Biocartis 2018 results, 2019 outlook and menu strategy

28 February 2019



Today's presenters



Simone Marticke Strategy Lead



Ewoud Welten Chief Financial Officer



Herman Verrelst Chief Executive Officer

NOTICES AND WARNINGS

This presentation has been prepared by the management of Biocartis Group NV (the "Company"). It does not constitute or form part of, and should not be construed as, an offer, solicitation or invitation to subscribe for, underwrite or otherwise acquire, any securities of the Company or any member of its group nor should it or any part of it form the basis of, or be relied on in connection with, any contract to purchase or subscribe for any securities of the Company or any member of its group, nor shall it or any part of it form the basis of or be relied on in connection with any contract or commitment whatsoever. It is not a prospectus or offering memorandum.

The information included in this presentation has been provided to you solely for your information and background and is subject to updating, completion, revision and amendment and such information may change materially. No person is under any obligation to update or keep current the information contained in this presentation and any opinions expressed in relation thereto are subject to change without notice. No representation or warranty, express or implied, is made as to the fairness, accuracy, reasonableness or completeness of the information contained herein. Neither the Company nor any other person accepts any liability for any loss howsoever arising, directly or indirectly, from this presentation or its contents.

This presentation includes forward-looking statements that reflect the Company's intentions, beliefs or current expectations concerning, among other things, the Company's results, condition, performance, prospects, growth, strategies and the industry in which the Company operates. These forward-looking statements are subject to risks, uncertainties and assumptions and other factors that could cause the Company's actual results, condition, performance, prospects, growth or opportunities, as well as those of the markets it serves or intends to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. The Company cautions you that forward-looking statements are not guarantees of future performance and that its actual results and condition and the development of the industry in which the Company operates may differ materially from those made in or suggested by the forward-looking statements contained in this presentation. In addition, even if the Company's results, condition, and growth and the development of the industry in which the Company operates are consistent with the forward-looking statements contained in this presentation. In addition, even if the company's results, condition, and growth and the development of the industry in which the Company operates are consistent with the forward-looking statements contained in this presentation. In addition, even if the company's results, or developments may not be indicative of results or developments in future periods. The Company and each of its directors, officers and employees expressly disclaim any obligation or undertaking to review, update or release any update of or revisions to any forward-looking statements are based, except as required by applicable law or regulation.

This document and any materials distributed in connection with this document are not directed to, or intended for distribution to or use by, any person or entity that is a citizen or resident or located in any locality, state, country or other jurisdiction where such distribution, publication, availability or use would be contrary to law or regulation or which would require any registration or licensing within such jurisdiction. The distribution of this document in certain jurisdictions may be restricted by law and persons into whose possession this document comes should inform themselves about, and observe any such restrictions.

The Company's securities have not been and will not be registered under the US Securities Act of 1933 (the "Securities Act") and may not be offered or sold in the United States absent registration under the Securities Act or exemption from the registration requirement thereof.





- 1. 2018 business review
- 2. Idylla[™] menu strategy
- 3. 2019 outlook
- 4. Q&A



2018 business review



Fully automated molecular testing with Idylla[™]





Superior sensitivity and ease-of-use, combined with sample to result turnaround time of 90 to 150* minutes

* Based on turnaround times of current on-market oncology tests

BIOCARTIS

Platform and consumable driven business model



- Commercial footprint
- Commercialization partnerships

- Menu of tests
- Regulatory registrations

- Reimbursement
- Competitive advantage

Gross margin driven by

- Volume
- Manufacturing automation



Key messages FY 2018 results

Growth of installed base to over 970 instruments Installed base 133k Idylla[™] cartridges, year-over-year increase of approx. 87% Cartridge volume Increased year-over-year with 46% to EUR 18.8m Product revenues Increased year-over-year with 24% to EUR 28.7m Total operating income EUR 64m per end 2018 Cash position Promising initial market adoption of the Idylla[™] MSI Test² Test menu Expansion partnership with Genomic Health and new collaboration with Partnerships AstraZeneca Successful first commercialization year in US, go-to market strategies Geographical expansion established for China and Japan



Strong continued placements & volume growth



Installed base (in *#* instruments)

- 326 instruments added in 2018, exceeding latest guidance of 300
- Majority of placements realized in European and US markets
- Installed base milestone of 1,000 instruments crossed early 2019

Commercial cartridge volume (x 1,000)



- Commercial cartridge volume of approx. 133k, in line with the latest 2018 guidance of 130k – 135k cartridges
- Year-over-year increase of approx. 87%, Europe followed by RoW¹ contributed most to the absolute volume growth

Delivering solid performance across markets

Europe

- Increase in installed base above expectation
- Strong ramp-up of commercial cartridge volumes due to:
 - Increased Idylla[™] usage in first line testing
 - Strong overall contribution from pharmaceutical collaborations
 - Launch Idylla[™] MSI Test¹

BIOCARTIS

- First full commercialization year
- Realization of promising initial US installed base driven by:

US

 Platform adoption at high profile customers such as



Cancer Center...

 Publication of several US Idylla[™] performance studies of which 8 were presented at AMP²

- RoW³
- Strong ramp-up in cartridge volumes driven by:
 - 57 new market authorizations for Idylla[™] products across 18 geographies
 - Strategic focus on geographies that are of interest to pharmaceutical partners

Product revenues increased with 46% in 2018

		· · · ·
By product	2018	2017
Idylla™ System sales	4,185	4,620
Idylla™ Cartridge sales	14,658	8,316
Product sales revenue	18,843	12,936
By type	2018	2017
Commercial revenue	17,843	12,748
R&D revenue	1,000	187
Product sales revenue	18,843	12,936

Breakdown product revenues (in EUR 1,000)

In EUR 1,000	2018	2017
Product sales revenue	18,843	12,936
Collaboration revenue	8,329	7,739
Service revenue	639	282
Total revenue	27,811	20,957
Grants and other income	840	2,153
Total operating income	28,651	23,110

Breakdown total operating income



2018 operating result of EUR -47m

Condensed income statement			
In EUR 1,000	2018	2017	
Total operating income	28,651	23,110	
COGS	(15,349)	(8,673)	
R&D expenses	(36,842)	(39,594)	
S&M expenses	(15,349)	(11,600)	
G&A expenses	(7,971)	(6,832)	
Total operating expenses	(75,511)	(66,699)	
Operating result	(46,860)	(43,589)	
Net financial result	(1,402)	(1,736)	
Income taxes	109	3,365	
Net result	(48,153)	(41,960)	



Cash position of EUR 64m end of 2018

Condensed cash flow statement

In EUR 1,000	2018	2017
Result for the period	(48,153)	(41,960)
Depreciation and amortization	4,273	5,096
Impairment losses	3,456	0
Working capital changes	(3,797)	(2,841)
Other adjustments	2,228	(1,700)
CF operating activities	(41,993)	(41,405)
CF investing activities	(5,820)	(4,320)
CF financing activities	(1,508)	75,256
Total net cash flow	(49,320)	29,531
Cash and cash equivalents ¹	63,539	112,765
Financial debt	35,335	35,388

1. Including EUR 1.2 million restricted cash related to KBC Lease financing

Remarks

- Cash flow from operating activities slightly lower as result of:
 - A lower net result for 2018
 - o Increased investments in working capital
 - Increased (non-cash) adjustments in 2018 due to impairment losses and an one-off income statement impact in 2017 related to a tax adjustment

Cash flow from investing activities:

- Consists of capitalization of Idylla[™] instrumentation as well as investments in laboratory and manufacturing equipment
- $_{\odot}\,$ Note: 2018 investments for cartridge manufacturing expansion were directly paid for via lease financing
- Cash flow from financing activities consisted of repayments on borrowings
 partially offset by proceeds from the exercise of warrants
- Net cash flow of EUR -49.3m, resulting in a cash position per year-end of EUR 64m. Note: due to the capital raise in January 2019, the cash position as per end January 2019 amounted to over EUR 110m (unaudited figure)



Successful EUR 55.5m capital raise in January 2019

Placement details

- Gross proceeds of EUR 55.5m by means of a private placement via an accelerated bookbuild offering
- Raised from high quality institutional investors, both existing and new international investors, from both Europe and the US
- New shares represent approx. 9.73% of the Company's share capital immediately prior to the capital raise
- One of the first equity capital markets transaction of the European Life Sciences and Healthcare industry in 2019

Ewoud Welten, Chief Financial Officer of Biocartis, commented:

"Today's oversubscribed private placement further strengthens the capitalisation of Biocartis. We are pleased to see that even in challenging market conditions, both existing and new international institutional investors continue to support Biocartis in the further execution of its business plan. That is a great motivator to our teams and partners as well as a strong recognition of the progress that Biocartis has made over the last year."



Go-to market strategies in place for China & Japan

Chinese go-to market strategy

ll/ondfo

- · Joint venture established with Wondfo for Chinese market
- Chinese MDx market one of fastest growing in the world²
- Wondfo (SHE:300482) is a fast growing diagnostics leader in China with focus on POC¹ testing, listed on Shenzhen Exchange (current market capitalization of USD ~1.3bn) with revenues in 2017 of ~ USD 160m
- Joint venture structure: 50%-50% ownership. Capital commitment of EUR 14m, split between parties and over several tranches
- Focus on local manufacturing, commercialization & registration with Chinese Regulatory Authorities of existing Idylla[™] oncology tests

Japanese go-to market strategy



- Commercialization agreement with Nichirei Bioscience for Japanese market
- Japanse MDx market is one of the largest in the world, representing around 10% of global MDx market¹
- Part of Nichirei Corporation (TYO: 2871), a holding company with an annual turnover of ${\sim}4~550~billion^2$
- Nichirei Bioscience to seek regulatory approval of Idylla[™] platform and its oncology tests with Japanese Ministry of Health, Labor and Welfare
- Upon successful registration, Nichirei Bioscience's sales force will distribute the Idylla[™] platform across its commercial network of approx. 2,000 pathology laboratories in Japan



Expansion of strategic collaboration with Senomic Health^{*}

Background collaboration

- Focused on exclusive test development of proprietary Genomic Health tests on the Idylla[™] platform
- Aimed at accelerating adoption and market access around the world of Genomic Health's tests
- First test to be developed on Idylla[™] is the Oncotype DX Breast Recurrence Score[®] test, second test is the Oncotype DX Genomic Prostate Score[®] Test

Oncotype DX Breast Recurrence Score[®] Test

- Examines the activity of 21 genes in a patient's breast tumor tissue to provide personalized information for tailoring treatment based on the biology of their individual disease.
- Only test proven to predict chemotherapy benefit
- Included in all major cancer guidelines worldwide and is now considered standard of care for early-stage breast cancer.

Background Genomic Health

- A leading provider of genomic-based diagnostic tests in cancer with revenues of USD 377m in 2017
- Based in California (US) and listed on NASDAQ (GHDX) with a market cap of approx. USD 2.97bn
- On-market tests for breast, prostate and colon cancer, currently offered through own service laboratories

Oncotype DX Genomic Prostate Score[®] Test

- Examines the activity of 17 genes in a patient's prostate biopsy sample to provide information on the aggressiveness of their individual disease
- Predicts risk of metastasis and helps to make better informed & more personalized treatment decisions
- Has been validated in > 4,500 patients, which is described in 18 publications

New pharma collaboration with AstraZeneca aimed at faster lung cancer biomarker results

Partnership details

- AstraZeneca is a global science-led biopharmaceutical company (LON: AZN)
- Agreement announced on 29 November 2018
- A prospective lung cancer study with the Idylla[™] EGFR Mutation Test (CE-IVD) will be conducted in selected European countries, aimed at demonstrating how the unique features of the Idylla[™] platform can overcome current complexity and long turnaround time for lung cancer patients by delivering accurate biomarker results faster and easier
- Study will be initiated at more than a dozen sites in Belgium, France, Germany and Italy

Background

- Lung cancer is most common cancer worldwide, contributing for 13% of all cancer types¹
- In total, 85% of lung cancers are non-small cell lung cancers (NSCLC)². Many lung cancers are driven by mutations in the epidermal growth factor receptor (EGFR), which occur in 10-15% of NSCLC patients in the US and the EU, and 30-40% of NSCLC patients in Asia³
- Current molecular testing of lung cancer samples is complex, also because obtaining high quality tissue samples is difficult. Results can take up to several weeks⁴, often because many laboratories do not have the necessary infrastructure to perform complex tests and need to send out their samples



1 Navani et al., Lancet Respir Med (2015). 2 American Cancer Society. Global Cancer Facts & Figures 2nd Edition (2011). 3 Website AstraZeneca. 4 Neal I. Lindeman et al. Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors, Guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology (2014)

Launch IdyllaTM CE-IVD MSI Test

Background MSI

- MSI is the abbreviation of Micro Satellite Instability
- MSI is the result of inactivation of the body's socalled DNA mismatch repair (MMR) system.
 Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, contributing to tumor growth and evolution
- MSI testing is included in international guidelines for colorectal cancer, but is present in several other tumor types as well, such as gastric & endometrial cancer
- MSI is an independent factor that may predict a patient's response to certain immunotherapies



The Idylla[™] MSI Test¹

 Includes novel set of 7 MSI biomarkers⁵, exclusively licensed to Biocartis² in 2013

• Unique characteristics:

- o Fully automated
- Fast and accurate information on MSI status in colorectal cancer directly from FFPE tissue without the need for matched normal samples³
- $\circ~$ High concordance (> 97%) and lower failure rates compared to standard methods 3
- No need for paired normal tissue testing
- Unbiased results reporting for a variety of cancer types independent of ethnicities³
- Expected to overcome drawbacks of conventional MSI testing, making MSI testing available to a larger patient population

Key addition to Biocartis' colorectal cancer menu



1 The Idylla[™] MSI Test was launched as a CE-IVD marked test on 28 February 2019. 2 From VIB, the life sciences research institute in Flanders (Belgium), and originated from the research of the group of Prof. Diether Lambrechts (VIB-KU Leuven, Belgium). 3 Clinical Performance Study showed 99,7% concordance for MSI testing vs Promega (unpublished data); De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268; De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639)>. 4 FFPE = formalin fixed, paraffin embedded. 5 Consisting of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2 genes.

High volume second cartridge manufacturing line



- Located in Mechelen (Belgium), providing an additional annual capacity of over 1,000,000 cartridges
- Fully automated assembly workstations (versus a semi-automated on first line with an annual capacity of over 200k cartridges)
- Plastic parts manufactured with new multi-cavity moulds (versus single cavity on first line)
- Operational since end of 2018
- Key driver in further reduction of cartridge unit costs

Strengthening of management team

Piet Houwen Chief Operating Officer

Responsibility	 Manufacturing and supply chain Cross-company initiatives and organizational development 	
Background	 + 25 years experience in various operational and general management roles Strong track record in manufacturing, process engineering, project and people management Was Chief Operations Officer at Ablynx and held global roles for Sanofi/Genzyme and Janssen Pharmaceuticals Holds a Master's Degree in Mechanical Engineering from the Delft University of Technology (The Netherlands) 	



Idylla™ test menu & strategy update



Uniquely positioned in attractive oncology MDx market

Fast growing market

- Represents 19% of the USD 6.5bn total MDx market in 2016¹
- Fastest growing segment in MDx, expected to grow 26% per annum (doubling of market) to 2020²
- Global incidence ~18.1bn; growing at ~2.5% per annum³
- Increased need for MDx testing:
 - o Broader availability of targeted therapies
 - Significant clinical pipeline targeted therapies: in 2015,
 >800 cancer treatments were in development in the US⁴,
 ~70% has potential to be personalized medicines⁵
 - Addition of new application areas: immuno-oncology, liquid biopsy testing, etc.
- Growth of decentralized market (i.e. underpenetrated customer potential)

Idylla[™] unique selling points



- 1 Ability to combine advantages of pointof-care testing with performance of lab reference testing: enabling MDx in virtually any lab setting
- 2 Reduction of time-to-result from weeks to hours
- **3** Sample-to-result (i.e. full automation) capabilities for:
 - Solid biopsies: FFPE^{6*}, FNA^{7^}, fresh samples[^]
 - Liquid biopsies: Plasma*, whole blood^, urine^



Onco MDx

Market trends drive oncology menu strategy





Building blocks Idylla™ menu expansion strategy





Targeted therapies: towards actionable 2-cartridge menus and pan-cancer applications

Cancer-specific applications Pan-cancer applications 2-cartridge menus for current cancer markets New areas Core tests of cancer-specific menu are applicable for pan-• cancer applications Enhanced development capabilities allow for Development of new higher number of targets in one Idylla[™] cartridge tests for additional cancer types e.g.: Opportunity to offer actionable 1st line menus • based on two Idylla[™] cartridges only: Breast cancer Gastric cancers \bigcirc • Hematological KRAS/NRAS/BRAF cancers MSI menu Validation existing • menu for additional Idylla™ cartridge Select potential applications EGFR/BRAF+ (DNA-based) sample types Breast, endometrial, cervical GeneFusion (RNA-based) KRAS/NRAS/BRAF • • MSI Gastric, prostate, endometrial •

• Gastro-intestinal, breast

Efficient access to pan-cancer setting (validation of existing menu)

GeneFusion (NTRK)

•

Comprehensive actionable 1st-line menu in 2-cartridge format allows for higher market shares and gross margins

BIOCARTIS

Immunotherapy: towards menu serving major therapy classes





Prevent tumor from hiding from the immune system

- Immune cells can fight cancer
- Cancers can hide from immune cells
- Immune checkpoint inhibitors such as Keytruda^{®1} prevent this hiding
- Such inhibitors often act pan-cancer





Idylla™ for immune checkpoint inhibitors	Idylla™ for both major therapeutic classes	Idylla™ for cell therapy
Idylla™ MSI test	Idylla [™] Hot-Cold signature	Idylla™ test(s) for patient management
 May be validated for immunotherapy (i.e. immune checkpoint inhibitors) selection 	 Is the immune system already fighting this cancer? Does it need to be enabled? 	Cell therapies are highly successfulTherapy cost (e.g., hospitalization) and side
Initial focus on CRC immunotherapyPan-cancer validation in the future	Idylla [™] immunotherapy resistance test • Is the tumor resistant to immunotherapy?	effects create high need for rapid patient management around treatment

Growth in emerging therapeutic areas. Address testing needs of major immuno-therapies and leverage menu toward pan-cancer applications

Monitoring: liquid biopsy testing for on- and post-therapy monitoring

Liquid biopsy testing	Idylla™ liquid biopsy and monitoring menu		
Access genetic tumor information via	Cancer care continuum	Menu focus	
liquid samples: ○ Blood ○ Urine	Pre-diagnosis • Inherited risk • Screening / early detection	 Therapy selection Liquid biopsies complement solid biopsy menu Focus: if tissue not available at diagnosis or at progression 	
SalivaAdvantages over solid biopsy testing	Pre-therapy • Prognostics / stratification • Therapy selection 1	Response monitoring and post-therapy MRD ¹	
 Less invasive Less expensive Less sampling bias 	Treatment Start On-therapy • Response monitoring • Resistance monitoring	 Focus: applications that require Idylla[™] speed and are backed by growing evidence of clinical utility: On-therapy monitoring Post-treatment MRD¹ 	
More repeatableReal-time mutation status	Treatment Stop • Post-therapy MRD1	 Population: Mid and late stage patients across most cancer types 	
 Improved detection of low burden disease Earlier and more accurate than current protein tests; earlier than imaging Advantage for MRD¹, recurrence 	Post-therapy • Recurrence monitoring Relapse • Therapy selection • Recurrence management • Therapy selection	 Recurrence monitoring Focus: on hematological cancers (e.g., CML²) as these are established markets (i.e. guidelines inclusion) Population: long-term therapy and recurrence monitoring 	
monitoring A high volume menu for repeat-testing applications that require Idylla™'s unmatched turn-around-time. Address testing needs across early and late stage cancers for a range of major cancer treatments. Access new customer base: hemato-oncologists and blood testing laboratories			

Gene signatures: high value and volume menu developed by partners

Market landscape

- Growing number of tests
 - Driven by genomic discovery and validation efforts over past decade
- Broad range of testing applications
 - Prognostic, risk stratification, screening tests, etc.
 - Tests are generally cancer-specific

Diverse cancers and sample types

- On-market or in development for many solid and hematological cancers
- Solid & liquid samples

Example collaboration Genomic Health

Senomic Health

- Merilet les der in bresst
- Market leader in breast, urology cancer

Test selection criteria

- Focus on oncology tests
- Clinically validated content
 - Increases barrier to entry for competitors

High clinical utility and reimbursement

• Provides attractive pricing and fast market adoption

High volume applications

- Large addressable population
- High market share potential
- Repeat testing

Idylla[™] opportunity

- Additional cancer franchises
 - Complementary menu (e.g. breast cancer)
- Expansion into new customer segments
 - General oncology
 - Oncology sub-specialties within urology, dermatology, hematology...
- Broader commercial footprint
 - Commercialization supported by sales network partner
- Development mainly partner-funded

- Biocartis development partner
 - Clinically validated
 - ✓ High reimbursement
 - Attractive volumes

- Breast: launch 2020
- Urology franchise opportunity
 - \circ Initial focus on prostate cancer

Complementary menu with proprietary high value and volume tests with a focus on existing and potentially additional customer segments



Idylla™ addressable market potential



BIOCARTIS

+ Depicts annual long term addressable IdyllaTM cartridge volume potential. Based on management estimates. Focused on Europe, US and Japan (excluding China and RoW), For indicative purposes only, 1. Based on incidence / prevalence, potential eligibility (e.g., according to tumor stage and treatment) and # tests / patient. 2. Based on incidence and current / potential guideline testing eligibility for cancer types where immune checkpoint inhibitors and cell therapies are most relevant. 3. Based on incidence and incidence and current / anticipated cancer types where immune checkpoint inhibitors and cell therapies are most relevant. 3. Based on incidence and incidence and current / anticipated cancer guidelines for CRC, lung, and skin cancer. 4. Based on current partner content collaborations and addition of new content that could benefit from IdyllaTM dependent on partnerships. 5. MRD = Minimal Residual Disease 29

2019 outlook



Guidance 2019



Targeting installed base growth in 2019 of 350 new instrument placements, bringing the total installed base to over 1,300 Idylla[™] instruments by year-end



Targeting a commercial volume of 210k-225k Idylla[™] cartridges in 2019, representing a yearover-year increase of around 60%-70%



Targeted cash position in the range of EUR 55m – EUR 65m by 2019 year end, excluding drawdowns on the Company's multiple purpose credit facility.



Short term **menu outlook** (selection)

Area	Test	Timing
	• CE-marking Idylla™ MSI Assay	• Q1 2019 🗸
Colorectal	• US FDA 510(k) submission Idylla™ MSI Test	• 2020
cancer	• Submission of Idylla [™] RAS PMA ¹ documentation with US FDA	• 2020
	 Launch Idylla[™] ctEGFR Assay (RUO²) 	• Mid-2019
Lung cancer	 Launch Idylla™ GeneFusion Panel 	• 2020
Breast cancer	 Start European validation studies Idylla[™] Oncotype DXi IVD Breast Recurrence Score[™] test 	• H2 2019
Dicust currect	 Launch of the Idylla[™] Oncotype DXi IVD Breast Recurrence Score[™] test in Europe 	• 2020

Financial **Calendar** 2019

- Publication 2018 annual report
- Q1 2019 Business Update
- Annual General Meeting
- H1 2019 results
- Q3 2019 Business Update

- 4 April 2019
- 25 April 2019
- 10 May 2019
- 5 September 2019
- 14 November 2019







