares of the Issuer prior to the Closing Date, whether such transactions are effected on the regulated market of Euronext Brussels or otherwise, should be aware that the issuance and delivery of the Offered Shares may not take place on the expected Closing Date, or at all, if certain conditions or events referred to in the Underwriting Agreement (as defined below) are not satisfied or waived or do not occur on or prior to such date. Euronext Brussels NV/SA may annul all transactions effected in the shares of the Issuer if the Offered Shares are not delivered on the Closing Date. See *"Risk factors—Risks related to the shares and the Offering—The shares will be listed and traded on the regulated market of Euronext Brussels on an "if-and-when-issued and/or delivered" basis from the Listing Date until the Closing Date. Euronext Brussels NV/SA may annul all transactions effected in the shares if they are not issued and delivered on the Closing Date"*. Euronext Brussels NV/SA cannot be held liable for any damage arising from the listing and trading on an "if-and-when-issued and/or delivered" basis as of the Listing Date until the expected Closing Date.

### **Share lending**

RMM S.A. is expected to agree to lend to the Stabilisation Manager (acting on behalf of the Underwriters) a number of shares equal to up to 15% of the number of New Shares subscribed for in the Offering, in order to enable the Stabilisation Manager to settle any over-allotments.

### **Over-allotment Option**

The Issuer is expected to grant to the Stabilisation Manager, acting on behalf of the Underwriters, an Over-allotment Option in the form of the Over-allotment Warrant, which will entitle the Stabilisation Manager, acting on behalf of the Underwriters, to subscribe to additional new shares in an aggregate amount equal to up to 15% of the New Shares subscribed for in the Offering at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering. The Over-allotment Option will be exercisable for a period of 35 days following Listing Date.

**Authorisations**

This Prospectus and the participation of the Issuer in the Offering were approved by the board of directors of the Issuer on 13 April 2015. The issuance of the Offered Shares and required amendments to the Issuer's articles of association, both of which are subject to the condition precedent of the closing of the Offering, were approved by the shareholders of the Issuer at their extraordinary general shareholders' meeting held on 13 April 2015.

**Jurisdiction and competent courts**

The Offering is subject to Belgian law and the Dutch speaking courts of Brussels are exclusively competent to adjudicate any and all disputes with investors concerning the Offering.

## PLAN OF DISTRIBUTION

### Underwriting

The Underwriters are KBC Securities NV/SA, having its registered office at Havenlaan 12, 1080, Brussels, Belgium, Kempen & Co N.V., having its registered office at Beethovenstraat 300, 1077, WZ Amsterdam, the Netherlands, and Petercam NV/SA, having its registered office at Sint-Goedeleplein 19, 1000 Brussels, Belgium.

The Underwriters are expected (but have no obligation) to enter into a placement and soft underwriting agreement (the "**Underwriting Agreement**"), upon the determination of the Offer Price, which is expected to take place on or about 30 April 2015. The entering into the Underwriting Agreement may depend on various factors including, but not limited to, market conditions and the result of the book-building process.

Subject to the terms and conditions to be set forth in the Underwriting Agreement, the Underwriters will severally but not jointly agree to subscribe and procure payment for the following percentage of the total number of New Shares less those New Shares subscribed to by the Participant Shareholders pursuant to their pre-commitment (the "**Underwritten Shares**"), in their own name but for the account of the relevant subscribers in the Offering to whom those Underwritten Shares have been allocated:

	<u>Percentage of Underwritten Shares to be subscribed for</u>
<b>Underwriters</b>	
KBC Securities NV/SA .....	40%
Kempen & Co N.V .....	30%
Petercam NV/SA .....	30%
<b>Total percentage of the Underwritten Shares to be subscribed for .....</b>	<b>100.0%</b>

The Underwriters shall have no obligation to underwrite any of the Underwritten Shares prior to the execution of the Underwriting Agreement (and then only in accordance with the terms and subject to the conditions set forth therein).

The Underwriters shall underwrite the Underwritten Shares and immediately after receipt will deliver such Underwritten Shares to the relevant subscribers in the Offering and the Underwriters shall guarantee to the Issuer the payment of the Offer Price.

In the Underwriting Agreement, the Issuer will make certain customary representations and warranties and the Issuer will agree to indemnify each of the Underwriters against certain liabilities in connection with the Offering, including liability under the US Securities Act. If the Underwriting Agreement is not entered into, a supplement to the Prospectus to this effect will be published.

The Underwriting Agreement will provide that each Underwriter shall have the right to terminate the Underwriting Agreement before the realisation of the capital increase in relation to the Offering, if in their reasonable opinion an event such as the following shall have occurred: (i) the publication of a supplement or the amendment to any other offering document, or any statement in any offering document is, or has become materially inaccurate or misleading, or any matter has arisen which would, if any of the offering documents was to be approved at such time, constitute a material inaccuracy or omission of such offering document, (ii) there has been a breach of any of the representation and warranties or the Issuer has failed to perform any of its undertakings or to comply with its obligations set forth in the Underwriting Agreement, or there has been or it is likely that there will be a material adverse effect, (iii) the application for listing on Euronext Brussels has been withdrawn or refused, (iv) there has been a force majeure event, or (v) any of the conditions precedent has not been satisfied such as (a) the performance of the Participating Shareholders or (b) the delivery of the closing documents. Following termination of the Underwriting Agreement, each of the Underwriters shall be released from the obligation to subscribe for any Underwritten Shares.

In the event that the Underwriting Agreement is not executed or is executed but subsequently terminated, a supplement to this Prospectus shall be published. After publication of the supplement, the subscriptions for the Offered Shares will automatically be cancelled and withdrawn, and subscribers will not have any claim to delivery of the Offered shares or to any compensation.

### Standstill

The Issuer is expected to agree pursuant to the Underwriting Agreement (which is expected to be entered into on or about 30 April 2015) in respect of (i) shares and all other "*effecten met een aandelenkarakter*" as defined in article 6 of the Belgian Prospectus Act, issued by the Issuer, (ii) certificates and contractual rights (including options, futures, swaps and other derivatives) issued or contracted by the Issuer or any of its subsidiaries and representing, giving right to or being exchangeable for any of the instruments referred to in (i) that are issued by the Issuer (together the "**Standstill Financial Instruments**"), that it will not for a period of 365 days from the Listing Date, otherwise than with the prior written consent of the Global Coordinator and at least one other Underwriter (subject to certain limited exceptions (the main ones being described below)): (i) directly or indirectly, issue, sell, solicit any offer to buy, attempt to dispose, make any offering, short sale or other disposal of any Standstill Financial Instruments or grant any options, convertible securities or other rights to subscribe for or purchase Standstill Financial Instruments or enter into any contract (including any derivative transaction) or commitment with similar effect, nor publicly disclose the intention of any of the abovementioned actions, and (ii) directly or indirectly, purchase any of its Standstill Financial Instruments or otherwise reduce its share capital. The foregoing undertaking shall not apply to the Offered Shares and the new shares following the exercise of existing warrants that are set forth in the Prospectus nor to the granting of options or warrants under existing option of warrant plans that are described in the Prospectus.

### Lock-up

The current shareholders of the Issuer (excluding some minority shareholders holding in the aggregate 1.65% of the currently outstanding shares) and each of the executive managers have entered into a lock-up arrangement with the Global Coordinator in respect of (i) the shares and all other "*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 Issuer, an affiliate of the Issuer or in cooperation with the Issuer 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 Issuer (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 six months from the Listing Date: (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 six month-period, a new period of six months starts during which the shareholders and executive managers 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 the Global Coordinator and (ii) any such transfer shall solely be effected through a coordinated sale.

None of the restrictions for the shareholders and executive managers referred to above apply to (i) shares being lent to the Stabilisation Manager, (ii) transfers to legal successors or other transferees in case of death of a natural person or in case of liquidation, concursus, merger

or de-merger (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), (iii) 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), (iv) acceptance of a public tender offer, (v) any transfer of shares subscribed for or acquired after the Offering (except if those shares are acquired pursuant to one of the other exemptions), (vi) any transfer of shares pursuant to the shadow option agreements entered into by the Issuer, Benaruca SA, Mr. Ferdinand Verdonck and Mr. Philippe Renaud dated 2 July 2009, as amended, in relation to the 2008 Plan, and (vii) any transfer of shares under a stock lending agreement to a financial institution for market making and liquidity providing purposes.

### **Over-allotment Option and price stabilisation**

In connection with the Offering, KBC Securities NV/SA will act as Stabilisation Manager on behalf of the Underwriters and may engage in transactions that stabilise, maintain or otherwise affect the price of the shares or any options, warrants or rights with respect to, or other interest in, the shares or other securities of the Issuer for up to 30 days from the Listing Date (the “**Stabilisation Period**”). These activities may support the market price of the shares at a level higher than that which might otherwise prevail. Stabilisation will not be executed above the Offer Price. Such transactions may be effected on the regulated market of Euronext Brussels, in the over-the-counter markets or otherwise. The Stabilisation Manager and its agents are not required to engage in any of these activities and, as such, there is no assurance that these activities will be undertaken; if undertaken, the Stabilisation Manager or its agents may discontinue any of these activities at any time and they must terminate at the end of the 30-day period mentioned above.

Under the possible stabilisation measures, investors may, in addition to the New Shares being offered, be allocated up to 15% of the New Shares subscribed for in the Offering as additional shares as part of the allocation of the shares to be placed. Within the scope of a possible over-allotment, the additional shares will be provided for the account of the Stabilisation Manager, acting on behalf of the Underwriters, in the form of a securities loan from RMM S.A.

The Issuer is expected to grant to the Stabilisation Manager, acting on behalf of the Underwriters, an Over-allotment Option in the form of the Over-allotment Warrant, which will entitle the Stabilisation Manager, acting on behalf of the Underwriters, to subscribe to additional new shares in an aggregate amount equal to up to 15% of the New Shares subscribed for in the Offering at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering.

The Stabilisation Manager may elect to reduce any short position by exercising all or part of the Over-Allotment Option. The Over-Allotment Option will be exercisable for a period of 35 days from the Listing Date. The Over-Allotment Option will be exercisable in whole or in part, and in one or in several times, only to cover over-allotments of additional shares, if any. The possibility to over-allot shares in the Offering and to exercise the Over-Allotment Option will exist whether or not the Offering is fully subscribed.

If the Stabilisation Manager creates a short position in the shares in connection with the Offering (*i.e.* over-allot additional shares), they may reduce that short position by purchasing shares or by exercising all or part of the Over-Allotment Option. Purchases of shares to stabilize the trading price or to reduce a short position may cause the price of the shares to be higher than it might be in the absence of such purchases. Neither the Issuer, nor the Global Coordinator nor the other Underwriters make any representation or prediction as to the direction or the magnitude of any effect that the transactions described above may have on the price of the shares.

Within five business days of the end of the Stabilisation Period, the following information will be made public in accordance with article 5, §2 of the Belgian Royal Decree of 17 May 2007 on primary markets practices: (i) whether or not stabilisation was undertaken; (ii) the date at



which stabilisation started; (iii) the date on which stabilisation last occurred; (iv) the price range within which stabilisation was carried out, for each of the dates on which stabilisation transactions were carried out; and (v) the final size of the Offering, including the result of the stabilisation and the exercise of the Over-allotment Option, if any.

### **Other relationships with the Underwriters**

In connection with the Offering, each of the Underwriters and any of their respective affiliates, acting as an investor for its own account, may take up Offered Shares in the Offering and in that capacity may retain, purchase or sell for its own account such securities and any shares or related investments and may offer or sell such shares or other investments otherwise than in connection with the Offering. Accordingly, references in the Prospectus to shares being offered or placed should be read as including any offering or placement of Offered Shares to any of the Underwriters or any of their respective affiliates acting in such capacity. None of the Underwriters intend to disclose the extent of any such investment or transactions otherwise than in accordance with any legal or regulatory obligation to do so. In addition certain of the Underwriters or their affiliates may enter into financing arrangements (including swaps) with investors in connection with which such Underwriters (or their affiliates) may from time to time acquire, hold or dispose of shares.

Certain of the Underwriters and/or their respective affiliates have in the past provided, and may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and ancillary activities in the ordinary course of their business with the Issuer or any parties related to it, in respect of which they may, in the past have received, or in the future receive, customary fees and commissions. As a result of these transactions, these parties may have interests that may not be aligned, or could possibly conflict with the interests of investors.

Petercam NV/SA, acting as nominee on behalf of certain of its clients, is also a direct shareholder of the Issuer. As a result thereof, it may have interests that may not be aligned, or could possibly conflict with the interests of other investors.

### **No public offering outside Belgium**

No action has been or will be taken in any jurisdiction other than Belgium that would permit a public offering of the Offered Shares, or the possession, circulation or distribution of this Prospectus or any other material relating to the Offered Shares, in any jurisdiction where action for that purpose is required. Accordingly, the Offered Shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other offering material or advertisements in connection with the Offered Shares may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of such country or jurisdiction.

Purchasers of the Offered Shares may be required to pay stamp taxes and other charges in accordance with the laws and practices of the country of purchase in addition to the Offer Price.

### **Selling restrictions**

#### ***General***

No public offer is being made and no one has taken any action that would, or is intended to, permit a public offering in any country or jurisdiction, other than Belgium, where any such action for such purpose is required. Accordingly, the shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other offering material or advertisement in connection with the shares may be distributed or published in any country or jurisdiction except in compliance with any applicable rules and regulations of such country or jurisdiction.

Persons into whose hands this Prospectus comes are required by the Issuer and the Underwriters to comply with all applicable laws and regulations in each country or jurisdiction in or from which they purchase, offer, sell or deliver shares or have in their possession or distribute such offering material, in all cases at their own expense. Neither the Issuer or the Underwriters

accept any legal responsibility for any violation by any person, whether or not a prospective subscriber or purchaser of any of the shares, of any such restrictions.

### ***United States***

The shares have not been and will not be registered under the US Securities Act or with any state securities regulatory authority for offer or sale as part of their distribution and may not be offered, sold, pledged or transferred within the United States, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act.

The shares may only be resold: (i) in the United States to QIBs in reliance on Rule 144A under the US Securities Act or pursuant to another exemption from the registration requirements of the US Securities Act; and (ii) outside the United States in offshore transactions in compliance with Regulation S under the US Securities Act and in accordance with applicable law. Any offer or sale of shares in reliance on Rule 144A or pursuant to another exemption from, or transaction not subject to, the registration requirements of the US Securities Act will be made by broker-dealers who are registered as such under the US Exchange Act. Terms used above shall have the meanings given to them by Regulation S and Rule 144A under the US Securities Act. Resales of the shares are restricted as described under "*Transfer restrictions.*"

### ***European Economic Area***

In relation to each Relevant Member State an offer to the public of any shares may not be made in that Relevant Member State unless the Prospectus has been approved by the competent authority in such Relevant Member State or passported and published in accordance with the European Prospectus Directive as implemented in such Relevant Member State, except that the shares may be offered to the public in that Relevant Member State at any time under the following exemptions under the European Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor as defined in the European Prospectus Directive;
- by the Underwriters to fewer than 150 natural or legal persons (other than qualified investors as defined in the European Prospectus Directive) subject to obtaining the prior consent of the Global Coordinator for any such offer; or
- in any other circumstances falling within article 3(2) of the European Prospectus Directive,

provided that no such offer of shares shall result in a requirement for the publication by the Issuer or any Underwriter of a prospectus pursuant to article 3 of the European Prospectus Directive or supplement a prospectus pursuant to article 16 of the European Prospectus Directive and each person who initially acquires shares or to whom any offer is made will be deemed to have represented, warranted and agreed to and with the Underwriters and the Issuer that it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing article 2(1)I of the European Prospectus Directive.

The Issuer, the Underwriters and their affiliates and others will rely upon the truth and accuracy of the foregoing representation, acknowledgement, and agreement. Notwithstanding the above, a person who is not a qualified investor and who has notified the Underwriters of such fact in writing may, with the consent of the Underwriters, be permitted to subscribe for shares in the Offering.

### ***United Kingdom***

Any offer or sale of the shares may only be made to persons in the United Kingdom who are "qualified investors" or otherwise in circumstances which do not require publication by the Issuer of a prospectus pursuant to section 85(1) of the U.K. Financial Services and Markets Act 2000. Any investment or investment activity to which this Prospectus relates in the United Kingdom is available only to, and will be engaged in only with, investment professionals falling within article 19(5), or falling within section 49(2)(a) to (d) ("high net worth; unincorporated

associations, etc.”), of the UK Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or other persons to whom such investment or investment activity may lawfully be made available (together, “**Relevant Persons**”). Persons in the United Kingdom who are not Relevant Persons should not take any action on the basis of this Prospectus and should not act or rely on it.

### ***Japan***

The shares have not been and will not be registered under the Financial Instruments and Exchange Act, as amended, or any successor legislation thereto (the “**FIEL**”). This document is not an offer of securities for sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or entity organised under the laws of Japan) or to others for reoffer or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements under the FIEL and otherwise in compliance with such law and any other applicable laws, regulations and ministerial guidelines of Japan.

### ***Switzerland***

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“**SIX**”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the shares or the Offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this Prospectus nor any other offering or marketing material relating to the Offering, the Issuer or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this Prospectus will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the Offering has not been and will not be authorised under the Swiss Federal Act on Collective Investment Schemes (“**CISA**”). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

## TRANSFER RESTRICTIONS

The shares have not been and will not be registered under the US Securities Act or the applicable securities laws of any state or other jurisdiction of the United States and may not be offered, sold, pledged or transferred within the United States, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act and applicable state securities laws.

Each purchaser and each subsequent purchaser of the Offered Shares outside the United States in compliance with Regulation S will be deemed to have represented and agreed that it has received a copy of this Prospectus and such other information as it deems necessary to make an informed investment decision and that:

- (1) the purchaser is authorised to consummate the purchase of the Offered Shares in compliance with all applicable laws and regulations;
- (2) the purchaser acknowledges that the Offered Shares have not been and will not be registered under the US Securities Act, or with any securities regulatory authority of any state of the United States, and, subject to certain exceptions, may not be offered or sold within the United States;
- (3) the purchaser and the person, if any, for whose account or benefit the purchaser is acquiring the Offered Shares, was located outside the United States at the time the buy order for the Offered Shares was originated and continues to be located outside the United States and has not purchased the Offered Shares for the account or benefit of any person in the United States or entered into any arrangement for the transfer of the Offered Shares or any economic interest therein to any person in the United States;
- (4) the purchaser is not an affiliate of the Issuer or a person acting on behalf of such affiliate;
- (5) the Offered Shares have not been offered to it by means of any "directed selling efforts" as defined in Regulation S;
- (6) the purchaser acknowledges that the Issuer shall not recognise any offer, sale, pledge or other transfer of the Offered Shares made other than in compliance with the above-stated restrictions;
- (7) if it is acquiring any of the Offered Shares as a fiduciary or agent for one or more accounts, the purchaser represents that it has sole investment discretion with respect to each such account and that it has full power to make the foregoing acknowledgements, representations and agreements on behalf of each such account; and
- (8) the purchaser acknowledges that the Issuer, the Underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing acknowledgements, representations and agreements, and undertakes promptly to notify the Issuer and the Underwriters if, at any time prior to the purchase of the Offered Shares, any of the foregoing ceases to be true.

Each purchaser and each subsequent purchaser of the Offered Shares within the United States purchasing pursuant to an exemption from the registration requirements of the US Securities Act will be deemed to have represented and agreed that it has received a copy of this Prospectus and such other information as it deems necessary to make an informed investment decision and that:

- (1) the purchaser is authorised to consummate the purchase of the Offered Shares in compliance with all applicable laws and regulations;
- (2) the purchaser acknowledges that the Offered Shares have not been and will not be registered under the US Securities Act or with any securities regulatory authority of any state of the United States and are subject to restrictions on transfer;
- (3) the purchaser: (i) is a qualified institutional buyer (as defined in Rule 144A under the US Securities Act); (ii) is aware that the sale to it is being made pursuant to an exemption from the registration requirements of the US Securities Act; and (iii) is acquiring such Offered Shares for its own account or for the account of a qualified institutional buyer;

- (4) the purchaser is aware that the Offered Shares are being offered in the United States in a transaction not involving any public offering in the United States within the meaning of the US Securities Act and the seller of the shares may be relying on the exemption from the registration requirements of Section 5 of the US Securities Act, provided by Rule 144A thereunder;
- (5) if in the future, the purchaser decides to offer, resell, pledge or otherwise transfer such Offered Shares, or any economic interest therein, such Offered Shares or any economic interest therein may be offered, sold, pledged or otherwise transferred only: (i) to a person whom the beneficial owner and/or any person acting on its behalf reasonably believes is a qualified institutional buyer in a transaction meeting the requirements of Rule 144A; (ii) in compliance with Regulation S under the US Securities Act; or (iii) in accordance with Rule 144 under the US Securities Act (if available), in each case in accordance with any applicable securities laws of any state of the United States or any other jurisdiction;
- (6) the purchaser acknowledges that the Offered Shares are “restricted securities” within the meaning of Rule 144(a)(3) under the US Securities Act and no representation is made as to the availability of the exemption provided by Rule 144 for resales of any Offered Shares;
- (7) the purchaser will not deposit or cause to be deposited such Offered Shares into any depository receipt facility established or maintained by a depository bank other than a Rule 144A restricted depository receipt facility, so long as such Offered Shares are “restricted securities” within the meaning of Rule 144(a)(3) under the US Securities Act;
- (8) the purchaser acknowledges that the Issuer shall not recognise any offer, sale, pledge or other transfer of the Offered Shares made other than in compliance with the above-stated restrictions;
- (9) if it is acquiring any of the Offered Shares as a fiduciary or agent for one or more accounts, the purchaser represents that it has sole investment discretion with respect to each such account and that it has full power to make the foregoing acknowledgements, representations and agreements on behalf of such account; and
- (10) the purchaser acknowledges that the Issuer, the Underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing acknowledgements, representations and agreements, and undertakes promptly to notify the Issuer and the Underwriters if, at any time prior to the purchase of the Offered Shares, any of the foregoing ceases to be true.

In addition, until the end of the 40<sup>th</sup> calendar day after the commencement of the Offering, an offer or sale of the shares within the United States by any dealer (whether or not participating in the Offering) may violate the registration requirements of the US Securities Act if such offer or sale is made otherwise than in accordance with Rule 144A or another exemption from registration under the US Securities Act.

Each person in a Relevant Member State, other than persons receiving offers contemplated in the Prospectus in Belgium, who receives any communication in respect of, or who acquires any Offered Shares under, the offers contemplated hereby will be deemed to have represented, warranted and agreed to and with each of the Underwriters and the Issuer that:

- (1) it is a qualified investor within the meaning of the law in that Relevant Member State implementing article 2(1) of the European Prospectus Directive; and
- (2) in the case of any Offered Shares acquired by it as a financial intermediary, as that term is used in article 3(2) of the European Prospectus Directive, (i) the Offered Shares acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the European Prospectus Directive, or in other circumstances falling within article 3(2) of the European Prospectus Directive and the prior consent of the Global Coordinator has been given to the offer or resale; or (ii) where Offered Shares have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those Offered Shares to it is not treated under the European Prospectus Directive as having been made to such persons.

## **LEGAL MATTERS**

Certain legal matters in connection with this Offering have been passed upon for the Issuer by Baker & McKenzie CVBA, with respect to the laws of Belgium, and by Baker & McKenzie LLP, with respect to the laws of the United States. Certain legal matters in connection with this Offering have been passed upon for the Underwriters by Freshfields Bruckhaus Deringer LLP, with respect to the laws of Belgium and the United States.

## STATUTORY AUDITOR

The Issuer's current statutory auditor is Deloitte Bedrijfsrevisoren BV ovve CVBA, with registered office at Berkenlaan 8B, 1831 Diegem, Belgium, member of the *Institut des Réviseurs d'Entreprises/Instituut der Bedrijfsrevisoren*, represented by Gert Vanhees, auditor.

The Issuer's current statutory auditor has been appointed for the statutory term of three years at the Issuer's incorporation on 24 November 2014.

The consolidated financial statements as of and for the financial years ended 31 December 2012, 31 December 2013 and 31 December 2014 have been audited by the Issuer's current statutory auditor, Deloitte Bedrijfsrevisoren BV ovve CVBA, represented by Gert Vanhees, who rendered an unqualified audit report on these financial statements with a matter of emphasis paragraph on going concern.

Belgian law limits an auditor's liability to €3 million (for a non-listed company) and €12 million (for a listed company) for tasks reserved to auditors by Belgian law or in accordance with Belgian law, such as auditing financial statements such as those described above, other than liability due to fraud or other deliberate breach of duty.

## TAXATION OF SHARES

### Belgian taxation

The paragraphs below present a summary of certain material Belgian federal income tax consequences of the ownership and disposal of the shares by an investor that acquires such shares in connection with this Offering. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this Prospectus, all of which are subject to change, including changes that could have retroactive effect.

Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the investment in, ownership in and disposal of the shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, shares as a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (i.e., an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (i.e., a corporate entity that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium), an Organisation for Financing Pensions subject to Belgian corporate income tax (i.e., a Belgian pension fund incorporated under the form of an Organisation for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (i.e., a legal entity other than a company subject to Belgian corporate income tax, that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium). A non-resident is any person that is not a Belgian resident.

Investors should consult their own advisers regarding the tax consequences of an investment in the shares in the light of their particular circumstances, including the effect of any state, local or other national laws.

### Belgian taxation of dividends on shares

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the Belgian Companies Code is not treated as a dividend distribution to the extent that such repayment is imputed to the fiscal capital. This fiscal capital includes, in principle, the actual paid-up statutory share capital and, subject to certain conditions, the paid-up issuance premiums and the cash amounts subscribed to at the time of the issue of profit sharing certificates.

Belgian withholding tax of 25% is normally levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Upon redemption of the shares, the redemption distribution (after deduction of the portion of fiscal capital represented by the redeemed shares) will be treated as a dividend subject to a Belgian withholding tax of 25%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if such redemption is carried out on Euronext or a similar stock exchange and meets certain conditions.

In case of liquidation of the Issuer, any amounts distributed in excess of the fiscal capital will in principle be subject to withholding tax at a rate of 25%, subject to such relief as may be available under applicable domestic or tax treaty provisions.



### ***Belgian resident individuals***

For Belgian resident individuals who acquire and hold the shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless elect to report the dividends in their personal income tax return. Where such individual opts to report them, dividends will normally be taxable at the lower of the generally applicable 25% withholding tax rate on dividends or at the progressive personal income tax rates applicable to the taxpayer's overall declared income. In addition, if the dividends are reported, the dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on the shares. This condition is not applicable if the individual can demonstrate that he has held the shares in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends.

For Belgian resident individuals who acquire and hold the shares for professional purposes, the Belgian withholding tax does not fully discharge their personal income tax liability. Dividends received must be reported by the investor and will, in such case, be taxable at the investor's personal income tax rate increased with local surcharges. Withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, subject to two conditions: (1) the taxpayer must own the shares in full legal ownership at the time the dividends are paid or attributed and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the shares. The latter condition is not applicable if the investor can demonstrate that he has held the full legal ownership of the shares for an uninterrupted period of twelve months prior to the attribution of the dividends.

### ***Belgian resident companies***

#### *Corporate income tax*

For Belgian resident companies, the dividend withholding tax does not fully discharge the corporate income tax liability. For such companies, the gross dividend income (including the withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 33.99%, unless the reduced corporate income tax rates apply.

Belgian resident companies can generally (subject to certain limitations) deduct 95% of gross dividends received from their taxable income (dividend received deduction), provided that at the time of a dividend payment or attribution: (1) the Belgian resident company holds shares representing at least 10% of the share capital of the Issuer or a participation in the Issuer with an acquisition value of at least €2,500,000; (2) the shares have been held or will be held in full ownership for an uninterrupted period of at least one year; and (3) the conditions relating to the taxation of the underlying distributed income, as described in article 203 of the Belgian Income Tax Code (the "**Article 203 ITC Taxation Condition**") are met (together, the "**Conditions for the application of the dividend received deduction regime**"). Under certain circumstances the conditions referred to under (1) and (2) do not need to be fulfilled in order for the dividend received deduction to apply.

The Conditions for the application of the dividend received deduction regime depend on a factual analysis, upon each distribution, and for this reason the availability of this regime should be verified upon each distribution.

Any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due, subject to two conditions: (1) the taxpayer must own the shares in full legal ownership at the time the dividends are paid or attributed; and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the shares. The latter condition is not applicable (a) if the company can demonstrate that it has held the shares in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends; or (b) if, during said period, the shares never belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the shares in a permanent establishment ("**PE**") in Belgium.

### *Withholding tax*

Dividends distributed to a Belgian resident company will be exempt from Belgian withholding tax provided that the Belgian resident company holds, upon payment or attribution of the dividends, at least 10% of the share capital of the Issuer and such minimum participation is held or will be held during an uninterrupted period of at least one year.

In order to benefit from this exemption, the Belgian resident company must provide the Issuer or its paying agent with a certificate confirming its qualifying status and the fact that it meets the two required conditions. If the Belgian resident company holds the required minimum participation for less than one year, at the time the dividends are paid on or attributed to the shares, the Issuer will levy the withholding tax but will not transfer it to the Belgian Treasury provided that the Belgian resident company certifies its qualifying status, the date from which it has held such minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The Belgian resident company must also inform the Issuer or its paying agent if the one-year period has expired or if its shareholding will drop below 10% of the share capital of the Issuer before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the Belgian resident company.

### ***Belgian resident organisations for financing pensions***

For organisations for financing pensions (“OFPs”), i.e., Belgian pension funds incorporated under the form of an OFP (*organismen voor de financiering van pensioenen/organismes de financement de pensions*) within the meaning of article 8 of the Belgian Act of October 27, 2006, the dividend income is generally tax exempt.

Subject to certain limitations, any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due.

### ***Other Belgian resident legal entities subject to Belgian legal entities tax***

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

### ***Non-resident individuals or non-resident companies***

#### *Non-resident income tax*

For non-resident individuals and companies, the dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds the shares in connection with a business conducted in Belgium through a fixed base in Belgium or a Belgian PE.

If the shares are acquired by a non-resident in connection with a business in Belgium, the investor must report any dividends received, which will be taxable at the applicable non-resident personal or corporate income tax rate, as appropriate. Belgian withholding tax levied at source may be credited against non-resident personal or corporate income tax and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (1) the taxpayer must own the shares in full legal ownership at the time the dividends are paid or attributed and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the shares. The latter condition is not applicable if (a) the non-resident individual or the non-resident company can demonstrate that the shares were held in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends or (b) with regard to non-resident companies only, if, during said period, the shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the shares in a Belgian PE.

Non-resident companies whose shares are invested in a Belgian PE may deduct 95% of the gross dividends received from their taxable income if, at the date the dividends are paid or

attributed, the Conditions for the application of the dividend received deduction regime are met. See "*—Belgian resident companies*". Application of the dividend received deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

#### *Belgian dividend withholding tax relief for non-residents*

Under Belgian tax law, withholding tax is not due on dividends paid to a foreign pension fund which satisfies the following conditions: (i) to be a legal entity with fiscal residence outside of Belgium and without a PE in Belgium; (ii) whose corporate purpose consists solely in managing and investing funds collected in order to pay legal or complementary pensions; (iii) whose activity is limited to the investment of funds collected in the exercise of its corporate purpose, without any profit making aim; (iv) which is exempt from income tax in its country of residence; and (v) provided that it is not contractually obligated to redistribute the dividends to any ultimate beneficiary of such dividends for whom it would manage the shares, nor obligated to pay a manufactured dividend with respect to the shares under a securities borrowing transaction. The exemption will only apply if the foreign pension fund provides a certificate confirming that it is the full legal owner or usufruct holder of the shares and that the above conditions are satisfied. The organisation must then forward that certificate to the Issuer or its paying agent.

Dividends distributed to non-resident qualifying parent companies established in a Member State of the EU or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause, will, under certain conditions, be exempt from Belgian withholding tax provided that the shares held by the non-resident company, upon payment or attribution of the dividends, amount to at least 10% of the share capital of the Issuer and such minimum participation is held or will be held during an uninterrupted period of at least one year. A non-resident company qualifies as a parent company provided that (i) for companies established in a Member State of the EU, it has a legal form as listed in the annex to the EU Parent-Subsidiary Directive of July 23, 1990 (90/435/EC), as amended by Directive 2003/123/EC of December 22, 2003, or, for companies established in a country with which Belgium has concluded a qualifying double tax treaty, it has a legal form similar to the ones listed in such annex; (ii) it is considered to be a tax resident according to the tax laws of the country where it is established and the double tax treaties concluded between such country and third countries; and (iii) it is subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime.

In order to benefit from this exemption, the non-resident company must provide the Issuer or its paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions.

If the non-resident company holds a minimum participation for less than one year at the time the dividends are attributed to the shares, the Issuer must levy the withholding tax but does not need to transfer it to the Belgian Treasury provided that the non-resident company provides the Issuer or its paying agent with a certificate confirming, in addition to its qualifying status, the date as of which it has held the minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The non-resident company must also inform the Issuer or its paying agent when the one-year period has expired or if its shareholding drops below 10% of the Issuer's share capital before the end of the one-year holding period. Upon satisfying the one-year holding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the non-resident company.

Belgian dividend withholding tax is subject to such relief as may be available under applicable tax treaty provisions. Belgium has concluded tax treaties with more than 90 countries, reducing the dividend withholding tax rate to 20%, 15%, 10%, 5% or 0% for residents of those countries, depending on conditions, among others, related to the size of the shareholding and certain identification formalities.

Prospective holders should consult their own tax advisers to determine whether they qualify for a reduction in withholding tax upon payment or attribution of dividends, and, if so, to understand the procedural requirements for obtaining a reduced withholding tax upon the payment of dividends or for making claims for reimbursement.

## **Belgian taxation of capital gains and losses on shares**

### ***Belgian resident individuals***

In principle, Belgian resident individuals acquiring the shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the shares and capital losses will not be tax deductible.

However, capital gains realised by a Belgian resident individual are taxable at 33% (plus local surcharges) if the capital gain on the shares is deemed to be realised outside the scope of the normal management of the individual's private estate. Capital losses are, however, not tax deductible. Moreover, capital gains realised by Belgian resident individuals on the disposal of the shares to a non-resident company (or body constituted in a similar legal form), to a foreign State (or one of its political subdivisions or local authorities) or to a non-resident legal entity, each time established outside the European Economic Area, are in principle taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned, directly or indirectly, alone or with his/her spouse or with certain relatives, a substantial shareholding in the Issuer (i.e., a shareholding of more than 25% in the Issuer).

Capital gains realised by Belgian resident individuals upon redemption of the shares or upon liquidation of the Issuer will generally be taxable as a dividend. See "*Taxation of dividends on shares—Belgian resident individuals*".

Belgian resident individuals who hold the shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realised upon the disposal of the shares, except for the shares held for more than five years, which are taxable at a separate rate of 16.5% (plus local surcharges). Capital losses on the shares incurred by Belgian resident individuals who hold the shares for professional purposes are in principle tax deductible.

### ***Belgian resident companies***

Belgian resident companies (other than small companies within the meaning of article 15 of the Belgian Companies Code ("**SMEs**")) are subject to Belgian capital gains taxation at a separate rate of 0.412% on gains realised upon the disposal of the shares provided that: (i) the Article 203 ITC Taxation Condition is met and (ii) the shares have been held in full legal ownership for an uninterrupted period of at least one year. The 0.412% separate capital gains tax cannot be off-set against any tax assets (such as e.g. tax losses) and can moreover not be off-set against any tax credits.

Belgian resident companies qualifying as SMEs are normally not subject to Belgian capital gains taxation on gains realised upon the disposal of the shares provided that (i) the Article 203 ITC Taxation Condition is met and (ii) the shares have been held in full legal ownership for an uninterrupted period of at least one year.

If the one-year minimum holding period condition is not met (but the Article 203 ITC Taxation Condition is met), the capital gains realised upon the disposal of the shares by Belgian resident companies (both non-SMEs and SMEs) are taxable at a separate corporate income tax rate of 25.75%.

If the Article 203 ITC Taxation Condition would not be met, any capital gain realised would be taxable at the standard corporate income tax rate of 33.99%, unless the reduced corporate income tax rates apply.

Capital losses on the shares incurred by Belgian resident companies (both non-SMEs and SMEs) are as a general rule not tax deductible.

Shares held in the trading portfolios of Belgian qualifying credit institutions, investment enterprises and management companies of collective investment undertakings are subject to a different regime. The capital gains on such shares are taxable at the ordinary corporate income tax rate of 33.99% and the capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realisation.

Capital gains realised by Belgian resident companies upon redemption of the shares or upon liquidation of the Issuer will, in principle, be subject to the same taxation regime as dividends.

#### ***Belgian resident organisations for financing pensions***

Capital gains on the shares realised by OFPs within the meaning of article 8 of the Belgian Act of October 27, 2006 are in principle exempt from corporate income tax and capital losses are not tax deductible.

#### ***Other Belgian resident legal entities subject to Belgian legal entities tax***

Capital gains realised upon disposal of the shares by Belgian resident legal entities are in principle not subject to Belgian income tax and capital losses are not tax deductible.

Capital gains realised upon disposal of (part of) a substantial participation in a Belgian company (i.e., a participation representing more than 25% of the share capital of the Issuer at any time during the last five years prior to the disposal) may, however, under certain circumstances be subject to income tax in Belgium at a rate of 16.5%.

Capital gains realised by Belgian resident legal entities upon redemption of the shares or upon liquidation of the Issuer will, in principle, be subject to the same taxation regime as dividends.

#### ***Non-resident individuals or non-resident companies***

Non-resident individuals or companies are, in principle, not subject to Belgian income tax on capital gains realised upon disposal of the shares, unless the shares are held as part of a business conducted in Belgium through a fixed base in Belgium or a Belgian PE. In such a case, the same principles apply as described with regard to Belgian individuals (holding the shares for professional purposes) or Belgian companies.

Non-resident individuals who do not use the shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the shares to Belgium, might be subject to tax in Belgium if the capital gains arise from transactions which are to be considered speculative or beyond the normal management of one's private estate or in case of disposal of a substantial participation in a Belgian company as mentioned in the tax treatment of the disposal of the shares by Belgian individuals. See "*Taxation of capital gains and losses on shares—Belgian resident individuals*". Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax adviser.

Capital gains realised by non-resident individuals or non-resident companies upon redemption of the shares or upon liquidation of the Issuer will, in principle, be subject to the same taxation regime as dividends.

#### ***Uncertain effect of article 228, §3 ITC for non-residents***

Under a strict reading of article 228, §3 ITC, capital gains realised on the shares by non-residents could be subject to Belgian taxation, levied in the form of a professional withholding tax, if the following three conditions are cumulatively met: (i) the capital gain would have been taxable if the non-resident were a Belgian tax resident; (ii) the income is "borne by" a Belgian resident or by a Belgian establishment of a foreign entity (which would, in such a context, mean that the capital gain is realised upon a transfer of the shares to a Belgian resident or to a Belgian establishment of a foreign entity, together a Belgian Purchaser); and (iii) Belgium has the right to

tax such capital gain pursuant to the applicable double tax treaty, or, if no such tax treaty applies, the non-resident does not demonstrate that the capital gain is effectively taxed in its state of residence.

However, it is unclear whether a capital gain included in the purchase price of an asset can be considered to be "borne by" the purchaser of the asset within the meaning of the second condition mentioned above.

Furthermore, applying this withholding tax would require that the Belgian Purchaser is aware of (i) the identity of the non-resident (to assess the third condition mentioned above); and (ii) the amount of the capital gain realised by the non-resident (since such amount determines the amount of professional withholding tax to be levied by the Belgian Purchaser). Consequently, the application of this professional withholding tax on transactions with respect to the shares occurring on the central stock exchange of Euronext would give rise to practical difficulties as the seller and purchaser typically do not know each other.

In addition to the uncertainties referred to above, the parliamentary documents of the law that introduced article 228, §3 ITC support the view that the legislator did not intend for article 228, §3 ITC to apply to a capital gain included in the purchase price of an asset.

On July 23, 2014, formal guidance on the interpretation of article 228, §3 ITC has been issued by the Belgian tax authorities (published in the Belgian Official Gazette of July 23, 2014). The Belgian tax authorities state therein that article 228, §3 ITC only covers payments for services, as a result of which no professional withholding tax should apply to capital gains realised by non-residents in the situations described above. It should, however, be noted that a formal guidance issued by the tax authorities does not supersede and cannot amend the law if the latter is found to be sufficiently clear in itself. Accordingly, in case of dispute, it cannot be ruled out that the interpretation of article 228, §3 ITC made by the tax authorities in their formal guidance is not upheld by the competent courts.

### **Belgian tax on stock exchange transactions**

The purchase and the sale and any other acquisition or transfer for consideration of the shares (secondary market) in Belgium through a professional intermediary is subject to the tax on stock exchange transactions (*taks op de beursverrichtingen/taxe sur les opérations de bourse*) of 0.27% of the purchase price, capped at €800 per transaction and per party. A separate tax is due from each party to the transaction, both collected by the professional intermediary. Upon the issue of the new shares (primary market), no tax on stock exchange transactions is due.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in article 2,9° and 10° of the Belgian Law of August 2, 2002; (ii) insurance companies described in article 2, §1 of the Belgian Law of July 9, 1975; (iii) professional retirement institutions referred to in article 2,1° of the Belgian Law of October 27, 2006 concerning the supervision on institutions for occupational pension; (iv) collective investment institutions; and (v) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

The EU Commission adopted on February 14, 2013 the Draft Directive on an FTT. The Draft Directive currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of November 28, 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

### **Certain US federal income tax considerations**

HOLDERS ARE HEREBY NOTIFIED THAT: (A) ANY DISCUSSION OF US FEDERAL TAX ISSUES IN THIS PROSPECTUS IS NOT INTENDED OR WRITTEN TO BE RELIED UPON, AND CANNOT BE RELIED

UPON, BY HOLDERS FOR THE PURPOSE OF AVOIDING PENALTIES THAT MAY BE IMPOSED ON HOLDERS UNDER THE INTERNAL REVENUE CODE OF 1986, AS AMENDED (THE "CODE"); (B) SUCH DISCUSSION IS INCLUDED HEREIN BY THE ISSUER IN CONNECTION WITH THE PROMOTION OR MARKETING BY THE ISSUER OF THE TRANSACTIONS OR MATTERS ADDRESSED HEREIN; AND (C) HOLDERS SHOULD SEEK ADVICE BASED ON THEIR PARTICULAR CIRCUMSTANCES FROM AN INDEPENDENT TAX ADVISER

The following is a description of certain US federal income tax consequences that may be relevant with respect to the acquisition, ownership and disposition of the Offered Shares by a US Holder (as defined below). This summary deals only with initial purchasers of Offered Shares in the Offering, who use the US Dollar as their functional currency and will hold the Offered Shares as capital assets.

This description does not purport to address all material US tax consequences of the acquisition, ownership and disposition of the Offered Shares and does not address aspects of US federal income taxation that may be applicable to investors that are subject to special tax rules, including without limitation:

- certain financial institutions;
- dealers or certain traders in securities;
- real estate investment trusts, regulated investment entities or grantor trusts;
- persons holding Offered Shares as part of a straddle, wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the Offered Shares;
- persons whose functional currency for US federal income tax purposes is not the US Dollar;
- persons who receive Offered Shares as compensation for the performance of services;
- persons who are resident in or have a permanent establishment in Belgium;
- tax-exempt entities;
- certain US expatriates;
- "dual resident" corporations;
- persons that own or are deemed to own ten per cent. or more of the Issuer's voting stock; or
- persons holding Offered Shares in connection with a trade or business outside the United States.

Further, this description does not address state, local, foreign or other tax laws, nor does it address the 3.8 per cent. US federal Medicare tax on net investment income, the alternative minimum tax or the US federal gift and estate tax consequences of the acquisition, ownership and disposition of the Offered Shares.

This description is based on the Code, its legislative history, existing and proposed regulations promulgated thereunder, published rulings and court decisions, as well as on the Income Tax Convention Between the United States of America and Belgium (the "Treaty"), in each case as in effect on the date of this Offering, all of which are subject to change (or to changes in interpretation), possibly with retroactive effect. The Issuer has not requested, and does not intend to request, a ruling from the US Internal Revenue Service (the "IRS") with respect to matters addressed herein.

### ***US Holders***

You are a "US Holder" for purposes of this discussion if for US federal income tax purposes you are a beneficial owner of the Issuer's Offered Shares and are:

- a citizen or individual resident of the United States;

- a corporation created or organised in or under the laws of the United States, any state therein or the District of Columbia;
- an estate, the income of which is subject to US federal income taxation regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over its administration and one or more US persons have the authority to control all of the substantial decisions of such trust, or (ii) such trust has a valid election in effect to be treated as a US person for US federal income tax purposes.

If a partnership (or any other entity treated as a partnership for US federal income tax purposes) holds Offered Shares, the tax treatment of the partnership and a partner in such partnership will generally depend on the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax adviser as to the US federal income tax consequences of acquiring, holding, or disposing of the Offered Shares.

THE SUMMARY OF US FEDERAL INCOME TAX CONSEQUENCES SET OUT BELOW IS FOR GENERAL INFORMATION ONLY. ALL PROSPECTIVE PURCHASERS SHOULD CONSULT THEIR TAX ADVISERS AS TO THE PARTICULAR TAX CONSEQUENCES TO THEM OF OWNING THE OFFERED SHARES, INCLUDING THE APPLICABILITY AND EFFECT OF STATE, LOCAL, FOREIGN AND OTHER TAX LAWS AND POSSIBLE CHANGES IN TAX LAW.

### ***Taxation of distributions***

Subject to the PFIC rules discussed below, distributions paid on the Offered Shares (including the amount of any Belgian taxes withheld), other than certain pro rata distributions of Offered Shares to all shareholders, will be treated as dividends to the extent paid out of the Issuer's current or accumulated earnings and profits, as determined under US federal income tax principles. Because the Issuer does not maintain calculations of its earnings and profits under US federal income tax principles, it is expected that distributions generally will be reported to you as dividends. For US federal income tax purposes, US Holders will be treated as having received the amount of Belgian taxes withheld by the Issuer, and as then having paid over the withheld taxes to the Belgian taxing authorities. As a result of this rule, the amount of dividend income included in gross income for US federal income tax purposes by a US Holder with respect to a payment of dividends may be greater than the amount of cash actually received (or receivable) by the US Holder from the Issuer with respect to the payment.

Subject to applicable limitations, if you are a non-corporate US Holder, dividends paid to you may be eligible for taxation as "qualified dividend income" and therefore may be taxable at favourable rates. Dividends will be treated as qualified dividends if (a) certain holding period requirements are satisfied, (b) the Issuer is eligible for the benefits of the Treaty, which the Issuer expects will be the case provided that its shares are regularly traded on the regulated market of Euronext Brussels, and (c) the Issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a PFIC. The Issuer does not believe it has been or will become a PFIC in the future. However, its status in the current year and future years will depend upon its income and assets (which for this purpose depends in part on the market value of the Offered Shares) in those years. See the discussion below under "*—Passive foreign investment company rules*". You should consult your tax adviser regarding the availability of the reduced tax rate on qualified dividends.

Dividends will generally be included in your income on the date of receipt. Dividends will not be eligible for the dividends-received deduction generally available to US corporations under the Code. The amount of any dividend income paid in euro will be the US Dollar amount calculated by reference to the spot rate in effect on the date of receipt, regardless of whether the payment is in fact converted into US Dollars. If the dividend is converted into US Dollars on the date of receipt, you should not be required to recognise foreign currency gain or loss in respect of the amount received. You may have foreign currency gain or loss if the dividend is converted into US Dollars after the date of receipt, and any such gain or loss will be US-source ordinary income or loss.



Dividends paid by the Issuer generally will constitute income from sources outside the United States for US foreign tax credit limitation purposes and will be categorised as “passive income” or, in the case of certain US holders, as “general category income,” for US foreign tax credit purposes. Subject to applicable limitations, some of which vary depending upon your circumstances, Belgian income taxes withheld from dividend payments on Offered Shares at a rate not exceeding the applicable Treaty rate will be creditable against your US federal income tax liability. Belgian income taxes withheld in excess of the applicable Treaty rate will not be eligible for credit against your US federal income tax liability. The rules governing foreign tax credits are complex, and you should consult your tax adviser regarding the creditability of foreign taxes in your particular circumstances. In lieu of claiming a foreign tax credit, you may elect to deduct foreign taxes, including any Belgian taxes, in computing your taxable income, subject to applicable limitations. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the relevant taxable year.

### ***Sale or other taxable disposition of Offered Shares***

Subject to the PFIC rules discussed below, you generally will recognise taxable gain or loss on a sale or other taxable disposition of the Offered Shares equal to the difference between the amount realised on the sale or disposition and your tax basis in the Offered Shares, each as determined in US Dollars. This gain or loss will generally be capital gain or loss, and will be long-term capital gain or loss if at the time of sale or disposition the Offered Shares have been held for more than one year. Any gain or loss will generally be US-source for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If you receive euro (or other currency other than US Dollars) upon a sale, exchange or other disposition of the Offered Shares, the amount realised generally will be the US Dollar value of the payment received determined on (a) the date of receipt of payment in the case of a cash basis US Holder and (b) the date of disposition in the case of an accrual basis US Holder. If the Offered Shares are traded on an “established securities market”, a cash basis taxpayer or, if it so elects, an accrual basis taxpayer, will determine the US Dollar value of the amount realised by translating the amount received at the spot rate of exchange on the settlement date of the sale. A US Holder will have a tax basis in the foreign currency received equal to the US Dollar amount realised. Any currency exchange gain or loss realised on a subsequent conversion of the foreign currency into US Dollars for a different amount generally will be treated as ordinary income or loss from sources within the United States. However, if such foreign currency is converted into US Dollars on the date received by the US Holder, a cash basis or electing accrual basis US Holder should not recognise any gain or loss on such conversion.

### ***Passive foreign investment company rules***

A non-US corporation will be classified as a “passive foreign investment company”, or a PFIC, for US federal income tax purposes in any taxable year in which, after applying certain look-through rules, either:

- at least 75.0 per cent. of its gross income is “passive income”; or
- at least 50.0 per cent. of the quarterly average value of its gross assets is attributable to assets that produce “passive income” or are held for the production of passive income.

Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. However, rents and gains derived in the active conduct of a trade or business in certain circumstances are considered active income. In determining whether a non-US corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25.0 per cent. interest (by value) is taken into account.

The Issuer does not believe that it was a PFIC for US federal income tax purposes for its most recent taxable year and does not expect that it will be a PFIC for its current taxable year or in the foreseeable future. However, the determination of PFIC status is a factual determination that must be made annually at the close of each taxable year and, therefore, there can be no certainty

as to its status in this regard until the close of the current or any future taxable year. The Issuer's status could change depending, among other things, upon a decrease in the trading price of the Offered Shares, changes in the composition and relative values of its assets, and the sources of its income. If the Issuer were a PFIC in any year during a US Holder's holding period for the Offered Shares, the Issuer would ordinarily continue to be treated as a PFIC for each subsequent year during which the US Holder owned the Offered Shares.

If the Issuer were a PFIC for a taxable year during a US Holder's holding period for the Offered Shares, US Holders generally would be subject to additional taxes (including taxation at ordinary income rates and an interest charge) on any "excess distributions" received from the Issuer and on any gain realised from a sale or other disposition of the Offered Shares. A US Holder would have an excess distribution to the extent that distributions on the Offered Shares during a taxable year exceed 125.0 per cent. of the average amount received during the three preceding taxable years (or, if shorter, the US Holder's holding period). To compute the tax on excess distributions or any gain, (i) the excess distribution or gain would be allocated ratably over the US Holder's holding period, (ii) amounts allocated to the current taxable year and any year before the Issuer became a PFIC would be taxed as ordinary income in the current year and (iii) amounts allocated to other taxable years would be taxed at the highest applicable marginal rate in effect for each such year (i.e., at ordinary income tax rates) and (iv) an interest charge would be imposed to recover the deemed benefit from the deferred payment of the tax attributable to each year described in (iii). Gain on the disposition of the Offered Shares will be subject to taxation in the same manner as an excess distribution, described immediately above.

You would not be able to avoid the tax consequences described above by electing to treat the Issuer as a qualified electing fund ("QEF"), because the Issuer does not intend to provide US Holders with the information that would be necessary to make a QEF election with respect to the Offered Shares. However, a US Holder may be able to avoid some of the adverse impacts of the PFIC rules described above with respect to Offered Shares by electing to mark the Offered Shares to market annually. The election is available only if the Offered Shares are regularly traded in more than de minimis quantities on Euronext Brussels. Any gain from marking the Offered Shares to market or from disposing of them would be ordinary income. Any loss from marking the Offered Shares to market would be recognised only to the extent of unreversed gains previously included in income. Loss from marking the Offered Shares to market would be ordinary, but loss on disposing of them would be capital loss except to the extent of mark to market gains previously included in income. Each US Holder should ask its own tax adviser whether a mark to market election is available or desirable. A valid mark to market election cannot be revoked without the consent of the IRS unless the Offered Shares cease to be marketable.

If you own the Issuer's Offered Shares during any year in which the Issuer is a PFIC, you must file IRS Form 8621 with respect to the Issuer, generally with your federal income tax return for that year.

You should consult your tax adviser regarding whether the Issuer is a PFIC and the potential application of the PFIC rules to your ownership of Offered Shares for any taxable year.

### ***Backup withholding and information reporting***

Payments of dividends and sales proceeds that are made within the United States or through US or certain US-related financial intermediaries will generally be subject to information reporting and backup withholding, unless (i) you are an exempt recipient or (ii) in the case of backup withholding, you provide a correct taxpayer identification number and certify that you are not subject to backup withholding. Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against your US federal income tax liability, provided that the required information is timely furnished to the IRS. You may be required to report information relating to non-US accounts through which the Offered Shares are held (or information regarding the Offered Shares if the Offered Shares are not held through any financial institution). You should consult your tax adviser regarding your reporting obligations with respect to the shares.

US Holders who acquire any stock for cash may be required to file a IRS Form 926 (Return by a US Transferor of Property to a Foreign Corporation) with the IRS and to supply certain additional information to the IRS if (i) immediately after the transfer, the US holder owns directly or indirectly at least 10.0 per cent. of the Issuer's total voting power or value, or (ii) the amount of cash transferred to the Issuer in exchange for stock when aggregated with all related transfers under applicable regulations, exceeds US\$100,000. Substantial penalties may be imposed on a US Holder that fails to comply with this reporting requirement. Each US Holder is urged to consult with its own tax adviser regarding this reporting obligation.

## ANNEX A—GLOSSARY

<b>Assay</b>	In the field of diagnostics, an assay is a process or method aimed at determining the presence or amount (quantitative assay) of a certain substance in a sample.
<b>Serine/threonine-protein kinase B-raf (BRAF)</b>	BRAF is a protein that, in humans, is encoded by the BRAF gene. The BRAF protein is involved in sending signals within cells and in cell growth. Certain inherited BRAF mutations cause birth defects. Alternatively, other acquired mutations in adults may cause cancer.
<b>Biomarker</b>	A Biomarker is any molecular characteristic, feature or parameter that can be objectively measured through an assay and evaluated as an indicator of: (i) normal biologic processes; (ii) abnormal biologic processes; (iii) pathogenic processes; or (iv) pharmacologic responses to a therapeutic intervention or other action/intervention.
<b>Companion Diagnostics (CDx)</b>	CDx is a bio-analytical method designed to assess: (i) whether or not a patient will respond favourably to a specific medical treatment; (ii) what the optimal dose is for a patient; and (iii) whether the patient can expect certain side effects from a medical treatment. Any prescription of a drug with a CDx is based on the outcome of the CDx. CDx tests are also used in the drug development process.
<b>CE-mark</b>	The CE-mark is a mandatory conformance mark on many products placed on the market in the European Union. With the CE-marking on a product, the manufacturer ensures that the product is in conformity with the essential requirements of the applicable European Union directives. The letters “CE” stand for “Conformité Européenne” (“European Conformity”).
<b>cfDNA</b>	This is cell free plasma DNA.
<b>Clinical Laboratory Improvement Amendments of 1988 (CLIA)</b>	CLIA is US federal legislation that promulgates quality assurance practices in clinical laboratories and requires them to measure performance at each step of the testing process, from the beginning, through to the end-point, of a response and eventually a test result.
<b>CLIA-Waived</b>	This is an FDA classification for medical devices that, in accordance with US rules and regulations (including CLIA), can be operated outside of specialised, dedicated laboratory environments and without the need for technically specialised and highly trained staff.
<b>Current Procedural Terminology (CPT)</b>	CPT is a medical code set maintained by the American Medical Association through the CPT Editorial Panel. The CPT code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organisations, and payors for administrative, financial, and analytical purposes.
<b>Deoxyribonucleic acid (DNA)</b>	DNA is a nucleic acid molecule that contains the genetic instructions used in the development and functioning of living organisms.

<b>EDTA</b>	Ethylene Diamine Tetra Acetic Acid.
<b>Epidermal growth factor receptor (EGFR)</b>	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.
<b>Emergency Use Authorisation (EUA)</b>	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.
<b>Exome sequencing</b>	This is a technique for sequencing all the protein-coding genes in a genome (known as the exome).
<b>US Food and Drug Administration (FDA)</b>	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.
<b>Formalin fixed, paraffin embedded (FFPE)</b>	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.
<b>Genomics</b>	This is a discipline in genetics that applies recombinant DNA, DNA sequencing methods, and bioinformatics (the science of collecting and analysing complex biological data) to sequence, assemble, and analyse the function and structure of genomes (the complete set of DNA within a single cell of an organism).
<b>Hospital information systems (HIS)</b>	HIS is a platform that assists hospitals and clinics with their management of medical and administrative information with the aim of enhancing the integrity of information and significantly reducing inefficiencies.
<b>Investigational Device Exemption (IDE)</b>	IDE is an FDA exemption that allows an investigational device to be used in a clinical study in order to collect the safety and effectiveness data required to support a PMA application or premarket notification to the FDA.
<b>Immunoassay</b>	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.
<b>Influenza</b>	Also known as "the flu" is a highly contagious respiratory tract infection caused by the family of influenza viruses.

<b>Investigational Use Only (IUO)</b>	In the United States, certain IVD products may be sold (subject to certain restrictions) as IUO products for use in clinical studies, without 510(k) clearance or PMA approval. Producers selling IUO IVD products must comply with certain rules.
<b>In vitro diagnostics or In vitro diagnosis (IVD)</b>	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).
<b>Kirsten rat sarcoma-2 virus oncogene (KRAS)</b>	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.
<b>Laboratory developed test (LDT)</b>	An LDT is a type of IVD testing in the United States that is intended for clinical use and designed, manufactured and used within a single laboratory and does currently not require pre-clearance from the FDA before use.
<b>Laboratory information systems (LIS)</b>	LIS are a class of software that process, store and manage data from all stages of medical laboratory processes and tests. LIS systems often interface with other information systems such as HIS.
<b>Molecular diagnostics (MDx)</b>	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.
<b>Methylation (of DNA)</b>	The addition of a methyl group to the DNA, specifically to the cytosine nucleotide, in vertebrates. DNA methylation locally changes the activity state of the genome, generally reducing gene expression with the increased level of methylation. This form of regulation is crucial for cellular differentiation and the development of normal organisms. Irregular states of methylation are associated with the development of many types of cancer.
<b>Mismatch repair (MMR)</b>	MMR is a DNA repair system whereby errors in DNA are corrected within the cell. MMR works by detecting and replacing bases in the DNA that are wrongly paired (or mismatched).
<b>Multi-component nucleic acid enzyme (MNAzyme)</b>	MNAzyme is a particular type of DNAzyme (a DNA molecule with enzymatic activity) which can be used as a probe to detect specific target nucleic acid sequences in a (PCR) assay.
<b>Micro satellite instability (MSI)</b>	MSI is a genetic hyper-mutability condition resulting from MMR that is functioning abnormally.
<b>Multiplexing</b>	The simultaneous detection of more than one analyte or biomarker from a single sample.

<b>Neuroblastoma RAS viral (v-ras) oncogene (NRAS)</b>	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 signalling, and the mutation of a NRAS gene is associated with the development of many cancers.
<b>Next-generation sequencing (NGS)</b>	Next generation sequencing refers to massively parallel DNA sequencing technologies.
<b>Overall survival</b>	A measure to determine whether (cancer) patients treated with a drug live longer than patients who are not treated with the drug.
<b>Polymerase chain reaction (PCR)</b>	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.
<b>Pre-market approval (PMA)</b>	PMA is the most stringent type of device marketing clearance required by the FDA before a medical device can be marketed in the United States. PMA is the FDA process of scientific and regulatory review to evaluate and review the safety and effectiveness of Class III medical devices. Class III medical devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
<b>Progression free survival (PFS)</b>	A measure of the activity of a treatment of a disease. It is the time that passes from a certain date (generally the first day of treatment, or the day in which a patient is enrolled in a clinical trial) and the date on which disease “progresses” or the date on which the patient dies, from any cause. PFS can only be measured in patients in which a tumour is present (a similar term that applies to patients that have been successfully operated, and are therefore free from disease, is Disease-Free Survival).
<b>Protein</b>	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.
<b>Rapid response laboratory</b>	Short turn-around time laboratory. This is a free-standing laboratory capable of performing an abbreviated battery of tests, and serving as a receiving ‘node’ for a larger laboratory to which the rapid response laboratory is ultimately responsible.

<b>Ribonucleic acid (RNA)</b>	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.
<b>Respiratory Syncytial Virus (RSV)</b>	RSV is a major cause of lower respiratory tract infection that is a frequent infection in children.
<b>Research Use Only (RUO)</b>	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.
<b>Reverse Transcriptase</b>	This is an enzyme used to generate complementary DNA (cDNA) from an RNA template, a process termed reverse transcription.
<b>Sample preparation</b>	Sample preparation refers to the ways in which a sample is treated prior to its analysis. Sample preparation is a very important step in most analytical techniques, because the techniques are often not responsive to the analyte in its original matrix, or the results are distorted by the presence of interfering substances. Sample preparation may involve dissolution of matrix components, reaction with certain chemicals, pulverizing the sample, treatment with a chelating agent (e.g. EDTA), masking or neutralisation of interfering substances, filtering, dilution or concentration of the analyt, sub-sampling or many other techniques.
<b>Sensitivity and specificity</b>	Sensitivity and specificity are statistical measures of the performance of a binary classification test, also known in statistics as classification function. Sensitivity (also called recall rate in some fields) measures the proportion of actual positives that are correctly identified as such (e.g. the percentage of sick people who are correctly identified as having the condition). Specificity measures the proportion of negatives that are correctly identified (e.g. the percentage of healthy people who are correctly identified as not having the condition). These two measures are closely related to the concepts of type I and type II errors. A theoretical, optimal prediction aims to achieve 100% sensitivity (i.e., predict all people from the sick group as sick) and 100% specificity (i.e., not predict anyone from the healthy group as sick), however theoretically any predictor will possess a minimum error bound known as the Bayes error rate.
<b>Sepsis</b>	Severe overall inflammatory response of the body to an infection.
<b>Viral Load (VL)</b>	As is customary in the field of molecular virology, viral load refers to the level of viraemia of a viral infection. Viral load is, strictly, the complete and absolute amount of virus in a certain organ or person, while viraemia level is the concentration, usually indicated in the number of copies or units per millilitre. Normal viraemia level ranges of HCV, for example, are between 100 copies and a 10 million copies/millilitre.



**Western Europe**

Austria, Belgium, Denmark, Germany, Ireland, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

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**1 INDEPENDENT AUDITOR'S REPORT ON THE CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED 31 DECEMBER 2014, 2013 AND 2012**



**Biocartis Group NV**

**Auditor's report on the consolidated financial statements as of and for the years ended  
31 December 2014, 2013 and 2012**

To the Board of Directors

We report on the financial information set out in the Prospectus of Biocartis Group NV (the "Company" and, together with its subsidiaries, the "Group") (the "Prospectus"). This financial information has been prepared for inclusion in the Prospectus on the basis of the accounting policies set out in note 2 to the financial information. This report is required by Annex I item 20.1 of Commission Regulation (EC) No 809/2004 (the "Prospectus Directive Regulation") and is given for the purpose of complying with that requirement and for no other purpose.

**Report on the consolidated financial statements—Unqualified opinion**

We have audited the consolidated financial statements of the Company and the Group as of and for the years ended 31 December 2014, 2013 and 2012 prepared in accordance with International Financial Reporting Standards as adopted by the European Union.

The consolidated balance sheet shows total assets of 53,012 (000) EUR as of 31 December 2014, 60,145(000) as of 31 December 2013 and 66,188 (000) EUR as of 31 December 2012 and the consolidated income statement shows a consolidated loss (Group share) of 9,118 (000) EUR for the year ended 31 December 2014, 35,620 (000) for the year ended 31 December 2013 and 44,431 (000) EUR for the year ended 31 December 2012.

*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, 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.

*Auditor's responsibility*

Our responsibility is to express an opinion on these consolidated financial statements based on our audit for the purposes of the Prospectus. 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 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 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.

Our work has been carried out in accordance with ISA and not with other auditing standards and practices generally accepted in jurisdictions outside Belgium, including the United States of America, and accordingly should not be relied upon as if it had been carried out in accordance with those standards and practices.

#### *Unqualified opinion*

In our opinion, the consolidated financial statements of Biocartis Group NV give a true and fair view, for the purposes of the Prospectus, of the Group's net equity and financial position as of 31 December 2014, 2013 and 2012, and of its results and its cash flows for the years then ended, in accordance with IFRS as adopted by the European Union.

#### *Emphasis of matter*

Without qualifying our opinion, we draw your attention to section 3.3.1 'Critical judgments—Going concern' of the consolidated financial statements, in which the board mentions the importance of attracting additional funding in order to be able to continue as a going concern. This indicates the existence of a material uncertainty that may cast significant doubt about the Group's ability to continue as a going concern.

#### *Declaration*

For the purposes of art. 61 of the Law of 16 June 2006, we are responsible for this report as part of the Prospectus and declare that we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the Prospectus in compliance with Annex III item 1.2 of the Prospectus Directive Regulation.

Diegem, 14 April 2015

#### **The statutory auditor**

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**DELOITTE Bedrijfsrevisoren /Reviseurs d'Entreprises**  
BV o.v.v.e. CVBA / SC s.f.d. SCRL  
Represented by Gert Vanhees

**2 CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED  
31 DECEMBER 2014, 2013 AND 2012**

**Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012**

**2.1 CONSOLIDATED BALANCE SHEET**

In €000	Notes	As of 31 December,		
		2014	2013	2012
<b>Assets</b>				
<b>Non-current assets</b>				
Intangible assets	3.14	9,652	9,985	10,278
Property plant and equipment	3.15	9,154	11,199	10,994
Participating interests		0	245	0
Other long term receivables		117	107	106
Deferred tax assets	3.27	947	0	0
		<u>19,870</u>	<u>21,536</u>	<u>21,378</u>
<b>Current assets</b>				
Inventory	3.16	3,583	1,116	183
Trade receivables	3.17	15,793	3,082	1,442
Other receivables	3.17	148	993	793
Other current assets	3.18	2,700	4,371	1,898
Cash and cash equivalents	3.19	10,919	29,047	40,494
		<u>33,142</u>	<u>38,609</u>	<u>44,810</u>
<b>Total assets</b>		<b><u>53,012</u></b>	<b><u>60,145</u></b>	<b><u>66,188</u></b>
<b>Equity and liabilities</b>				
<b>Capital and reserves</b>				
Legal share capital	3.20	222,268	926	795
Historical share capital adjustment	3.20	-221,232	0	0
Share premium	3.20	166,592	175,946	146,394
Gains and losses on defined benefit plans	3.23	0	-309	-379
Share based payment reserve	3.21	1,166	1,023	0
Accumulated deficit	3.20	-148,513	-145,631	-110,010
<b>Total equity attributable to owners of the Company</b>		<b>20,280</b>	<b>31,955</b>	<b>36,800</b>
<b>Non-current liabilities</b>				
Financial debt	3.22	8,528	12,822	10,089
Deferred income	3.25	4,534	1,711	5,002
Retirement benefit obligation	3.23	0	267	490
Accrued charges	3.26	1,955	1,741	2,026
		<u>15,017</u>	<u>16,541</u>	<u>17,607</u>
<b>Current liabilities</b>				
Financial debt	3.22	5,057	3,373	1,250
Trade payables	3.24	4,265	5,847	8,454
Deferred income	3.25	5,100	772	1,320
Other current liabilities	3.24	3,293	1,657	757
		<u>17,714</u>	<u>11,649</u>	<u>11,781</u>
<b>Total equity and liabilities</b>		<b><u>53,012</u></b>	<b><u>60,145</u></b>	<b><u>66,188</u></b>

**Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012**

**2.2 CONSOLIDATED INCOME STATEMENT**

In €000	Notes	For the years ended 31 December,		
		2014	2013 <sup>1</sup>	2012 <sup>1</sup>
<b>Revenue</b>				
Collaboration revenue	3.4	3,218	6,247	2,102
Product sales revenue	3.4	5,260	2,086	1,449
		<b>8,478</b>	<b>8,333</b>	<b>3,551</b>
<b>Other operating income</b>				
Grants and other income	3.5	1,889	3,504	2,632
<b>Operating expenses</b>				
Cost of goods sold	3.6	-4,251	-1,962	-1,168
Research and development expenses	3.7	-25,014	-27,838	-33,991
Marketing and distribution expenses	3.8	-3,095	-1,155	-691
General and administrative expenses	3.9	-7,180	-7,255	-6,131
		<b>-39,540</b>	<b>-38,210</b>	<b>-41,981</b>
<b>Operating loss for the period</b>				
		<b>-29,173</b>	<b>-26,373</b>	<b>-35,798</b>
Financial income	3.11	60	126	104
Financial expense	3.11	-933	-981	-836
Foreign exchange gains/(losses), net	3.11	-88	-212	16
<b>Financial result, net</b>				
		<b>-961</b>	<b>-1,067</b>	<b>-716</b>
<b>Loss for the year before taxes from continuing operations</b>				
		<b>-30,134</b>	<b>-27,440</b>	<b>-36,515</b>
Income taxes	3.27	947	-2	-4
<b>Loss for the year after taxes from continuing operations</b>				
		<b>-29,187</b>	<b>-27,442</b>	<b>-36,519</b>
Gain (loss) for the year after taxes from discontinued operations	3.12	19,472	-8,178	-7,912
<b>Loss for the year</b>				
		<b>-9,715</b>	<b>-35,620</b>	<b>-44,431</b>
attributable to owners of the Company		-9,118	-35,620	-44,431
attributable to non-controlling interest		-598	0	0
<b>Earnings per share</b>				
basic and diluted loss per share from continuing and discontinued operations	3.13	-0.36	-1.62	-2.62
basic and diluted loss per share from continuing operations	3.13	-1.14	-1.25	-2.15

<sup>1</sup> The figures for the years ended 31 December 2013 and 31 December 2012 were restated as a result of the discontinuation of the Evaluation™ business in 2014. Reference is made to note 3.12 for further detail.

**Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012**

**2.3 CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE INCOME**

In €000	Notes	For the years ended 31 December,		
		2014	2013	2012
<b>Loss for the year</b>		<b>-9,715</b>	<b>-35,620</b>	<b>-44,431</b>
<b>Other comprehensive income (loss), not to be reclassified to profit or loss</b>				
Actuarial gain (losses) on defined benefit plan	3.23	0	70	-210
<b>Other comprehensive gain (loss) for the year, net of tax from discontinued operations</b>		<b>0</b>	<b>70</b>	<b>-210</b>
<b>Total comprehensive loss for the year</b>		<b>-9,715</b>	<b>-35,550</b>	<b>-44,641</b>
Attributable to owners of the Company		-9,117	-35,550	-44,641
Attributable to non-controlling interest		-598	0	0

Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012

2.4 CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

in €000	Notes	Legal share capital	Historical share capital adjustment	Share premium	Share based payment reserve	Attributable to owners of the Company			Total equity attributable to the owners of the Company	Non-controlling interest	Total equity
						Share gains and losses on defined benefit plans	Accumulated deficit				
<b>Balance as at 01 January 2012</b>		<b>543</b>		<b>93,530</b>		<b>-170</b>	<b>-65,580</b>	<b>28,323</b>		<b>28,323</b>	
Loss for the period								-44,430		-44,430	
Other comprehensive loss for the period	3.23					-209		-209		-209	
Total comprehensive loss for the period						-209	-44,430	-44,639		-44,639	
Issue of ordinary shares	3.20	253		53,445				53,698		53,698	
Cost related to capital increase	3.20			-581				-581		-581	
<b>Balance as at 31 December 2012</b>		<b>795</b>		<b>146,394</b>		<b>-379</b>	<b>-110,010</b>	<b>36,800</b>		<b>36,800</b>	
Loss for the period						70	-35,621	-35,621		-35,621	
Other comprehensive loss for the period	3.23					70		70		70	
Total comprehensive loss for the period						70	-35,621	-35,551		-35,551	
Share-based payment expense	3.21				1,023			1,023		1,023	
Issue of ordinary shares	3.20	130		29,870				30,000		30,000	
Cost related to capital increase	3.20			-318				-318		-318	
<b>Balance as at 31 December 2013</b>		<b>926</b>		<b>175,946</b>	<b>1,023</b>	<b>-309</b>	<b>-145,631</b>	<b>31,955</b>		<b>31,955</b>	
Loss for the period							-9,118	-9,118	-598	-9,716	
Non-controlling interest of 20% in Mycartis NV	3.12						6,057	6,057	1,443	7,500	
Capital increase by incorporation of share premium	3.20	30,488		-30,488				0		0	
Disposal of interest in Mycartis NV through capital decrease	3.12	-30,488				309	178	-30,000	-845	-30,845	
Issue of preference shares	3.20	110		21,403				21,513		21,513	
Cost related to capital increase	3.20			-269				-269		-269	
Share-based payment expense	3.21				143			143		143	
Change in reporting entity	3.20	221,232	-221,232					0		0	
<b>Balance as at 31 December 2014</b>		<b>222,268</b>	<b>-221,232</b>	<b>166,592</b>	<b>1,166</b>	<b>0</b>	<b>-148,513</b>	<b>20,281</b>	<b>0</b>	<b>20,281</b>	

**Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012**

**2.5 CONSOLIDATED CASH FLOW STATEMENT**

in €000	Notes	For the years ended 31 December,		
		2014	2013	2012
<b>operating activities</b>				
Loss for the period		-9,715	-35,620	-44,431
<b>Adjustments for</b>				
Depreciation and amortization	3.14-3.15	4,437	3,557	2,622
Depreciation and amortization included in discontinued operations	3.14-3.15	81	181	156
Impairments	3.15	37	0	0
Tax income in profit and loss	3.27	-947	0	0
Financial result, net		897	1,065	600
Net movement in retirement benefit obligation	3.23	108	-153	25
Gain on disposal Mycartis NV	3.12	-26,624	0	0
Share based payment expense	3.21	143	1,023	0
<b>Changes in working capital</b>				
Net movement in inventories	3.16	-2,524	-933	-10
Net movement in trade and other receivables and other current assets	3.17-3.18	-2,736	-4,313	818
Net movement in trade payables & other current liabilities	3.24	1,860	-1,992	244
Net movement in deferred income	3.25	-746	-3,839	-1,286
Interests paid	3.11	-155	-155	0
<b>Cash flow from operating activities</b>		<b>-35,884</b>	<b>-41,179</b>	<b>-41,262</b>
<b>Investing activities</b>				
Interest received	3.11	60	100	102
Purchases of property, plant & equipment	3.15	-1,927	-3,138	-7,313
Purchases of intangible assets	3.14	-840	-512	-350
Acquisition shares in other companies		0	-245	0
Disposal shares in other companies		245	0	0
Acquisition of a subsidiary		7,514	0	0
Proceeds from sale and rent back of property, plant and equipment	3.15	0	0	1,904
<b>Cash flow from investing activities</b>		<b>5,052</b>	<b>-3,795</b>	<b>-5,657</b>
<b>Financing activities</b>				
Proceeds from issue of common equity shares	3.20	0	29,682	53,117
Proceeds from issue preference shares F	3.20	21,244	0	0
Proceeds from sale and lease back of property, plant and equipment	3.15	0	5,000	0
Disposal of Mycartis NV to capital owners of the parent	3.12	-5,138	0	0
Repayment of borrowings	3.22	-3,378	-894	0
Bank charges	3.11	-1	-18	0
<b>Cash flow from financing activities</b>		<b>12,727</b>	<b>33,770</b>	<b>53,117</b>
<b>Net increase in cash and cash equivalents</b>		<b>-18,105</b>	<b>-11,204</b>	<b>6,198</b>
Cash and cash equivalents at the beginning of the period	3.19	29,047	40,494	34,357
Effects of exchange rate changes on the balance of cash held in foreign currencies	3.11	-23	-243	-61
<b>Cash and cash equivalents at the end of the period</b>		<b>10,919</b>	<b>29,047</b>	<b>40,494</b>



### **3 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

#### **3.1 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 assays in the oncology and infectious diseases segments.

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

The Group has established subsidiaries in Mechelen (Belgium), Eindhoven (The Netherlands) and Lausanne (Switzerland).

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

The consolidated financial statements have been authorized for issue on 13/04/2015 by the board of directors of the Company (the “Board of Directors”).

#### **3.2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

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

##### **3.2.1 Statement of compliance**

The consolidated financial statements of the Group for the year ended 31 December 2014 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.

##### **3.2.2 Change in reporting entity**

Biocartis Group NV was created in November 2014 by the shareholders of Biocartis S.A., 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 S.A. on a share-for-share basis for a total amount of €222 million. 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 years ended 31 December 2014, 2013 and 2012 include Biocartis Group NV and its subsidiaries and constitute the Group. Prior to the incorporation of Biocartis Group NV the consolidation was performed at the level of Biocartis S.A. 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 2012.

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 € 222 million was offset by an identical, opposite entry in the capital distributed for €-222 million). Therefore, the activities of the consolidated group are given for 12 months for 2014, with comparative information for 2013 and 2012, respectively.

## Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012

### 3.2.3 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 (€) and all values are rounded to the nearest thousand (€000), 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 2014.

- IFRS 10 Consolidated Financial Statements (applicable for annual periods beginning on or after 1 January 2014)
- IFRS 11 Joint Arrangements (applicable for annual periods beginning on or after 1 January 2014)
- IFRS 12 Disclosures of Interests in Other Entities (applicable for annual periods beginning on or after 1 January 2014)
- IAS 28 Investments in Associates and Joint Ventures (applicable for annual periods beginning on or after 1 January 2014)
- Amendments to IAS 32 Financial Instruments: Presentation—Offsetting Financial Assets and Financial Liabilities (applicable for annual periods beginning on or after 1 January 2014)
- Amendments to IAS 36—Impairment of Assets—Recoverable Amount Disclosures for Non-Financial Asset (applicable for annual periods beginning on or after 1 January 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 2014, are listed in note 3.34.

## **Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012**

### **Consolidation principles**

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries as at 31 December 2014. 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.

#### **3.2.4 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.

#### **3.2.5 Intangible assets**

##### **3.2.5.1 Research and development costs**

Research and development costs are currently expensed as incurred. Developments 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.

## Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012

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, and its assays, 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 recognized in the consolidated income statement as incurred.

### 3.2.5.2 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:

	<u>Estimated useful life</u>
Patents	Patent life
Licenses	3 to 20 years
IT, 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.

### 3.2.6 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.

	<u>Estimated useful life</u>
IT, laboratory and manufacturing equipment	3 to 7 years
Fittings and leasehold improvements	The shorter of rent duration and 10 years
Other	10 years

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.

## **Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012**

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 de-recognition 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.

### **3.2.7 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 Group 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.

### **3.2.8 Inventory**

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

Net realizable 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.

### **3.2.9 Financial instruments**

Financial assets and financial liabilities are recognized 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 recognized immediately in profit or loss.

#### **3.2.9.1 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.

## **Biocartis Group NV—consolidated financial statements for the years ended 31 December 2014, 2013 and 2012**

### 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 recognized 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 participating equity interest in Immunexpress as an AFS financial asset as at 31 December 2013.

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.

The Company has sold its participating interest in Immunexpress at carrying value during 2014 with no gain or loss recognized in the consolidated income statement.

### 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 recognized 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 it 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 recognizes 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 recognize 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.

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For AFS financial assets, the Group assesses at each reporting date whether there is objective evidence that an investment is impaired. In the case of equity investments classified as AFS, objective evidence would include a significant or prolonged decline in the fair value of the investment below its cost. 'Significant' is evaluated against the original cost of the investment and 'prolonged' against the period in which the fair value has been below its original cost. When there is evidence of impairment, the cumulative loss—measured as the difference between the acquisition cost and the current fair value, less any impairment loss on that investment previously recognised in profit or loss—is removed from other comprehensive income and recognised in profit or loss. Impairment losses on equity investments are not reversed through profit or loss;

### **3.2.9.2 Financial liabilities**

The Group only has financial liabilities classified as "other financial liabilities" measured at amortized 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 derecognizes 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 derecognized and the consideration paid and payable is recognized in profit or loss.

### **3.2.9.3 Equity instruments**

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

### **3.2.10 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.

### **3.2.11 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 compute 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.

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### 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 entity 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".

## **3.2.12 Employee benefits**

### **3.2.12.1 Short-term employee benefits**

Short-term employee benefits include salaries and social security 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.

### **3.2.12.2 Post-employment benefits**

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



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Defined contribution plans

Under defined contribution plans, the Group pays 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.

The Belgian defined contribution pension plans are by law subject to minimum guaranteed rates of return, currently 3.25% on employer contributions and 3.75% on employee contributions. These rates, which apply as an average over the entire career, may be modified by a Royal Decree in which case the new rates apply to both the accumulated past contributions and the future contributions as from the date of modification. Taking into account the historical discussions on how to account for these specific type of plans where the contributions paid are subject to a minimum guaranteed return at the level of IFRIC, the application of the projected unit credit method to these plans is troublesome and will not provide a faithful representation of the liability with respect to these promises.

Therefore, the Group accounts for those plans as defined contribution plans, and at each reporting date, compares the “walk away liability” or the vested rights at reporting date with the fair value of the plan assets. If the vested rights are higher as compared to the fair value of the plan asset, a provision is recognised for the shortage.

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.

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 S.A. in Switzerland are considered as a defined benefit plan and have been included within the discontinued operations. The defined benefit plan has been transferred to MyCartis NV, which was subsequently disposed of on 6 November 2014. See note 3.12 for additional information.

**3.2.12.3 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

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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 recognizes 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.

### **3.2.13 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.

### **3.2.14 Revenue recognition**

The Group recognizes 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.

#### **3.2.14.1 Licensing, contracting and collaboration revenues**

Upfront fees received by the Group in license and collaboration arrangements that include future obligations are recognized pro rata over the expected performance period under each respective arrangement. The Group makes its best estimate of the period over which it expects to fulfil its performance obligations, which may include technology transfer assistance, research activities, development activities, and manufacturing activities from development through the commercialization of the product.

Contingent consideration received upon the achievement of a substantive milestone is recognized 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 recognize 100% of the contingent revenues when the contingency is achieved and collection is reasonably assured. Contingency and milestones payments, when recognized as revenue, are classified as contract revenues in the Group's Consolidated Income Statement.

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

### **3.2.14.2 Product sales**

Revenues from the sale of goods are recognized when the Group has transferred to the buyer the significant risks and rewards of ownership of the goods (that is generally at the time the goods are shipped), when the Group retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold, 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.

### **3.2.15 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 recognized in profit or loss on a systematic basis over the periods in which the Group recognizes 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 recognized in profit or loss over the life of a depreciable asset as a reduced depreciation expense

### **3.2.16 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.

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### **3.2.17 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.

### **3.3 CRITICAL ACCOUNTING ESTIMATES, ASSUMPTIONS AND JUDGMENTS**

#### **3.3.1 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 and upfront fees. 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.

#### **3.3.1 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 2014, and as of the date of these financial statements, as well as current burn rate projections for 2015 and 2016 and funding initiatives as decided by the Board of Directors, going concern is at least assured for 12 months from the dates of these financial statements.

The Board of Directors supports management's efforts in securing additional financial means by signing non-dilutive cash-generating deals (including for example non-refundable upfront payments on licensing deals, grants). Also the Board of Directors initiated fundraising activities in the second half of 2014, which resulted in the Group raising an additional € 64.5 million, of which € 43 million has been fully paid in the meanwhile (€ 21.5 million in August 2014 and € 21.5 million in January 2015). The remaining € 21.5 million is contingent upon reaching certain milestones prior to 15 December 2015 or upon completion of a successful public offering, whichever comes first).

Although it is clear that the Group needs additional funds to further grow its operations and there is some uncertainty which may cast doubt as to the Group's ability to continue as a going concern in the long run if the Group would not succeed in attracting such additional funding, the Board of Directors is confident that the Group's financial future will be safeguarded at least through the annual general meeting to be held in 2016. Should the Group not succeed in attracting additional funding in the future, it may be unable to realize its assets and discharge its liabilities in the normal course of business.

##### *Accounting for defined contribution plans in Belgium*

The Belgian defined contribution pension plans are by law subject to minimum guaranteed rates of return, currently 3.25% on employer contributions and 3.75% on employee contributions. These rates, which apply as an average over the entire career, may be modified by Royal Decree in which case the new rate(s) apply to both the accumulated past contributions and the future contributions as from the date of modification. In theory these plans qualify as defined benefit plans. However, when taken into account the historical discussions on how to account for these specific type of plans where the contributions paid are subject to a minimum guaranteed return

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at the level of IFRIC, the Group believes the application of the projected unit credit method to these plans is troublesome and will not provide a faithful representation of the liability with respect to these promises.

Therefore, at each reporting date the “walk away liability” or the vested rights at reporting date are compared with the fair value of the plan assets. If the vested rights are higher as compared to the fair value of the plan asset, a provision is recognised for the difference.

### *Accounting for the change in reporting entity*

Biocartis Group NV became the Group’s reporting entity after its creation in November 2014 by the shareholders of Biocartis S.A., 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 S.A. on a share-for-share basis for a total amount of €222 million.

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, management has opted to apply the continuity of the book values method.

The consolidated financial statements for the years ended 31 December 2014, 2013 and 2012 include Biocartis Group NV and its subsidiaries and constitute the Group. Prior to the incorporation of Biocartis Group NV the consolidation was performed at the level of Biocartis S.A. 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 2012.

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 €222 million was offset by an identical, opposite entry in the capital distributed for €-222 million). Therefore, the activities of the consolidated group are given for 12 months for 2014, with comparative information for 2013 and 2012, respectively.

### **3.3.2 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 3.23. 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. See note 3.12 for additional information.

#### *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 3.20.

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### 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 recognized when the revenue recognition criteria described above are met.

Upfront fees under collaboration or licensing agreements are recognized 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.

### 3.3.3 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 1 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 2014.

## 3.4 REVENUE

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

In €000	Years ended 31 December,		
	2014	2013	2012
<b>Collaboration revenues</b>			
R&D services	271	226	815
Upfront license revenues	1,946	4,019	1,286
Milestone revenues	1,000	2,000	0
Other	0	2	1
	<b>3,218</b>	<b>6,247</b>	<b>2,102</b>
<b>Product sales</b>			
System Sales	3,718	522	260
Cartridge Sales	1,542	1,564	1,189
	<b>5,260</b>	<b>2,086</b>	<b>1,449</b>
<b>Total revenue</b>	<b>8,478</b>	<b>8,333</b>	<b>3,551</b>

### 3.4.1 Collaboration revenues

License fees and milestone payments were earned under the Group's collaboration and development agreements.

#### *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. This agreement was initially signed on 20 December 2010 and subsequently amended on 9 October 2014. Under this agreement, the Group commits to further develop its Idylla™ platform and parties agree upon an assay development collaboration. In return, the Group is entitled to non-refundable upfront payments, performance milestones and royalties on certain future assay sales.

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### *bioMérieux*

In November 2010, the Group entered into a license and collaboration agreement with bioMérieux, a shareholder of the Group. Under this agreement, the Group committed to further develop its Idylla™ platform and parties agreed upon an assay development collaboration. In return, the Group was entitled to non-refundable upfront payments, performance milestones and royalties on certain future assay sales. On 27 November 2013, this collaboration was terminated and bioMérieux returned all rights under this agreement to Biocartis.

The remaining amount of the non-refundable upfront payment, received in 2010 (which was initially recognized pro rata over the estimated collaboration period) was recognized in full upon termination of the collaboration.

### *Abbott Molecular*

On 13 June 2014, Biocartis NV and Abbott Molecular announced a collaboration to develop and commercialize companion diagnostics tests. Under the agreement, the companies will leverage Biocartis' molecular diagnostics system, Idylla™, and Abbott's regulatory, scientific and commercialization expertise. The agreement is a framework agreement which will be supplemented with specific project agreements in the future including the determination of the collaboration fees.

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

### *Debiopharm International*

The Group has signed an amended and restated license and development agreement with Debiopharm International SA on 29 September 2014. The license agreement relates to a product license, being the "Triage Assay", which is a multiplex gene expression screening assay including algorithm that can be used to distinguish sepsis from SIRS with a high (>95%) negative predictive value for sepsis in emergency room populations using circulating blood as a sample type and intended to rule out sepsis in adult patients suspected of sepsis.

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

In aggregate the potential milestone revenues that can be earned by the Group over the remaining term of these collaboration agreements amounts to € 6 million.

## 3.4.2 Product sales

The 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 categorized as in vitro diagnostics and investigational or research use only.

	Years ended 31 December,		
	2014	2013	2012
In vitro diagnostics	1,985	0	0
Investigational/research use only	3,275	2,086	1,449
<b>Total revenue</b>	<b>5,260</b>	<b>2,086</b>	<b>1,449</b>

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**3.4.3 Revenues by region and major customers**

	31 December,		
	2014	2013	2012
Country of domicile	27	0	0
Switzerland	0	0	0
Belgium	27	0	0
Total all foreign countries, of which	<b>8,451</b>	<b>8,333</b>	<b>3,551</b>
United states of America	8,412	3,657	1,207
France	0	4,675	2,344
Rest of the world	39	0	0
<b>Total revenue</b>	<b>8,478</b>	<b>8,333</b>	<b>3,551</b>

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

The Group has recognized revenues from two customers with individual revenue representing at least 10% of the total revenues. The first customer accounts for € 8.4 million of the revenues in 2014 (2013: € 3.7 million; 2012: € 1.2 million). The second customer accounts for no revenues in 2014 (2013: € 4.6 million; 2012: € 2.3 million). No other customers represent individually for more than 10% of the total revenues.

**3.5 OTHER OPERATING INCOME**

In €000	Years ended 31 December,		
	2014	2013	2012
R&D project support (IWT) grants	1,482	1,656	1,305
Grant income for strategic investments & training support (Hermes)	0	1,357	927
Other project grants	407	491	400
<b>Total other operating income</b>	<b>1,889</b>	<b>3,504</b>	<b>2,632</b>

**3.6 COST OF GOODS SOLD**

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

In €000	Years ended 31 December,		
	2014	2013	2012
Staff costs	-1,423	-783	-466
Material	-1,872	-413	-246
Depreciation and amortization	-618	-649	-387
Royalty expense	-202	0	0
Lab consumables & small equipment	-67	-64	-38
Rent	-67	-53	-32
License	-2	0	0
<b>Total</b>	<b>-4,251</b>	<b>-1,962</b>	<b>-1,168</b>



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**3.7 RESEARCH AND DEVELOPMENT EXPENSES**

In €000	31 December,		
	2014	2013	2012
Staff costs	-12,634	-10,948	-8,208
Subcontracting	-4,031	-7,371	-16,692
Laboratory expenses	-1,385	-932	-934
Cartridge, instrument and consoles	-350	-2,163	-3,219
Consultancy	-968	-2,136	-586
Quality and regulatory	-95	-249	-182
Intellectual property	-782	-470	-855
Facilities	-1,003	-878	-766
Travel, training, office & other	-1,503	-1,114	-576
Depreciation and amortization	-3,336	-2,425	-1,972
Internally capitalized instruments	1,072	847	0
<b>Total</b>	<b>-25,014</b>	<b>-27,838</b>	<b>-33,991</b>

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

Cartridges, instruments and consoles relate to the development of diagnostic platform prototypes not taken into inventory for sale or into fixed assets for internal use.

Other expenses mainly relate to maintenance of equipment and logistics.

**3.8 MARKETING AND DISTRIBUTION EXPENSES**

In €000	Years ended 31 December,		
	2014	2013	2012
Staff costs	-2,000	-757	-364
Subcontracting	-302	0	0
Sales and marketing	-117	-31	-1
Business development	-54	-237	-203
Travel, training, office & other	-598	-127	-123
Depreciation and amortization	-25	-2	0
<b>Total</b>	<b>-3,095</b>	<b>-1,155</b>	<b>-691</b>

Sales and marketing expenses relate to costs of external market research, advertisement, and promotional activities related to the preparation of the launch of the Group's diagnostic products.

**3.9 GENERAL AND ADMINISTRATIVE EXPENSES**

In €000	Years ended 31 December,		
	2014	2013	2012
Staff costs	-2,918	-3,894	-2,274
External advice	-1,601	-1,380	-1,753
Facilities	-986	-884	-959
ICT	-220	-209	-209
Travel, training, office and other	-997	-406	-672
Depreciation and amortization expenses	-457	-481	-264
<b>Total</b>	<b>-7,180</b>	<b>-7,255</b>	<b>-6,131</b>

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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.

### 3.10 PERSONNEL EXPENSES

In €000	31 December,		
	2014	2013	2012
Short term employee benefits	-18,695	-14,478	-10,950
Post-employee defined benefit expense	-4	-466	-221
Post-employee defined contribution expense	-112	-338	-141
Other long term employee benefits	0	0	0
Termination benefits	-20	-77	0
Share based compensation	-143	-1,023	0
<b>Total</b>	<b>-18,975</b>	<b>-16,382</b>	<b>-11,312</b>

The headcount can be presented as follows:

In €000	31 December,		
	2014	2013	2012
Operations staff	65	63	28
Research and development staff	85	71	61
Marketing and distribution staff	20	6	3
General and administrative staff	24	21	19
<b>total headcount</b>	<b>194</b>	<b>161</b>	<b>111</b>
<b>Full time equivalents</b>	<b>189</b>	<b>157</b>	<b>109</b>

### 3.11 FINANCIAL INCOME AND EXPENSE

In €000	Years 31 December,		
	2014	2013	2012
Interest income	60	97	102
Other financial income	0	28	2
<b>Total financial income</b>	<b>60</b>	<b>126</b>	<b>104</b>
Interest expense	-923	-963	-792
Other financial expense	-9	-18	-44
<b>Total financial expense</b>	<b>-933</b>	<b>-981</b>	<b>-836</b>
Foreign exchange gains/(losses), net	-88	-212	16
<b>Total</b>	<b>-88</b>	<b>-212</b>	<b>16</b>
<b>Financial result, net</b>	<b>-961</b>	<b>-1,067</b>	<b>-716</b>

### 3.12 DISCONTINUED OPERATIONS

On 11 November 2014, the Group finalized the disposal of its Evaluation™ business for a total price of € 30 million resulting in a gain on disposal of € 26.6 million. Prior to 11 November 2014, the disposal was initiated by means of the following steps:

1. 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.
2. On 26 August 2014, Biocartis S.A. decreased its share capital for an amount of € 30.5 million (CHF 37.0 million), of which € 30.0 million (CHF 36.4 million) was paid out

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in kind in the form of all the shares held by Biocartis S.A. in MyCartis NV, and of which the remaining € 0.5 million (CHF 0.6 million) is an adjustment to the carrying value of the capital reduction liability towards shareholders, which is 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.

As part of the business acquisition (step 1) whereby the Group acquired a 80% stake in MyCartis NV at 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 € 7.5 million and resulted in a non-controlling interest measured at a fair value of € 1.5 million (20% of the fair value of MyCartis NV at the time of the business combination, which was € 7.5 million).

The non-controlling interest of €1.4 million as presented in the statement of changes in equity includes the non-controlling interest measured at fair value of €1.5 million, as explained above, less the proportionate share of 20% in the contributed net assets of the Evaluation™ branch of €-0.1 million.

The contribution of the Evaluation™ branch in MyCartis NV resulted in a gain on dilution of € 6 million which has been recognized directly in accumulated deficit. Upon disposal, the pension reserve for a total of € 0.3 million has been reclassified within equity from 'Gains and losses on defined benefit plans' to 'Accumulated deficit'. The difference of € 0.5 million between the capital decrease of € 30.5 million and the amount of € 30 million distributed to the shareholders, is accounted for as an adjustment in the carrying amount of the capital decrease liability due to a different amount of the capital decrease decided by the shareholders both in CHF and EUR and is recorded directly in accumulated deficit.

The results of the Evaluation™ business, including the results of Mycartis NV as from 1 July 2014, are presented in the line "income (loss) from discontinued operations" as follows:

In €000	For the years ended 31 December,		
	2014	2013	2012
Collaboration revenue	134	65	13
Product sales	0	145	199
Grants and other income	0	84	194
<b>Total revenues</b>	<b>134</b>	<b>294</b>	<b>406</b>
<b>Cost of Goods Sold</b>	<b>0</b>	<b>0</b>	<b>0</b>
Research and development expenses	-5,651	-6,875	-7,022
Marketing and distribution expenses	-531	-533	-178
General and administrative expenses	-1,097	-1,066	-1,041
<b>Total operating expenses</b>	<b>-7,278</b>	<b>-8,474</b>	<b>-8,241</b>
<b>Operating loss for the period</b>	<b>-7,144</b>	<b>-8,179</b>	<b>-7,834</b>
Financial income	0	0	258
Financial expense	0	0	-336
Foreign exchange gains/(losses), net	-8	2	0
<b>Financial result, net</b>	<b>-8</b>	<b>2</b>	<b>-78</b>
<b>Loss before taxes</b>	<b>-7,153</b>	<b>-8,178</b>	<b>-7,912</b>
Taxes	0	0	0
<b>Loss after taxes</b>	<b>-7,153</b>	<b>-8,178</b>	<b>-7,912</b>
Gain on disposal	26,624	0	0
Taxes on gain on disposal	0	0	0
<b>Net loss for the year from discontinuing operations</b>	<b>19,472</b>	<b>-8,178</b>	<b>-7,912</b>
attributable to the shareholders	20,070	-8,178	-7,912
attributable to non-controlling interest	-598	0	0

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The derecognized 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 derecognized</b>	<b><u>4,221</u></b>

The gain on disposal is calculated as follows:

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

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

in €000	Years ended 31 December,		
	2014	2013	2012
Cash flow from operating activities	-7,017	-8,261	-7,751
Cash flow from investing activities	-181	-87	-266
Cash flow from financing activities	0	0	0
	<u>-7,198</u>	<u>-8,348</u>	<u>-8,017</u>

The basic and diluted earnings per share (EPS) from the discontinued operations are detailed as follows. The Company has stock options plans, which are anti-dilutive as the adjusted exercise price (considering the fair value of the services to be rendered for the unvested options) is higher than the market value of the common shares. In addition, the written put option granted to Debiopharm Diagnostics SA in relation to the interest of Debiopharm Diagnostics SA in MyCartis NV and which is settled in common shares of the Company is considered neither dilutive or anti-dilutive as the exercise price is at market value (see note 3.20).

in €000	Years ended 31 December,		
	2014	2013	2012
Basic and diluted EPS from discontinued operations	0.79	-0.37	-0.47

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**3.13 EARNINGS PER SHARE**

The Company has stock options plans and written put options 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.

The preference F shares are treated as common shares for purposes of the earnings per share considering that the preference shares are convertible to common shares at the option of the holder and conversion is mandatory at the date of an initial public offering. Also, the only additional right compared to ordinary shares is a preferred liquidation proceed (at the time of a 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.

	Years ended 31 December,		
	2014	2013	2012
Loss for the year attributable to the owners of the Company (in €000)	-9,118	-35,620	-44,431
Weighted average number of common shares for basic and diluted loss per share (in number of shares)	25,522,088	21,923,298	16,986,389
<b>Basic and diluted loss per share (€)</b>	<b>-0.36</b>	<b>-1.62</b>	<b>-2.62</b>

**3.14 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 €000	Patents and licenses	Software	Total
<b>Year ended 31 December 2012</b>			
Opening			
Cost	11,488	248	11,736
Accumulated amortization	-1,057	-74	-1,131
<b>Opening net carrying value</b>	<b>10,431</b>	<b>174</b>	<b>10,605</b>
Additions	0	350	350
Amortization expense	-575	-102	-677
<b>Closing net carrying value</b>	<b>9,856</b>	<b>422</b>	<b>10,278</b>
<b>As at 31 December 2012</b>			
Cost	11,488	598	12,086
Accumulated amortization	-1,632	-176	-1,808
<b>Net carrying value</b>	<b>9,856</b>	<b>422</b>	<b>10,278</b>
<b>Year ended 31 December 2013</b>			
Opening net carrying value	9,856	422	10,278
Additions	75	437	512
Amortization expense	-575	-230	-805
<b>Closing net carrying value</b>	<b>9,356</b>	<b>629</b>	<b>9,985</b>
<b>As at 31 December 2013</b>			
Cost	11,563	1,035	12,598
Accumulated amortization	-2,207	-406	-2,613
<b>Net carrying value</b>	<b>9,356</b>	<b>629</b>	<b>9,985</b>

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in €000	<u>Patents and licenses</u>	<u>Software</u>	<u>Total</u>
<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
Amortization expense	-638	-323	-961
<b>Closing net carrying value</b>	<b><u>9,223</u></b>	<b><u>429</u></b>	<b><u>9,652</u></b>
<b>As at 31 December 2014</b>			
Cost	12,025	1,121	13,146
Accumulated amortization	-2,802	-692	-3,494
<b>Net carrying value</b>	<b><u>9,223</u></b>	<b><u>429</u></b>	<b><u>9,652</u></b>

Patents and licenses primarily include a number of technology licenses acquired by the Group from Philips in 2010 for € 10.0 million relating to the Group's primary diagnostic platform 'Idylla™'. The carrying amount per 31 December 2014 is € 7.5 million (2013: € 8.0 million, 2012: € 8.5 million). The remaining useful life is 14 years. In 2011, the Group acquired a license from the same partner for access to the 'Idylla™-Enrich' technology for € 0.5 million. 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.

Amortization 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.

### **3.15 PROPERTY, PLANT AND EQUIPMENT**

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

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in €000	ICT equipment	Laboratory equipment	Manufacturing equipment	Internally produced systems	Furniture and fixtures	Leasehold improvements	Other property and equipment	Equipment under construction	Assets held under Lease	Total
<b>Year ended 31 December 2012</b>										
Opening Cost	367	287	0	0	351	1,519	157	5,337	0	8,018
Accumulated amortization	-217	-74	0	0	-32	-8	-1	0	0	-332
<b>Opening net carrying value</b>	<b>150</b>	<b>213</b>	<b>0</b>	<b>0</b>	<b>319</b>	<b>1,511</b>	<b>156</b>	<b>5,337</b>	<b>0</b>	<b>7,686</b>
Additions	458	502	4,776	0	80	1,413	83	0	0	7,313
Disposals	0	0	0	0	0	-1,904	0	0	0	-1,904
Depreciation charge of the period	-30	-145	-1,785	0	-53	-85	-3	0	0	-2,101
Transfers	0	0	5,336	0	0	0	-230	-5,106	0	0
<b>Closing net carrying value</b>	<b>579</b>	<b>570</b>	<b>8,327</b>	<b>0</b>	<b>346</b>	<b>936</b>	<b>6</b>	<b>231</b>	<b>0</b>	<b>10,994</b>
<b>As at 31 December 2012</b>										
Cost	825	789	10,112	0	431	1,029	10	231	0	13,427
Accumulated depreciation	-247	-219	-1,785	0	-85	-93	-4	0	0	-2,433
<b>Net carrying value</b>	<b>579</b>	<b>570</b>	<b>8,327</b>	<b>0</b>	<b>346</b>	<b>936</b>	<b>6</b>	<b>231</b>	<b>0</b>	<b>10,994</b>
<b>Year ended 31 December 2013</b>										
Opening net carrying value	579	570	8,327	0	346	936	6	231	0	10,994
Additions	193	299	1,465	847	97	219	0	18	0	3,138
Depreciation charge of the period	-213	-210	-699	-42	-58	-285	-2	0	-1,424	-2,933
Transfers	3	27	-6,919	0	0	0	0	-229	7,118	0
<b>Closing net carrying value</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>
<b>As at 31 December 2013</b>										
Cost	1,021	1,115	4,658	847	528	1,248	10	20	7,118	16,565
Accumulated depreciation	-460	-429	-2,484	-42	-143	-378	-6	0	-1,424	-5,366
<b>Net carrying value</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>
<b>Year ended 31 December 2014</b>										
Opening net carrying value	562	686	2,174	805	385	870	4	20	5,694	11,199
Additions	174	296	177	1,072	119	90	0	0	0	1,927
Disposals	-159	-285	-19	-228	-228	-150	0	0	0	-841
Depreciation charge of the period	119	183	19	71	71	69	0	0	0	461
Impairment losses	-207	-257	-1,034	-237	-55	-309	-2	0	-1,455	-3,556
Transfers	-12	0	-10	-15	-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>

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Assets held under lease relate to the Idylla™ semi-automated cartridge manufacturing line which was refinanced on 8 March 2013 via a € 7.9 million sale and lease back operation with KBC Lease. There is a purchase option at the end of the 5 year lease period for an amount of € 0.2 million.

The manufacturing equipment is related to the Idylla™ instrument and console manufacturing tooling and moulds and the Idylla™-Enrich pilot. The net carrying value in 2012 includes also the Idylla™ semi-automated cartridge manufacturing line. All production facilities are located in Mechelen, Belgium.

57 Idylla™ instruments were activated in 2013. In 2014, 24 Idylla™ consoles and 63 Idylla™ instruments were additionally activated. The total of internally produced systems consist thus of 24 Idylla™ consoles and 120 Idylla™ instruments per 31 December 2014.

### 3.16 INVENTORY

The inventory can be analysed as follows:

In €000	As at 31 December,		
	2014	2013	2012
<b>Inventory</b>			
Raw materials	1,958	1,041	183
Semi-finished products	107	24	0
Finished products	1,518	50	0
<b>Total</b>	<b>3,583</b>	<b>1,116</b>	<b>183</b>
Amount recognized as an expense	4,251	1,962	1,168

### 3.17 TRADE AND OTHER RECEIVABLES

The trade and other receivables can be analysed as follows:

In €000	As at 31 December,		
	2014	2013	2012
Trade receivables	15,793	3,082	1,442
Allowance for doubtful receivables	0	0	0
<b>Total trade receivables</b>	<b>15,793</b>	<b>3,082</b>	<b>1,442</b>
VAT receivables	116	975	793
Other receivables	32	18	0
<b>Total other receivables</b>	<b>148</b>	<b>993</b>	<b>793</b>

At 31 December 2014, trade receivables include € 15.7 million (2013: € 2.7 million; 2012: € 0.3 million) from JPNV of which € 4.5 million (2013: € 0.7 million; 2012: nil) related to Idylla™ prototype sales and € 11.2 million (2013: € 2 million; 2012: € 0.3 million) related to collaboration revenue.

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 account for more than 10% of the total trade receivable balance. The credit concentration risk is limited in view of the JPNV creditworthiness. Reference is made to note 3.28.3.4 for further detail.



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**3.18 OTHER CURRENT ASSETS**

The other current assets can be analysed as follows:

In €000	31 December,		
	2014	2013	2012
Accrued grant income	2,168	3,849	1,610
Deferred charges	533	522	288
<b>Total</b>	<b>2,700</b>	<b>4,371</b>	<b>1,898</b>

Other current assets include accrued income mainly related to Flemish government grants from the Hermes fund for strategic investments and training support totalling € 1.7 million (2013: € 2.5 million; 2012: € 0.8 million) and from IWT for R&D projects totalling € 0.4 million (2013: € 1.3 million; 2012: € 0.8 million). The Group evaluates continuously if it fulfils the specific conditions as per specific grant agreements to justify that none of the grants receivables are to be impaired.

**3.19 CASH AND CASH EQUIVALENTS**

The cash and cash equivalents can be analysed as follows:

In €000	31 December,		
	2014	2013	2012
<b>Cash and cash equivalents</b>			
Cash at bank and on hand	9,419	27,047	40,494
<b>Total cash and cash equivalents</b>	<b>9,419</b>	<b>27,047</b>	<b>40,494</b>
Total restricted cash	1,500	2,000	0
<b>Total cash and cash equivalents for cash flow purposes</b>	<b>10,919</b>	<b>29,047</b>	<b>40,494</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 via KBC lease.

**3.20 SHARE CAPITAL**

Issued share capital

The table below summarises the share capital and the outstanding shares of Biocartis Group NV as at 31 December 2014 and Biocartis S.A. as at 31 December 2013 and 2012. The shares are fully paid, registered shares.

As mentioned in section 3.2.2., 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.

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

	Biocartis SA				Biocartis Group NV		
	Number of common shares issued and outstanding	Number of preference F shares issued and outstanding	Share capital in '000 CHF	Share capital in '000€	Number of common shares issued and outstanding	Number of preferred F shares issued and outstanding	Share capital in '000€
<b>At 1 January 2012</b>	<b>15,338,618</b>	<b>0</b>	<b>767</b>	<b>543</b>			
Share issue—Round C.2 at 30 April 2012	2,054,400		103	83			
Share issue—Round D at 7 December 2012	4,087,844		204	169			
<b>At 31 December 2012</b>	<b>21,480,862</b>	<b>0</b>	<b>1,074</b>	<b>795</b>			
Share issue—Round E at 4 November 2013	3,210,002		161	131			
<b>At 31 December 2013</b>	<b>24,690,864</b>	<b>0</b>	<b>1,235</b>	<b>926</b>			
Capital increase by conversion reserves	0	0	37,036	30,487			
Capital decrease on 26 August 2014, in effect on 6 November 2014			-37,036	-30,487			
Share issue—Round F.1 at 29 Augustus 2014	0	2,645,868	132	109			
<i>Change in reporting entity</i>							
Incorporation Biocartis Group NV at 24 November 2014 by contribution in kind	-18,812				16,992	1,820	153
Contribution in kind at 25 November	-24,672,052	-2,645,868			24,673,872	2,644,048	222,115
<b>At 31 December 2014</b>	<b>0</b>	<b>0</b>	<b>1,367</b>	<b>1,035</b>	<b>24,690,864</b>	<b>2,645,868</b>	<b>222,268</b>

*Biocartis S.A.*

The following capital transactions took place at Biocartis S.A., the reporting entity until 25 November 2014, during the periods reported:

- On 30 April 2012, Biocartis S.A. raised € 19.2 million (CHF 23.1 million) fully paid by an increase in share capital by € 0.1 million (CHF 0.1 million) and an increase in share premium by € 19.1 million (CHF 23.0 million);
- On 7 December 2012, Biocartis S.A. raised € 34.5 million (CHF 41.7 million) fully paid by an increase in share capital by € 0.2 million (CHF 0.2 million) and an increase in share premium by € 34.3 million (CHF 41.5 million);
- On 4 November 2013, Biocartis S.A. raised € 30.0 million (CHF 36.9 million) fully paid by an increase in share capital by € 0.1 million (CHF 0.1 million) and an increase in share premium by € 29.9 million (CHF 36.8 million);

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- On 23 July 2014, the share capital of Biocartis S.A. was increased by € 30.5 million (CHF 37.0 million) from € 0.9 million (CHF 1.2 million) to € 31.4 million (CHF 38.2 million) by way of conversion of freely distributable reserves into share capital;
- On 26 August 2014, Biocartis S.A. decreased its share capital for an amount of € 30.5 million (CHF 37.0 million), of which € 30.0 million (CHF 36.4 million) was paid out in kind in the form of all the shares held by Biocartis S.A. in MyCartis NV, and of which the remaining € 0.5 million (CHF 0.6 million) is a gain on the capital decrease, which is accounted for as an equity transaction. The capital decrease was completed, following the legally required waiting period, on 11 November 2014.
- On 29 August 2014, Biocartis S.A. concluded the first tranche of € 21.5 million (CHF 25.9 million) of an in total € 64.5 million series F round. The second and third tranche of this series F round has been/will be completed at the level of Biocartis Group NV (see below).

### *Biocartis Group NV*

The Company has 24,690,864 common shares issued and outstanding which are fully paid with no nominal value but with a par value of (rounded) € 8.1307 per share. In addition, the Company has 2,645,868 preference shares F issued and outstanding which are fully paid with no nominal value but with a par value of (rounded) € 8.1307 per share.

The preference shares F have the following additional liquidation right attached compared to the common shares:

- In case of liquidation and in case of certain sales, the holders of the preference shares F shall be reimbursed up to their preference F shares amount paid prior to reimbursement to the holders of common shares. The maximum amount that can be reimbursed to the holders of preference F shares is the preference F shares amount less any income already received from the liquidation. The liquidation preference is terminated at the earlier of the completion of a Qualified IPO and the full repayment of the preference F shares amount. The preference F shares can be converted in common shares at any time and upon request of the preference F shareholder. The preference F shares will be converted in common shares at the time of the completion of a Qualified IPO.

The second tranche of the above-mentioned series F round of € 21.5 million has been implemented on 15 January 2015. See section 3.33 for more information.

The third tranche of € 21.5 million will be implemented upon the realization, by no later than 15 December 2015, of one of the two following events: (i) commercial sales amounting to 75% of Q1 and Q2 2015 quarter sales projected in the current version of the business plan and budget and (ii) the closing of an initial public offering of the Company's common shares on Euronext Brussels or another agreed upon international exchange with aggregate proceeds of such initial public offering of at least € 30 million (the "Qualified IPO"). In the event of a Qualified IPO, the third tranche will be invested at standard underwriting terms in the IPO at the then applicable IPO price (without preferred shares being issued in such case). The issuance price will be € 8.5373 or, if triggered by a Qualified IPO, the IPO price.

### *Option to acquire shares in the Company*

The options disclosed below have been transferred by Biocartis S.A. to the Company in the view of the change in parent company:

The following third parties have been granted option rights as follows:

- On 15 August 2011, at the occasion of the Idylla™-Enrich technology acquisition, Philips, a shareholder of the Group, has been granted two conversion options, of which one remains outstanding per 31 December 2014. This option foresees that the Group can, at its sole discretion, grant Philips the right to convert all or part of the future payments

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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 enters into force when a specific milestone under the agreement is met or 31 December 2015, and ends on 31 December 2018. However, the Group is also contractually able to replace future royalty and revenue sharing payments by a lump sum payment to Philips, reducing the above conversion option.

- The Company has contractually agreed to issue an option to Whitmarsh, a business advisory firm, to acquire 100,000 common shares pursuant to a decision of the board of directors of Biocartis S.A. of April 24, 2014. The option has not been formally granted at 31 December 2014.
- On 25 August 2014 Biocartis S.A. 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 in January 2015. See section 3.33 for more information.

### *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.

## **3.21 SHARE BASED COMPENSATION**

All the stock option plans that were issued by Biocartis S.A. have been transferred to the Company.

### ESOP 2008 (Shadow options)

On 2 July 2008, the board of directors of Biocartis S.A. approved a share option plan, further amended on 29 June 2009, for share options to be granted to employees, consultants or directors selected by the board of directors of Biocartis S.A. (the "SOP 2008"). The SOP 2008 is a non-dilutive option plan and is established on the basis of the "shadow options" for a total amount of 1,263,236 stock options (shares of Biocartis S.A. to be transferred by Benaruca, Ferdinand Verdonck and Philippe Renaud, respectively, to Biocartis S.A. at a price of CHF 4.14 per share based on the understanding that Biocartis S.A. will then grant these shares to the beneficiaries under the SOP 2008). Under the SOP 2008 a total of 943,819 options were granted.

Upon the 1 to 5 reverse share split concluded on 25 August 2011, the total number of share options granted was reduced to 188,764 of which 11,460 were exercised prior to the date of conversion.

The board of directors of Biocartis S.A. decided in its meeting of 26 June 2012 to update certain clauses of the SOP 2008 to bring them more in line with the general conditions of the stock option plan ESOP 2013 that was established in 2013. The most important changes relate to the harmonization of the exercise and vesting conditions of the stock options. These changes had no material impact on the fair value calculation of the share options granted under the plan ESOP 2008.

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The board of directors of Biocartis S.A. decided in its meeting of 24 April 2013 to cancel the remaining (not yet granted) share options under the SOP 2008 Plan. The Shadow Option Agreements with Benaruca, Ferdinand Verdonck and Philippe Renaud were amended in that respect in October 2013. Taking into account the exercise of a number of stock options in October 2013 and the cancellations, the total SOP 2008 stock options outstanding are 94.362 at 31 December 2014.

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

- Options are granted for free
- Exercise price: CHF 4.14
- Option term: 7 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) as of the effective starting date of the respective assignment.

The Company has signed shadow agreements with certain founders whereby, upon exercise of the stock options under the plan, certain founders will transfer common shares held by them to the option holder. As such, the ESOP 2008 has no dilutive effect.

	<u>SOP 2008</u>
Options granted	188,764
Options exercised	-11,460
Options cancelled	—
<b>Total outstanding at 31 December 2012</b>	<b><u>177,304</u></b>
Options exercised	-70,972
Options forfeited	-12,000
Options cancelled	0
<b>Total outstanding at 31 December 2013</b>	<b><u>94,332</u></b>
Options exercised	0
Options cancelled	0
<b>Total outstanding at 31 December 2014</b>	<b><u><u>94,332</u></u></b>

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 € 0.1 per option. The weighted average exercise price is CHF 4.76. The weighted average remaining contractual life is 4.8 years.

### ESOP 2013

On 7 February 2013 the board of directors of Biocartis S.A. decided to entirely devote the conditional capital, whereby a maximum of 1,000,000 shares can be issued to employees, consultants and management of the Group, to the stock option plan ESOP 2013.

In the course of 2013, a total number of 680,340 stock options have been granted. 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 15 May until 31 May,

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- (ii) as of 15 August until 31 August,
- (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) as of the effective starting date of the respective assignment.

With respect to the determination of the exercise price and with respect to the determination of the fair market value of the shares of the company for purposes of the ESOP 2013 the board of directors of Biocartis S.A. decided, based on the capital increase that took place in December 2012 at the occasion of which also certain third party investors invested into the company, as well as the capital increase of 4 November 2013, that the fair market value of the shares of the company underlying the stock options is for purposes of the ESOP 2013 equal to € 9.346 for all options granted until 15 July 2014. The company has granted 20,000 additional options at 15 July 2014 with an exercise price of € 9.346. The company has granted 20,000 additional options on 1 December 2014 with an exercise price of € 8.1308.

On 25 November 2014, the company also reduced the exercise price of the outstanding options granted until 15 July 2014 to € 8.1308 to reflect the MyCartis business disposal. The Group determined that reduction in exercise price, solely to preserve the rights of the warrant holders, is not considered a significant modification of the options terms & conditions given that the fair value of the underlying shares in the company has also decreased with a similar amount following the reduction in capital by distribution in kind of the MyCartis shares. The fair value of the options considering the modified exercise price (€ 1.56 per option) is below the grant date fair value. As such, the modification, which only had an immaterial impact on the fair value of the warrants, had no impact on the share-based payment expense.

	<u>SOP 2013</u>
Options granted	<u>680,340</u>
<b>Total outstanding at 31 December 2013</b>	<b><u>680,340</u></b>
Options granted at € 9,346	<u>20,000</u>
Options granted at € 8.1307	<u>20,000</u>
<b>Total outstanding at 31 December 2014</b>	<b><u><u>720,340</u></u></b>

The total outstanding options at 31 December 2014 have an exercise price of € 8.1307 following the modification of the exercise price discussed above.

This concerns new shares to issue by the Company and has therefore a dilutive effect.

Accounting for share-based payment

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

	<u>Years ended 31 December,</u>		
In € 000	<u>2014</u>	<u>2013</u>	<u>2012</u>
Share based compensation	<u>143</u>	<u>1,023</u>	<u>0</u>
<b>Total</b>	<b><u><u>143</u></u></b>	<b><u><u>1,023</u></u></b>	<b><u><u>0</u></u></b>

Options granted in 2013 and 2014 partially vested immediately at grant date which resulted in the immediate recognition of a share-based payment expense of € 0,1 million in 2014 (2013: € 1.0 million).

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

	Grants 2013	Grants July 2014	Grants November 2014
Number of warrants granted	680,340	20,000	20,000
Number of warrants not vested at 31/12/2014	112,500	17,500	19,167
Exercise price	€9.346	€9.346	€8.1307
Expected dividend yield	0	0	0
Expected stock price volatility	24.85%	30.04%	30.04%
Risk-free interest rate	0.68%	0.23%	0.06%
Expected duration	3.5	2.8	2.6
	years	years	years
Forfeiture rate	0%	0%	0%
Fair value	€1.78	€1.87	€1.56

The weighted average exercise price is € 8.1308 at 31 December 2014 taken into account the disposal of the MyCartis business (2013: € 9.346; 2012: € 9.346). The weighted average remaining contractual life is 7 years.

The weighted average risk-free interest rates used are based on Swiss 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).

No stock options have been exercised during 2012, 2013 and 2014.

### 3.22 FINANCIAL DEBT

The financial debt can be analyzed as follows:

In €000	As at 31 December,		
	2014	2013	2012
PMV	6,707	6,268	5,858
Senter Novem	0	3,566	4,226
KBC Lease	1,821	2,983	0
Other	0	5	5
<b>Total non-current</b>	<b>8,528</b>	<b>12,822</b>	<b>10,089</b>
Senter Novem	3,895	2,250	1,250
KBC Lease	1,161	1,123	0
<b>Total current</b>	<b>5,057</b>	<b>3,373</b>	<b>1,250</b>

In 2010, the Group was granted a loan facility for a total amount of € 5.0 million by PMV (ParticipatieMaatschappij Vlaanderen), a shareholder of the Group, bearing an interest rate of 7% and with a maturity date at 31 December 2016. The interest on the loan is capitalized 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 € 5.0 million from the Dutch government institution Senter Novem, conditional upon certain spending commitments and activities in the Netherlands. The annual interest on the Senter Novem loan amounts to 6.2% and is added to the total outstanding loan amount.

In 2013, the Group agreed with Senter Novem on the following repayment obligations for the capital amounts together with accrued interests:

- 45% of total capital loan amount on 1 October 2014
- 55% of total capital loan amount and total of accrued interests on 1 October 2015

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The Senter Novem loan is secured by a pledge on newly generated intellectual property assets related to the Idylla™ platform in the Netherlands, and by a guarantee from Biocartis S.A..

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 with KBC Lease. The lease has a term of 5 years at a 3.35% interest rate and includes a purchase option of € 0.2 million. As a security, a debt service reserve account is to be maintained, starting at € 2.5 million, decreasing over time according to the following milestones: fundraising 2013, CE approval, FDA approval.

The terms of the loans are summarised in the table below:

Loan	Year	Nominal amount (in €000)	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
KBC Lease	2013	7.910	S	3.35%	31/01/2018

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

In €000	As at 31 December,					
	2014		2013		2012	
	Minimum lease payments	Present value of minimum lease payments	Minimum lease payments	Present value of minimum lease payments	Minimum lease payments	Present value of minimum lease payments
<b>Financial lease</b>						
< 1 year	1,240	1,161	1,240	1,123	0	0
>1 and < 5 years	1,888	1,821	3,128	2,983	0	0
<b>Total</b>	<b>3,128</b>	<b>2,982</b>	<b>4,368</b>	<b>4,106</b>	<b>0</b>	<b>0</b>
less interests	-145		-262		0	
Present value	<b>2,982</b>	<b>2,982</b>	<b>4,106</b>	<b>4,106</b>	<b>0</b>	<b>0</b>

The net carrying value of the related leased assets amounts to € 4.2 million at 31 December 2014 (2013: € 5.7 million, 2012: nil)

### 3.23 RETIREMENTS BENEFIT PLANS

The retirement benefit plan liability is as follows:

In €000	As at 31 December,		
	2014	2013	2012
retirement benefit obligations	0	267	490
<b>Total</b>	<b>0</b>	<b>267</b>	<b>490</b>

#### 3.23.1 Defined contribution plans

The post-employment benefits of the employees of Biocartis NV are defined contribution plans with minimum guaranteed rates of return, currently 3.25% on employer contributions and 3.75% on employee contributions. The minimum guaranteed rates, which apply as an average over the entire career, may be modified by a Royal Decree in which case the new rates apply to both the accumulated past contributions as from the date of modification onwards.



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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. There is a risk that the Company may have to pay additional contributions related to past service. Any such additional contributions will depend on the actual investment returns as well as the future evolution of the minimum guaranteed rates of return.

In accordance with the Group's accounting policy, the Group accounts for those plans as defined contribution plan and compares the "walk away liability" or the vested rights at reporting date with the fair value of the plan assets. If the vested rights are higher as compared to the fair value of the plan asset, a liability is recognised for the shortage at the reporting date.

At 31 December 2014 no such net liability (2013: nil; 2012: nil) was recognized in the balance sheet as the minimum guaranteed reserves of € 1.1 million (2013: € 0.6 million; 2012: € 0.3 million) equal the fair value of the plan assets of € 1.1 million (2013: € 0.6 million; 2012: € 0.3 million).

The total expense recognized in the consolidated income statement for contributions made under these defined contribution plans amount to € 0.4 million in 2014 (2013: € 0.3 million; 2012: € 0.3 million).

The expected 2015 employer contributions amount to approximately € 0.6 million.

The average age of the 149 plan participants equals 40 years at 31 December 2014.

**3.23.2 Defined benefit plan**

The post-employment benefits of the employees of Biocartis S.A. in Switzerland are 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 S.A. has no further obligations under this plan. As such, the disclosures below relate to the years 2013 and 2012 only.

The principal assumptions used for the purposes of the actuarial valuation are as follows:

	2013 %	2012 %
Discount rate	2.00	2.25
Expected return on plan assets	2.45	2.50
Expected rate of salary increase	2.00	2.25
Expected rate of pension increase	0.00	0.00

All amounts recognised in the consolidated statement of income are presented in the line "loss from discontinued operations".

In €000	31 December,		
	2014	2013	2012
Service cost	0	436	193
Net interest expense	4	10	2
<b>Total in loss from discontinued operations</b>	<b>4</b>	<b>446</b>	<b>195</b>

Amounts recognised in other comprehensive income in respect of this defined benefit plan are as follows:

In €000	Years ended 31 December,		
	2014	2013	2012
Cumulative amount at beginning of the year	309	379	170
Net actuarial losses (gains)	0	-70	210
Disposal	-309	0	0
<b>Cumulative amount at the end of the year</b>	<b>0</b>	<b>309</b>	<b>379</b>

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The amount included in the consolidated balance sheet arising from the Group's obligation in respect of its defined benefit plans is as follows:

In €000	As at 31 December,		
	2014	2013	2012
Present value of funded defined benefit obligation	0	-2,158	-1,438
Fair value of plan assets	0	1,891	947
<b>Deficit recognized in the consolidated balance sheet</b>	<b>0</b>	<b>-267</b>	<b>-490</b>

Movements in the present value of the defined benefit obligation in the current year were as follows:

In €000	As at 31 December,	
	2013	2012
<b>Defined benefit obligation, beginning of the year</b>	<b>1,437</b>	<b>866</b>
Net service cost	284	130
Interest cost	30	19
Employee contributions	164	119
Net of benefits (paid)/received	181	118
Liability (gain)/loss due to experience	56	79
Liability (gain)/loss due to assumption changes	-127	99
Past service costs	152	0
Foreign exchange	-18	7
<b>Total, end of the year</b>	<b>2,159</b>	<b>1,437</b>

Movements in the fair value of the plan assets in the current year were as follows:

In €000	As at 31 December,	
	2013	2012
<b>Fair value of plan assets, beginning of the year</b>	<b>947</b>	<b>606</b>
Employer contributions	660	123
Employee contributions	165	119
Net of benefits (paid)/received	181	118
Actual administration expenses	-18	0
Interest income	20	17
Actuarial gain / (loss) on return on plan assets	-47	-41
Foreign exchange	-16	5
<b>Total, end of the year</b>	<b>1,892</b>	<b>947</b>

Pension assets consist of assets held by the insurance company that fully reinsures the Group's pension liabilities. The expected long-term return is based on the experience of the past and on future expectations. The overall expected rate of return is the weighted average of the expected returns of the various categories of plan assets held. Management's assessment of the expected returns is based on historical return trends and analysts' predictions of the market for these assets over the life of the plan.

The history of experience adjustments is as follows:

In €000	As at 31 December,	
	2013	2012
Present value of funded DBO	-2,158	-1,438
Fair value of plan assets	1,891	947
<b>Deficit recognized in the consolidated balance sheet</b>	<b>-267</b>	<b>-490</b>
Experience loss on plan assets	-47	-41
Experience loss on DBO	-56	-79

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**3.24 OTHER CURRENT LIABILITIES**

Other current liabilities include:

In €000	As at 31 December,		
	2014	2013	2012
Provision vacation pay	1,407	1,043	713
Other social liabilities	10	564	44
VAT payable	1,791	0	0
Other current liabilities	87	50	0
<b>Total other current liabilities</b>	<b>3,293</b>	<b>1,657</b>	<b>757</b>

**3.25 DEFERRED INCOME**

In €000	As at 31 December,		
	2014	2013	2012
Grants	75	213	34
Collaboration partner income	9,559	2,270	6,288
<b>Total deferred income</b>	<b>9,634</b>	<b>2,483</b>	<b>6,322</b>
Current	5,100	772	1,320
Non-current	4,534	1,711	5,002

Deferred partner income includes upfront payments received from JPNV in relation to the strategic licensing, development and commercialisation collaborations. This amount will be recognized as collaboration revenue in the following 3 years with a majority in 2015 and 2016.

	Deferred income
<b>As per 1 January 2012</b>	<b>7,573</b>
Recognized as collaboration partner income	-1,285
<b>As per 31 December 2012</b>	<b>6,288</b>
Recognized as collaboration partner income	-4,019
<b>As per 31 December 2013</b>	<b>2,270</b>
Invoiced	7,860
Recognized as collaboration partner income	-571
<b>As per 31 December 2014</b>	<b>9,559</b>

**3.26 ACCRUED EXPENSES**

Accrued expenses primarily include accruals for rental charges.

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**3.27 TAXES**

**3.27.1 Tax reconciliation**

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

In €000	31 December,		
	2014	2013	2012
<b>Loss before taxes</b>	<b>-10,662</b>	<b>-35,618</b>	<b>-44,427</b>
Income tax credit calculated at 7.8%	0	-2,778	-3,465
Income tax credit calculated at 33.99%	-3,624	0	0
Effect of different tax rates	-3,345	-1,844	-318
Effect of income that is exempt from taxation	-2,284	-661	-111
Effect of expenses that are non-deductible in determining tax profit	8,002	205	56
Effect of unused tax losses and tax offsets not recognized as deferred tax assets	10,094	5,080	3,843
Effect of previously unrecognized and unused tax losses	-8,844	0	0
Effect of tax credit for research and development	-947	0	0
<b>Income tax expense (profit) recognized in loss for the period</b>	<b>-947</b>	<b>2</b>	<b>4</b>

The tax rate used in 2014 reconciliations is the corporate tax rate of 33.99% applicable in Belgium. The tax rate used for the 2013 and 2012 reconciliations above is the corporate tax rate of 7.8% payable by corporate entities exempted in Canton de Vaud, Switzerland, on taxable profits but subject to federal tax law in that jurisdiction.

**3.27.2 Unrecognized 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 € 86.8 million (2013: € 173.5 million; 2012: € 122.9 million). The tax losses related to Biocartis S.A. amount to € 51.2 million in 2014 (2013: € 161.1 million; 2012: € 135.8 million) with the following expiration years. Each annual tax loss expires seven years after the fiscal period it has been realized.

**Tax losses at Biocartis S.A. (in CHF)**

<u>Year</u>	<u>amount</u>	<u>Expiry year</u>
2012	27,893	2019
2013	33,694	2020
2014	0	2021
<b>Total tax losses</b>	<b>61,587</b>	

The tax losses of Biocartis NV for € 34.6 million per 31 December 2014 (2013: € 11.9 million; 2012: € 3.6 million) in Belgium will not expire as they can be carried forward indefinitely.

**3.27.3 Recognized deferred tax assets**

The Group has R&D tax credit carry-forwards in Belgium for a total amount of € 0.9 million (2013: € 0.3 million; 2012: € 0.03 million) for which a deferred tax asset of € 0.9 million (2013: nil; 2012: nil) has been recognized in 2014 as the recognition criteria have been met as from 2014.

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### 3.28 FINANCIAL RISK MANAGEMENT

#### 3.28.1 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.

#### 3.28.2 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.

#### 3.28.3 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.

##### 3.28.3.1 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 identifies the main currency risk in Switzerland, since Biocartis S.A. is located in Switzerland and uses the Euro ("€") as its functional and reporting currency whereas most local costs are denominated in CHF. 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 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 2014, 2013 and 2012.

Financial assets include current bank accounts and petty cash. Financial liabilities include trade payables and accruals in foreign currency.

In €000	31 December,		
	2014	2013	2012
<b>Liabilities</b>			
CHF—Switzerland	1	237	603
USD—United States	78	108	129
AUD—Australia	0	211	440
<b>Assets</b>			
CHF—Switzerland	152	15	673
USD—United States	4	34	36
AUD—Australia	0	220	127

#### *Sensitivity analysis for the two significant currencies:*

- If the USD currency would increase (decrease) with 10% compared to the Euro, the net impact on the loss for the year would be € -0.01 million (€ 0.01 million).

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- If the CHF currency would increase (decrease) with 20% compared to the Euro, the net impact on the loss for the year would be € -0.03 million (€ 0.03 million).

### 3.28.3.2 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.

### 3.28.3.3 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.

### 3.28.3.4 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 €000	31 December,		
	2014	2013	2012
<b>carrying value</b>			
JPNV	15,723	2,680	328
bioMérieux	0	29	647
Other trade and other receivables	217	1,366	1,260
	<b>15,941</b>	<b>4,075</b>	<b>2,235</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 € 2.0 million guarantee for the KBC 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.

### 3.28.3.5 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.

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The Group maintains a credit line with one financial institution of € 0.5 million (2013: € 0.5 million; 2012: € 0.5 million) mainly being used for bank guarantees. As per 31 December 2014, the credit line was used for € 0.5 million (2013: € 0.5 million; 2012: € 0.5 million).

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 is exposed to significant liquidity risk in the medium term.

Analysis of contractual maturities of financial liabilities at 31 December is as follows (amounts in € 000):

In €000	31 December,								
	2014			2013			2012		
	Trade payables	financial debt	other current liabilities and accrued expense	Trade payables	financial debt	other current liabilities and accrued expense	Trade payables	financial debt	other current liabilities and accrued expense
Less than 1 month	4,265		3,293	5,847		1,657	8,454		757
1-3 months		287			277			0	
3 months to 1 year		4,770			3,096			1,250	
1-5 years		8,528	711		12,817	580		10,084	623
5+ years			1,244		5	1,161		5	1,403
<b>Total</b>	<b>4,265</b>	<b>13,585</b>	<b>5,248</b>	<b>5,847</b>	<b>16,195</b>	<b>3,398</b>	<b>8,454</b>	<b>11,339</b>	<b>2,783</b>

### 3.29 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 2014, 2013 and 2012.
- The fair value of the participating interest is determined based on its sales price.

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.
- The fair value of the written put option sold to Debiopharm Diagnostics SA is zero as the exercise price of the written put option equals market value.

#### *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;

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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 2014. At 31 December 2013, the Group had the participating interest carried at fair value and which is considered level 2 as it is based on a non-observable disposal price agreed by and with the Company during 2014.



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in '000 €

	Carrying value			Fair value		
	31 December, 2014	31 December, 2013	31 December, 2012	31 December, 2014	31 December, 2013	31 December, 2012
<b>Financial assets</b>						
<b>Loans and receivables measured at amortised cost</b>						
Trade and other receivables (current)	15,941	4,075	2,235	15,941	4,075	2,235
Other financial assets (non-current)	117	107	106	117	107	106
Other current assets	2,700	4,371	1,898	2,700	4,371	1,898
<b>Total loans and other receivables</b>	<b>18,757</b>	<b>8,553</b>	<b>4,239</b>	<b>18,757</b>	<b>8,553</b>	<b>4,239</b>
<b>Available for sale financial assets</b>						
Participating interest	—	245	—	—	245	—
<b>Total available for sale</b>	<b>—</b>	<b>245</b>	<b>—</b>	<b>—</b>	<b>245</b>	<b>—</b>
cash & cash equivalents	10,919	29,047	40,494	10,919	29,047	40,494
<b>Total cash &amp; cash equivalents</b>	<b>10,919</b>	<b>29,047</b>	<b>40,494</b>	<b>10,919</b>	<b>29,047</b>	<b>40,494</b>
<b>Financial liabilities</b>						
<b>Financial liabilities measured at amortized cost</b>						
Loans & Borrowings	13,585	16,195	11,339	14,077	17,442	12,896
Trade payables	4,265	5,847	8,454	4,265	5,847	8,454
Other liabilities and accrued charges	5,248	3,398	2,783	5,248	3,398	2,783
<b>Total financial liabilities measured at amortized cost</b>	<b>23,098</b>	<b>25,440</b>	<b>22,576</b>	<b>23,590</b>	<b>26,687</b>	<b>24,133</b>

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### 3.30 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 subsidised expenses or investments have been incurred and for which the grant was earned. Should this validation not occur or be deemed inadequate, the grant bodies have the right to reclaim funds previously granted.

#### *Royalties*

With respect to the Group's licensing agreements, 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 group. These payments may—at the sole discretion of the Group—be converted into common shares of the group following the conversion option granted to Phillips.

### 3.31 COMMITMENTS

#### 3.31.1 Capital commitments

Commitments related to capital expenditures at the balance sheet date are as follows:

In €000	31 December,		
	2014	2013	2012
Leasehold improvements	23	0	35
Property, plant and equipment	88	9	1,489
<b>Total</b>	<b>111</b>	<b>9</b>	<b>1,524</b>

Capital commitments relate to the cartridge production facilities 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 2014.

#### 3.31.2 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), Lausanne (Switzerland) and in Eindhoven (the Netherlands), 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 2014 under its leasing contracts per nature and maturity is summarized in the table below.

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In line with the rental/lease agreements, a total amount of € 0.5 million (2013: € 0.5 million; 2012: € 0.5 million) in bank guarantees has been provided.

In €000	31 December,					
	2014		2013		2012	
	Rent/Lease facilities	Car Lease	Rent/Lease facilities	Car Lease	Rent/Lease facilities	Car Lease
not later than 1 year	1,294	498	1,373	534	1,275	360
between 1 and 5 years	5,175	703	5,493	1,051	4,145	1,037
more than 5 years	4,483	0	6,283	0	4,971	0
<b>Total</b>	<b>10,952</b>	<b>1,201</b>	<b>13,149</b>	<b>1,585</b>	<b>10,391</b>	<b>1,397</b>

In €000	31 December,		
	2014	2013	2012
	<b>Payments recognized as an expense</b>		
minimum lease payments	1,867	1,817	1,647
<b>Total</b>	<b>1,867</b>	<b>1,817</b>	<b>1,647</b>

### 3.32 RELATED-PARTY TRANSACTIONS

The Group is owned by several minority investors and financial investors. 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 3.4), Share Capital (Note 3.20) and Share Based Compensation (Note 3.21).

#### 3.32.1 Remuneration of key management

Remuneration of key management consists of the Directors and the members of the Executive Management Team. Only one non-executive Director receives a yearly remuneration of € 25,000 per year.

In €000	31 December,		
	2014	2013	2012
Short-term employee benefits (salaries, social security bonuses and fringe benefits)	1,177	1,352	1,459
Post -employment benefits (Group insurance)	7	47	0
Share based payment	67	585	0
<b>Total</b>	<b>1,184</b>	<b>1,984</b>	<b>1,459</b>

The post-employment benefits for the key management are part of the retirement benefit scheme to which all qualifying personnel is 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 granted in 2013 and 2014 under the ESOP 2013 plan.

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**3.32.2 Transactions with non-executive directors and shareholders**

In €000	<u>Sales of goods and services</u>	<u>Purchase of good and services</u>	<u>Interest cost</u>	<u>Trade receivables</u>	<u>Trade payables</u>	<u>Financial Debt</u>
<b>Shareholders</b>						
31 December 2014	8,412	-81	-439	15,723	0	6,707
31 December 2013	8,333	-20	-410	2,266	1	6,273
31 December 2012	3,550	-33	-383	975	1	5,863

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

- Sales of goods and services and trade receivables concern the collaboration and product sales towards Johnson & Johnson (or entities belonging to this group) and bioMérieux. Further detail is provided in notes 3.4 and 3.17.
- The interest cost and financial debt relate to the loan granted by PMV (see note 3.22).
- The participation in Immunexpress was sold at its carrying value of €0.2 million in 2014 to Debiopharm, a shareholder of the group.

**3.32.3 Subsidiaries**

Details of the Company's subsidiaries at 31 December 2014 are as follows:

Name of subsidiary	Principal activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2014	2013
Biocartis S.A.	Intermediate holding company	Scientific Parc EPFL, PSE-C 1015 Lausanne Switzerland	100%	100%
Biocartis NV	Develop and market diagnostic platforms	Generaal De Wittelaan 11 B—2800 Mechelen	99.99%*	99.99%*
Biocartis B.V.	Develop and market diagnostic platforms	High Tech Campus 9 PO Box 775 NL—5600 AT Eindhoven The Netherlands	100%	100%

\* all shares held by Biocartis S.A., except for one share held by Biocartis BV

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

**3.33 EVENTS AFTER THE BALANCE SHEET DATE**

On 15 January 2015, Biocartis Group NV concluded the second tranche of EUR 21,512,796 of the total EUR 64,538,390 series F round, against the issuance of 2,519,855 new Preferred F Shares with an issuance price of EUR 8.5373 and without nominal value per Preferred F Share.

Debiopharm Diagnostics has, by virtue of a letter dated 11 December 2014, exercised the put option with respect to certain shares of MyCartis NV, as provided for in the put option agreement dated 25 August 2014, as restated and amended as per 25 November 2014. The issuance of the respective shares by Biocartis Group NV (contribution in kind) was concluded on 15 January 2015 on the occasion of the second tranche.

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On 15 January 2015 a new and additional option plan 'SOP 2015' has been issued, on the basis of which an additional option pool of 217,934 options has been created. The new plan entitles the option holders, subject to the terms of the option plan and the respective option agreements, to subscribe to 217,934 additional ordinary shares of the Company.

In 2014, a milestone contingent promise to grant 100,000 options on ordinary Biocartis shares was promised to Whitemarsh Capital, a U.S. business advisory firm. The options were formally granted by an award letter on 13/04/2015. None of the options have been vested to this date.

### **3.34 STANDARDS AND INTERPRETATIONS PUBLISHED, BUT NOT YET APPLICABLE FOR THE ANNUAL PERIOD BEGINNING ON 1 JANUARY 2014**

The following IFRS standards, interpretations and amendments that have been issued but that are not yet effective, have not been applied to the first IFRS financial statements closed on 31 December 2013:

- IFRS 9—Financial Instruments and subsequent amendments (normally applicable for annual periods beginning on or after 1 January 2018, but not yet endorsed in EU)
- IFRS 15—Revenue from Contracts with Customers (applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed in EU)
- Improvements to IFRS (2010-2012) (normally applicable for annual periods beginning on or after 1 July 2014)
- Improvements to IFRS (2011-2013) (normally applicable for annual periods beginning on or after 1 January 2015)
- Improvements to IFRS (2012-2014) (normally 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 January 2015)
- IFRIC 21—Levies (applicable for annual periods beginning on or after 17 June 2014)
- Amendments to IAS 16 and IAS 38—Clarification of Acceptable Methods of Depreciation and Amortisation (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- Amendments to IFRS 11—Accounting for Acquisitions of Interests in Joint Operations (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- Amendments to IFRS 10 and IAS 28—Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)

It is not expected that the initial application of the above mentioned IFRS standards, interpretations and amendments will have a significant impact on the consolidated financial statements.

**THE ISSUER**

**Biocartis Group NV**  
Generaal De Wittelaan 11 bus B  
2800 Mechelen  
Belgium

**GLOBAL COORDINATOR**

**KBC Securities NV/SA**  
Havenlaan 12  
1080 Brussel  
Belgium

**JOINT BOOKRUNNERS**

**KBC Securities NV/SA**

Havenlaan 12  
1080 Brussel  
Belgium

**Petercam NV/SA**

Sint-Goedeleplein 19  
1000 Brussels  
Belgium

**Kempen & Co N.V.**

Beethovenstraat 300  
1077 WZ Amsterdam  
The Netherlands

**LEGAL ADVISERS  
TO THE ISSUER**

*As to Belgian law*

**Baker & McKenzie CVBA**  
Avenue Louise/Louizalaan 149  
1050 Brussels  
Belgium

*As to US law*

**Baker & McKenzie LLP**  
100 New Bridge Street  
London EC4V 6JA  
United Kingdom

**LEGAL ADVISERS  
TO THE UNDERWRITERS**

*As to Belgian law*

**Freshfields Bruckhaus Deringer LLP**  
Marsveldplein 5  
1050 Brussels  
Belgium

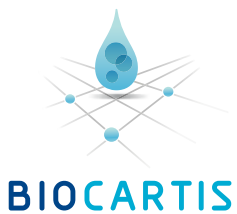
*As to US law*

**Freshfields Bruckhaus Deringer LLP**  
Bockenheimer Anlage 44  
60322 Frankfurt am Main  
Germany

**INDEPENDENT AUDITOR OF THE ISSUER**

**Deloitte Bedrijfsrevisoren/Reviseurs d'Entreprises BV CVBA**  
Berkenlaan 8b  
1831 Diegem  
Belgium





Biocartis NV  
Generaal De Wittelaan 11 B3  
2800 Mechelen - Belgium

[www.biocartis.com](http://www.biocartis.com)