PART 1

INTRODUCTION

BIOCARTIS' MISSION IS TO OFFER

RAPID & EASY

MOLECULAR DIAGNOSTICS SOLUTIONS AIMED AT ENABLING FASTER & MORE ACCURATE TREATMENT DECISIONS FOR PATIENTS ACROSS THE GLOBE

Idylla™
A revolutionary, fully automated system that makes molecular testing convenient and exceptionally fast.
Suitable for any lab.

ABOUT THIS REPORT

The board of directors of Biocartis Group NV (the 'Company') is responsible for the contents of this document and declares that, having taken all reasonable care to ensure that such is the case, the information contained in this Biocartis annual report 2020 is, to the best of its knowledge, in accordance with the facts, contains no omissions likely to affect it materially and contains the required information in accordance with applicable Belgian Law. In accordance with Article 3:32 of the Belgian Code of Companies and Associations, the annual reports on the statutory and consolidated annual accounts have been combined.

In defining its initial sustainability disclosures, Biocartis has taken into account the Sustainable Development Goals[1] (SDG) and the Global Reporting Initiative (GRI) guidelines[2]. The SDG framework includes 17 goals which were developed by the United Nations Development Program in January 2016 and are considered to be the guiding universal sustainability framework. The GRI guidelines represent the global reference for sustainability reporting[3]. The SDG framework places more emphasis on how corporations organize and manage their activities to contribute to a more sustainable world, whereas the GRI framework focuses mainly on how to report on a company's impact. The chapter 'sustainability' in this report provides information on how sustainability is embedded in Biocartis' core activities, as well as how Biocartis acts responsibly as a company with the social and environmental resources it uses.

According to Belgian law, Biocartis must publish its annual report in Dutch. Biocartis also provides an English version. In case of difference in interpretation, the English version shall prevail. An electronic version of the annual report 2020 is available on **www.biocartis.com** under 'investors'. Other information on the website of Biocartis or on other websites is not a part of this annual report. The annual report reflects the performance and results of Biocartis in the period between 1 January 2020 and 31 December 2020. An overview of the securities legislation and listed company reporting requirements can be found on the Belgian Financial Authorities' website, **www.fsma.be**.

ABOUT BIOCARTIS

Biocartis Group NV is a limited liability company organized under the laws of Belgium and has its registered office at Generaal de Wittelaan 11 B, 2800 Mechelen, Belgium. Throughout this report, the term 'Biocartis NV' refers to the Belgian subsidiary on a standalone basis and references to 'the Group' or 'Biocartis' include Biocartis Group NV together with its subsidiaries.

FORWARD-LOOKING STATEMENT

Certain statements, beliefs and opinions in this report are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this report regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this report, those results or developments may not be indicative of results or developments in future periods. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this report as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this report or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this report.

USE OF THE IDYLLA™ TRADEMARK, LOGO AND PRODUCT LABELING

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

RESPONSIBILITY STATEMENT

The undersigned hereby declare that to the best of their knowledge: a) the annual accounts, which have been drawn up in accordance with the applicable accounting standards, give a true and fair view of the net equity, financial position and results of the Company and the companies included in the consolidation, and b) the annual report gives a true and fair view of the development and results of the business and the position of the Company and the companies included in the consolidation, as well as a description of the main risks and uncertainties they are confronted with.

HERMAN VERRELST
CHIEF EXECUTIVE OFFICER

CHRISTIAN REINAUDO
CHAIRMAN OF THE BOARD OF DIRECTORS

1.1 MESSAGE FROM THE CHAIRMAN AND THE CEO

"2020 was an extraordinary year, to say the least. The pandemic deprioritized and disrupted cancer care globally. Patient access to hospitals was significantly restricted throughout almost the entire year and customer prospection was severely hampered. Nevertheless, we showed resilience and delivered on our pre-pandemic outlook. Oncology volumes continued to grow, mostly in the US, but also in Europe, and the versatility of Idylla™ allowed the rapid rollout of a pandemic response test menu that alleviated the pressure on oncology testing volumes. Furthermore, we continued to expand our global Idylla™ ecosystem, attracted new partners and made significant operational progress on our path towards continued growth.

We look ahead with confidence and start 2021 with a better than expected cash position that we plan to put at work to accelerate test menu expansion and diversification in a year that will again be marked by continued impact of the pandemic. We are determined to serve and build on the undebated need for rapid response testing in an overburdened healthcare system, convinced that we are very well equipped to deliver on our customers' needs in oncology as well as in infectious diseases."

HERMAN VERRELST, CEO BIOCARTIS &
CHRISTIAN REINAUDO, CHAIRMAN OF THE BOARD OF BIOCARTIS

CONTINUED GROWTH THROUGH AGILITY AND RESILIENCE IN PANDEMIC TIMES

Despite the global pandemic we grew commercial cartridge volumes by 31% and placed 335 new Idylla™ instruments. We delivered on our pre-pandemic outlook in unprecedented market circumstances: global lock-down measures significantly restricted access to hospitals throughout almost the entire year and severely hampered our sales activities. Nevertheless, oncology volumes continued to grow and our newly developed Idylla™ SARS-CoV-2 Test kept us on track. In the US, we tripled commercial cartridge volumes compared to 2019. In Europe, sales volumes remained very resilient throughout the entire year. In distributor markets, that were particularly hit by the pandemic, we also managed to grow cartridge volumes, except in those countries where the pandemic impact was compounded by a significant weakening of the local currency versus the euro. Overall, we came out of this pandemic year in a position of strength thanks to our agility and resilience as an organization, and as a team.

STRATEGIC EXPANSION INTO INFECTIOUS DISEASES WITH A PANDEMIC RAPID RESPONSE MENU ON IDYLLA™

More than ever, the pandemic has demonstrated that the pressing need for rapid and easy diagnostic testing. We helped find solutions to our customers' high testing demand during this pandemic with the development of a pandemic rapid response test menu on Idylla™. The Idylla™ SARS-CoV-2 Test yielded strong demand especially in the US but also in Europe, where the CE-IVD version of the Idylla™ SARS-CoV-2 Test was launched on 10 November 2020. Together with SeptiCyte® RAPID on Idylla™, released as CE-IVD on European markets on 6 October 2020, the Idylla™ pandemic test menu was ideally positioned to alleviate the pressure on intensive care units (ICUs) and is expected to drive further growth in 2021.

GROWING THE PARTNER BUSINESS MODEL

Numerous new partners strengthened the Idylla™ ecosystem last year. On the oncology side, we were particularly proud to expand the partnership with lung cancer targeted therapy leader AstraZeneca to, amongst others, the area of liquid biopsy testing. The FACILITATE[4] study[5], performed under the framework agreement with AstraZeneca, was selected for presentation at the renowned ESMO Virtual Congress in September 2020 and concluded that Idylla™ reduced turnaround time by more than a week versus reference methods, allowing earlier patient management decisions. Another great milestone was the expansion of our partnership with BMS to now also pursue the registration of the Idylla™ MSI test as a CDx test in metastatic colorectal cancer in China. Early November, we also marked our entry in the domain of thyroid cancer with GeneproDx, a Chile-based MDx company with who we joined forces to develop an Idylla™ version of their novel genomic test ThyroidPrint®. This test helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant. Together we aim to make this test available to laboratories and hospitals around the world, to help address this high clinical unmet need in thyroid patients. On the infectious diseases side, we strengthened our partnership with LifeArc and also with Immunexpress who now also rely on us to commercialize SeptiCyte® RAPID on Idylla™ in Europe. The partnership with Endpoint Health to develop and commercialize a novel test on Idylla™ will support therapeutic decisions for critical illnesses, adding to our suite of rapid response testing in ICUs.

IDYLLA™ AS THE UNIQUE PLATFORM FOR DUAL USE

Focused on the specific needs of sepsis and COVID-19 testing in acute settings, the pandemic test menu we put together again demonstrated Idylla™'s uniqueness and versatility, providing speed and simplicity on one single platform to address the customers' needs in both oncology and infectious disease testing. Thanks to the Idylla™ pandemic test menu, we managed to get a first foothold of infectious disease testing customers in Europe and the US. In November, this set the tone for a strategy update during our Capital Markets Day event. In infectious diseases, we will build a menu focused on rapid triage and therapy selection of critically ill patients in acute settings. This menu will be based on the further development of the existing Idylla™ SARS-CoV-2 Test and the SeptiCyte® RAPID on Idylla™ as well new tests such as the Idylla™ Endpoint Test and the development of syndromic panels, one of the fastest growing MDx segments, on Idylla™. In oncology, which remains our core business, we reaffirmed our mission to help revolutionize the lung cancer testing workflow bringing numerous advantages of Idylla™ first-line testing versus traditional workflows that line up multiple testing methods, including NGS, all of which are slow and require large quantities of tissue that is often scarce. We also gear up to provide further evidence of the pan-cancer applicability of our oncology menu, for example for MSI testing, and we expressed the intent to develop new tests in endometrium, brain and thyroid cancer. We will innovate the development process of new tests through our new Idylla™ FLEX technology. Without compromising the ease-of-use of Idylla™, it is designed to deliver tests at reduced costs and lead times, while offering the customer the potential to customize and even personalize future oncology assays, which will give us an avenue into the vast market of molecular surveillance monitoring. As such, Idylla™' will cover a broad need for molecular testing supporting clinical decisions in diagnosis, therapy selection, on-therapy monitoring and post-therapy recurrence monitoring.

TOWARDS THE LARGEST MENU IN RAPID ONCOLOGY MDx TESTING

Today, we already have an outstanding menu in rapid oncology MDx testing, and our pipeline of new Idylla™ tests is expected to grow our total addressable market from 4m to over 10m tests per year. The unique combination on Idylla™ of fast time- to-result, ease of use, high and stable performance and sample versatility offers an opportunity to expand in other areas such as infectious diseases and will culminate in an unrivaled menu.

The year 2020 was undeniably challenging, but we came out more agile and more resilient and are ready to make 2021 a success. Together with our trusted customers, partners, employees, shareholders and other stakeholders, we look forward to making a difference for patients across the world by establishing Idylla™ as the go-to platform for dual use in oncology and infectious diseases.

HERMAN VERRELST
CHIEF EXECUTIVE OFFICER

CHRISTIAN REINAUDO
CHAIRMAN OF THE BOARD OF DIRECTORS

1.2 WHO WE ARE

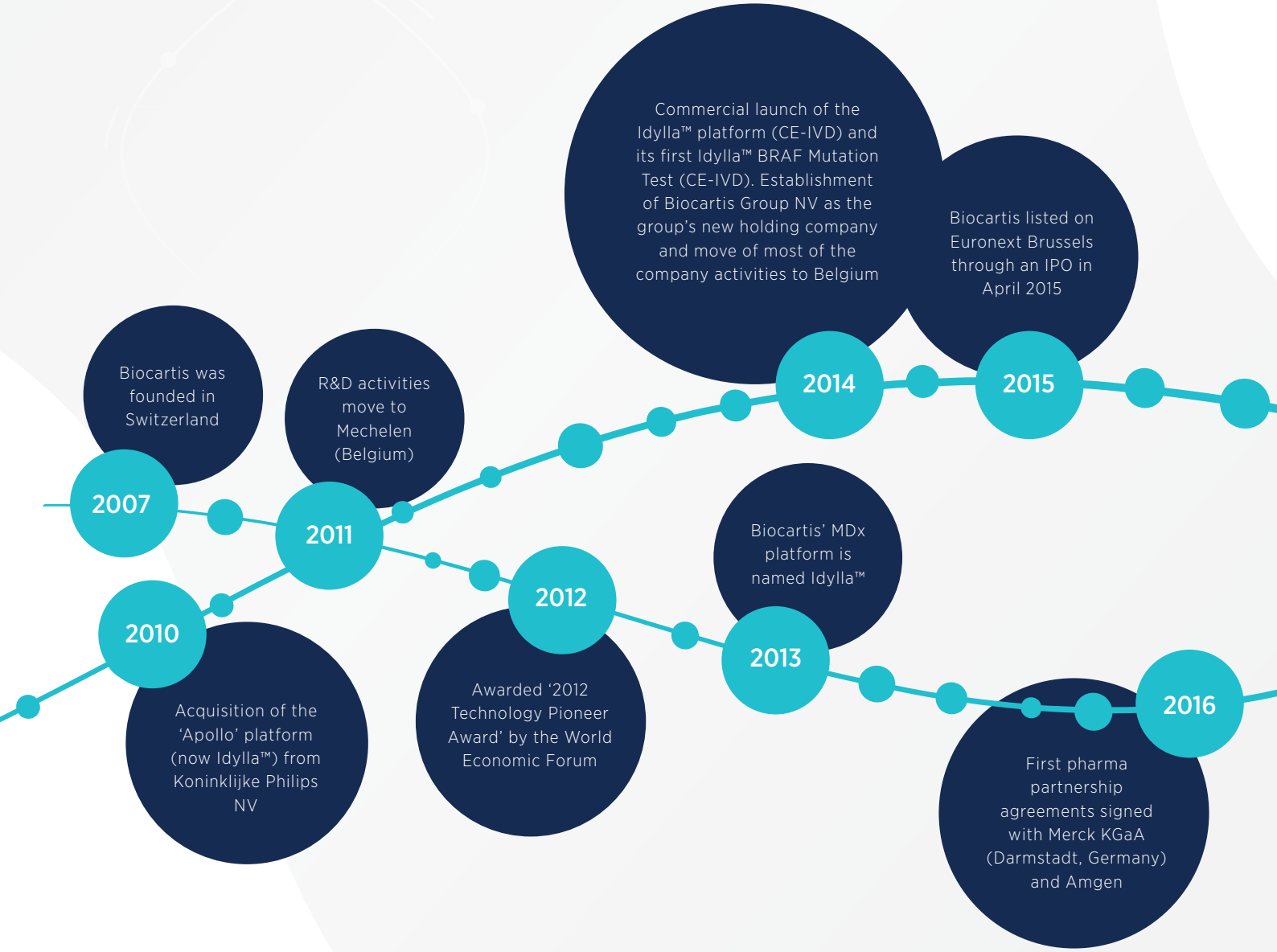
Biocartis is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions with its unique proprietary Idylla™ platform, aimed at improving clinical practice for the benefit of patients, clinicians, payers and the healthcare industry.

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

- LISTED ON EURONEXT BRUSSELS, TICKER BCART
- HEADQUARTERED IN BELGIUM (MECHELEN)
- COMMERCIALLY ACTIVE IN +70 COUNTRIES
- 366 EMPLOYEES[6]
- SOLID MENU OF ONCOLOGY TESTS
- EXPANDING IN INFECTIOUS DISEASES

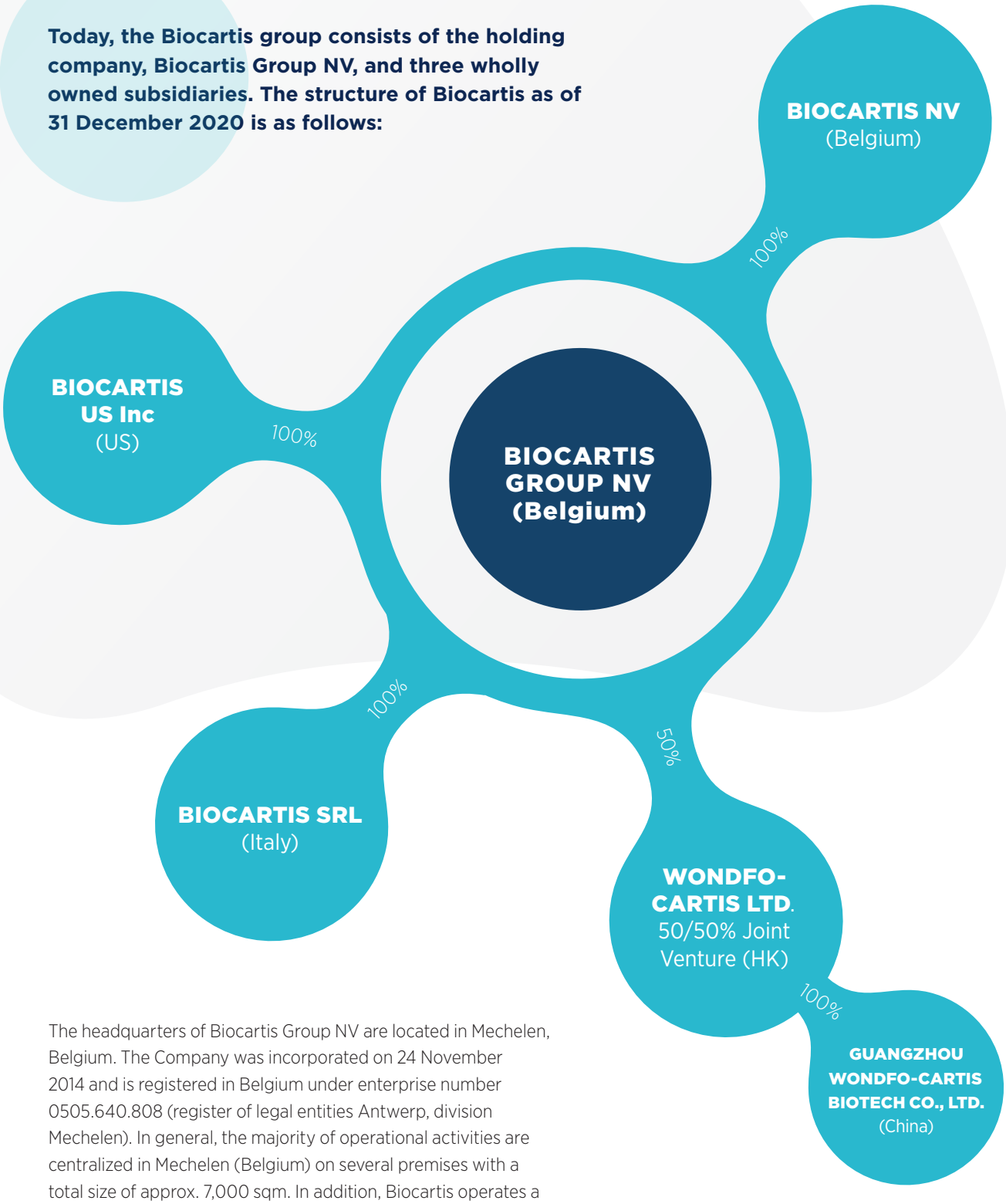
Biocartis' mission is to offer rapid and easy molecular diagnostic solutions aimed at enabling faster and more accurate treatment decisions for patients across the globe.

HISTORY


2007
Biocartis was founded in Switzerland
2010
Acquisition of the 'Apollo' platform (now Idylla™) from Koninklijke Philips NV
2011
R&D activities move to Mechelen (Belgium)
2012
Awarded '2012 Technology Pioneer Award' by the World Economic Forum
2013
Biocartis' MDx platform is named Idylla™
2014
Commercial launch of the Idylla™ platform (CE-IVD) and its first Idylla™ BRAF Mutation Test (CE-IVD). Establishment of Biocartis Group NV as the group's new holding company and move of most of the company activities to Belgium
2015
Biocartis listed on Euronext Brussels through an IPO in April 2015
2016
First pharma partnership agreements signed with Merck KGaA (Darmstadt, Germany) and Amgen


Biocartis US Inc., established in the US. Content partnership agreements signed with MRC Technology (a medical research charity), ETPL (the commercialization arm of A*STAR, Singapore's Agency for Science, Technology and Research). Biocartis signs its first CDx agreement for Amgen's drug Vectibix® (panitumumab)
2017
Partnership agreement signed with Immunexpress for the development and commercialization of Immunexpress' RAPID SeptiCypte™ test on Idylla™. Partnership agreement signed with AstraZeneca. Establishment of a joint venture with Wondfo[7], a fast growing diagnostics leader in China
2018
2019
New direct go-to-market strategy for the US market. Distribution partnership agreement signed with Nichirei Biosciences for Japan. Entry into immuno-oncology with two new partnerships, with Bristol-Myers Squibb Company (NYSE: BMY) and Kite Pharma, Inc., a Gilead Company (NASDAQ: GILD)

Today, the Biocartis group consists of the holding company, Biocartis Group NV, and three wholly owned subsidiaries. The structure of Biocartis as of 31 December 2020 is as follows:



The headquarters of Biocartis Group NV are located in Mechelen, Belgium. The Company was incorporated on 24 November 2014 and is registered in Belgium under enterprise number 0505.640.808 (register of legal entities Antwerp, division Mechelen). In general, the majority of operational activities are centralized in Mechelen (Belgium) on several premises with a total size of approx. 7,000 sqm. In addition, Biocartis operates a US office grouping commercial, regulatory and clinical activities in Jersey City (New Jersey, US). Furthermore, Biocartis' joint venture, WondfoCartis Ltd., was established in 2018 in China as a joint venture owned 50% by Biocartis Group and 50% by Wondfo Biotech (HK) Co., Ltd.

1.3 STRATEGY

1.3.1 THE MARKET OF MOLECULAR DIAGNOSTICS

The study of diseases has led to the discovery of macromolecules associated with specific diseases or treatment response. These macromolecules can be used as biomarkers and can be detected in patient samples such as blood, urine, sputum, saliva or tissue such as tumor tissue. Molecular testing or diagnostics (MDx) is the primary tool used to identify the presence of molecular biomarkers in these patient samples. In cancer, measuring the presence of a biomarker associated with a patient's tumor can provide crucial information on the applicability of a new generation of more effective targeted treatments, providing an opportunity for better health outcomes and reduced healthcare costs. Tailoring treatment to the genetic profile of a patient is part of a trend towards personalized medicine.

Speed is of the essence. Rapid access to accurate data about the relevant pathogens in infectious diseases, or about the relevant cancer mutations or treatment resistance in oncology, is vital. Early disease interception[8] reduces the anxiety while waiting for results and the time before starting the best possible treatment. In molecular diagnostics, current technologies are often complex, require a lot of hands-on time and are difficult to implement in the local laboratory. As a consequence, most laboratories do not perform molecular tests in-house, but send them out to specialized centers, where samples are batched in order to optimize costs[9]. This delays the fast delivery of results, preventing rapid initiation of the most beneficial therapy.

In the case of cancer, this means the tumor has time to grow or spread. Fast initiation of immunotherapy or targeted therapy as first-line treatment is crucial for cancer patients, as it increases overall survival rates[10]. Timely detection of biomarkers therefore is very important. Today, turnaround times of reference technologies are on average 18 days, with 14% of patients waiting longer than a month to be able to start treatment. 95% of the patients must wait more than a week in order to receive the biomarker results[11]. This means that precious time is lost whereas treatment initiation could have been started and unnecessary use of chemotherapy with its side effects could have been avoided.

1.3.2 METHODS AND TECHNOLOGIES IN MOLECULAR DIAGNOSTICS

Over the years, a variety of molecular diagnostic testing methods have been utilized in clinical diagnostic laboratories in the analysis of patient samples. Polymerase Chain Reaction or PCR, the technology on which Idylla™ is based, remains the most commonly used technique. It's a fast and inexpensive technique, replicating DNA molecules into millions of copies, thereby amplifying an attached label such that it becomes visible and allows scientists to study it in detail.

Furthermore, Biocartis is increasingly porting RNA based tests on its Idylla™ platform, such as the Idylla™ SARS-CoV-2 Test. RNA expression or gene signature tests are based on the differential mRNA expression levels that are calculated into a clinically meaningful score, namely the 'signature' that guides patient management decisions. The technology, including the complex sample preparation yielding RNA that is prone to degradation, has now been validated in Idylla™ and can be applied to hundreds of potential applications. Another increasingly popular technique the past years is next-generation sequencing or NGS, which is a technique

The worldwide COVID-19 pandemic has created an increased demand for molecular diagnostic testing. The global molecular diagnostics market is now expected to grow and reach USD 19.9 bn by the year 2027, reflecting a post COVID-19 CAGR[12] of 9.8% over the analysis period 2020 through 2027[13] .

The high prevalence of infectious diseases primarily drives growth in this market, as well as other factors such as various types of cancers, increasing awareness and acceptance of personalized medicine, the use of companion diagnostics, growth in the biomarker identification market and advancements in molecular techniques.

that uses a single format where a wide range of biological phenomena can be tested, such as, mRNA expression and methylation status. With NGS, the time between tumor sampling and the availability of results for all markers can easily run into multiple weeks. As the full genome is sequenced, NGS requires the use of different systems and many laboratories do not have these. As a consequence, samples are often shipped to external service providers, which also takes precious time of an anxious patient in desperate need of timely treatment. For many laboratories, the implementation and validation of an NGS workflow is technically too challenging. Additionally, the need for bioinformatics to generate reliable results and to interpret the massive amount of data is a big hurdle to routine use. Finally, another complexity is the fact that NGS, often in combination with other techniques consumes a significant amount of the tumor sample, which is rather scarce in certain types of cancer, such as non-small cell lung cancer. Most biopsies are small and heterogeneous and the lack of sample quality and quantity may lead to invalid results for a significant portion of the samples.

With Idylla™, customers get access to actionable markers in a comprehensive results format, offering speed, simplicity and reliable performance. Furthermore, Idylla™ only requires minimal amounts of sample so that first-line testing on Idylla™ for fast actionable results does not exclude more comprehensive NGS to maximize a patient's options and explore eligibility for clinical trials or experimental therapy. Memorial Sloan Kettering Cancer Center in New York, one of the largest NGS centers in the world, has performed several studies comparing EGFR testing on Idylla™ and NGS, demonstrating that Idylla™ allows rapid first assessment of the most common EGFR mutations preceding NGS.

1.3.3 OUR STRATEGY

Biocartis is focused on executing a profitable growth strategy that builds value in the MDx market by making personalized medicine an everyday reality.

The worldwide COVID-19 pandemic in 2020 clearly showed the undebated value of high quality, rapid and easily accessible diagnostic testing. Unfortunately, it also showed that MDx testing today still suffers from many inefficiencies, which delay results and impact patients. The Idylla™ platform provides a unique solution in this context: results available in minutes or hours instead of days or weeks, a fully automated workflow with little to no hands-on time and superior performance in one single unique and versatile platform that can be used both in oncology and infectious diseases.

Since 2017, Biocartis has mainly focused its efforts on developing and commercializing oncology tests, which resulted in a solid on-market menu of proprietary Idylla™ oncology tests in colorectal cancer, lung cancer and melanoma, and ongoing developments in breast and thyroid cancer. The Idylla™ platform offers unique features in oncology allowing to accelerate in this field. Next to ongoing efforts to have a complete lung cancer menu, we see opportunities in pan-cancer applications of our tests and expansion opportunities in new areas including endometrium, brain and hematological cancers.

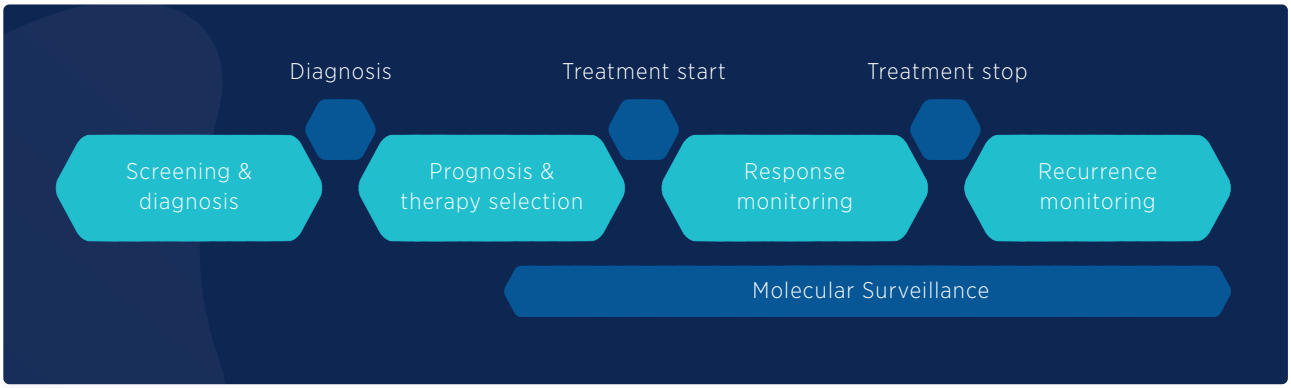
The current pandemic market conditions now also bring opportunities to grow in infectious diseases and as such accelerate the expansion of our installed base, offering this market the advantage of Idylla™'s speed and simplicity, together with the dual use for oncology testing.

ONCOLOGY STRATEGY

The oncology MDx market continues to grow rapidly due to a rise in global incidence of cancer, an increased decentralization of testing and an increased need for molecular testing as more and more targeted therapies become available. Within oncology, the Idylla™ platform is uniquely positioned in this market:

1. Idylla™ enables to combine the performance of lab reference testing with the benefits of point-of-care testing, allowing molecular testing in virtually any lab setting
2. Idylla™ enables the reduction of time-to-results from weeks to hours
3. Idylla™ offers fully automated sample-to-result capabilities for both solid and liquid biopsies

Positioned within the patients' cancer treatment continuum, the cancer patient gets confronted with cancer diagnostic testing at several moments. First, at potential screening before diagnosis, second, during diagnosis and staging itself, third, after diagnosis to determine the right therapy, and fourth, to follow up on the efficiency of the therapy. Also when monitoring potential tumor residue in the body and, if needed, to start up therapy again.



Across the cancer treatment continuum, there are five important strategic trends where Idylla™ can play a unique role:

1. **Targeted therapies:** Biocartis' current products are primarily geared at therapy selection. Especially within colorectal and lung cancer, Biocartis has built a comprehensive actionable panel of first-line tests.

2. **Pan-tumor:** An adjacent trend is the application of targeted therapies in a pan-tumor setting, where therapy selection is increasingly driven by the genetic make-up of the tumor rather than its tissue of origin within the body. This allows the use of treatments and their corresponding tests across different cancer types, which leads to a broader applicability of our Idylla™ test menu.

3. **Gene signatures:** Gene signatures have popped up as an important new class of molecular diagnostic test, offering applications beyond therapy selection, such as cancer risk or prognostics. The value of these tests is potentially high, but their development and validation is long and costly. As such, Biocartis is tackling these developments through a partnership strategy; partnerships where an already validated, proprietary, high-value oncology gene signature test is ported onto the Idylla™ platform. The growing Idylla™ installed base then facilitates the global roll-out of these high-value gene signature tests.

4. **Immuno-oncology:** This is a rapidly rising new class of cancer treatments, based on therapies that harness the immune system to fight cancer. In particular, Biocartis aims at a test menu for two major therapeutic classes: immune checkpoint inhibitors and cell-based therapy. The three primary components of this menu include (1) MSI validation for immune checkpoint inhibitor selection in colorectal cancer and later pan-cancer settings, (2) immune signatures that provide information about the immune system's activity within a tumor, and (3) tests that can predict the response or resistance of the tumor to immune therapies.

5. **Liquid-biopsy based monitoring applications:** Liquid biopsy testing continues to gain a lot of momentum. Today, it is already being used for therapy selection when insufficient tumor tissue is available. Beyond diagnosis, liquid biopsy can also be used in prognosis and therapy response. Within liquid biopsy, Biocartis will focus on key applications where Idylla™'s speed is required and thus represents a critical competitive advantage, including on-therapy monitoring and post-treatment MRD (Minimal Residual Disease) assessment for solid tumors, as well as select long-term recurrence monitoring applications in hematological cancers where guidelines already exist.

The diversity of Biocartis' oncology strategic roadmap is further supported by Biocartis' ambition to enter new high-growth oncology segments, both in its existing as well as new oncology areas.

- **Existing oncology areas:** development of additional Idylla™ tests in lung cancer and maximize the use of its existing products through the expansion of the intended use of the current Idylla™ oncology product portfolio. An example here is the potential use of the Idylla™ MSI Assay beyond colorectal cancer, based on the clinical value of MSI testing for endometrial cancer, gastric cancer, ovarian cancer and pancreatic cancer[14].

- **New oncology areas:** development of new Idylla™ tests in the domains of brain, breast and endometrium cancer and in the field of hematology.

Supported by the above-mentioned diversification strategy in oncology, in combination with geographical expansion, Biocartis aims to build the largest menu in rapid oncology molecular diagnostic testing in the years to come. More information on the Idylla™ test menu can be found in the Biocartis corporate presentation on the Biocartis investor website.

INFECTIOUS DISEASE STRATEGY

The pandemic context in 2020 brought about a higher need for decentralized molecular diagnostic testing, which matches Biocartis' ambition to more rapidly build an installed base in acute settings such as the intensive care unit (ICU). The current Idylla™ pandemic menu is geared towards:

- **COVID-19:** The Idylla™ SARS-CoV-2 Test (CE-IVD) is targeted to help healthcare providers manage the pandemic through rapid and easy testing of individuals with flu-like symptoms;

- **Sepsis:** Sepsis is a field with high unmet needs and where current markers such as blood cultures are not rapid or are non-specific and there is an increased risk in pandemic times. The SeptiCyte® RAPID on Idylla™ is a host-response test that distinguishes sepsis from non-infectious systemic inflammation in patients. When used together, this combined testing solution on Idylla™ has the unique potential to identify patients with severe disease, as recent data[15] indicate that sepsis is the most frequently observed complication in COVID-19[16].

As such, this pandemic test menu on Idylla™ is a steppingstone towards a broader Biocartis' infectious disease menu, aimed at supporting the patient journey with easy and rapid Idylla™ testing in acute settings, including rapid triage and therapy selection for critically ill patients. Furthermore, Biocartis sees that Idylla™'s unique multiplexing platform capabilities can bring clear unique benefits in the area of syndromic panel testing, one of the fastest growing MDx segments.

LEVERAGING THROUGH PARTNERSHIPS

A key strategic element for Biocartis is to accelerate its menu expansion through partnerships:

- **Partnerships with pharmaceutical and biotech companies:** Focusing on the (joint) development and registration of CDx tests on the Idylla™ platform. This is expected to allow Biocartis to reach faster commercial adoption as well as high market shares. Biocartis' partners are expected to benefit from an increased number of eligible patients for their targeted therapies driven by the key benefits of the Idylla™ platform: fast turnaround times, thereby reducing competition with therapies not requiring a biomarker and higher penetration of the potential market due to higher access to testing with Idylla™.

- **Partnerships with diagnostic test content partners:** Aiming at transfer of proprietary biomarker panels of partners, in most cases already developed and clinically validated, to the Idylla™ platform. By doing so, Biocartis adds proprietary content to its menu that will further increase the attractiveness of the Idylla™ test menu. Driven by its unique features, partners are expected to benefit from an accelerated global roll-out of their content, cost efficiencies and faster customer adoption since no platform education is needed.

- **Partnerships with diagnostic test development partners:** Targeting the development of Idylla™ tests, predominantly in collaboration with IVD developers. This allows Biocartis to reduce initial test menu development costs while benefiting from the collective knowledge of its development partner. Through such collaborations, partners can further contribute to medical innovation as well as benefit from knowledge sharing and building.

More information on the Idylla™ test menu can be found in the Biocartis corporate presentation on the Biocartis investor website.