5 MARCH 2020

FY 2019 results & 2020 outlook





TODAY'S PRESENTERS



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- 1. Commercial highlights 2019
- 2. Business review 2019
- 3. Financial results 2019
- 4. Outlook 2020
- 5. Q&A



FULLY AUTOMATED MOLECULAR TESTING WITH $IDYLLA^{{\scriptscriptstyle\mathsf{TM}}}$





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



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BIOCARTIS

MARKET TRENDS DRIVE ONCOLOGY MENU STRATEGY



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TOWARDS AN IDYLLATM ECOSYSTEM







Commercial highlights 2019



CONTINUED INSTALLED BASE & CARTRIDGE VOLUME GROWTH

Installed base (in # instruments)



- 337 Idylla[™] instruments added in 2019, to a total installed base of 1,310 end 2019
- Continued installed base growth in EU and US and strong ramp-up in new placements in RoW¹ markets
- Initial instruments were placed in China

Commercial cartridge volume (x 1,000)



- Commercial cartridge volume increased to 175k, year-over-year volume growth of 32%
- The EU & RoW¹ markets contributed most to the absolute volume growth
- Promising pick-up in US cartridge volume was realized in Q4 2019



NEW US GO-TO-MARKET STRATEGY

Description US go-to-market strategy

- Joint termination of distribution collaboration with Fisher Healthcare on 5 September 2019
- Biocartis' US direct sales team to drive commercialization going forward
- Focus on large tier 1 pathology labs where Idylla[™] adds value as rapid & easy targeted method complementary to other technologies such as NGS



Activities H2 2019

- All customers successfully transitioned from Fisher Healthcare to Biocartis
- Actions to address amongst others US market specific operational lessons learned were implemented:
 - Strengthening of US direct sales team
 - Increased US customer support for Idylla[™] integration within standard operational procedures
 - Roll-out US-specific enhancements to Idylla[™] platform software
- Promising pick-up of US cartridge volume was realized in Q4 2019
- Addition of new tier 1 high profile US Idylla[™] users



NGS = Next Generation Sequencing. PCR = Polymerase Chain Reaction.

The graph implies the use of PCR as a rapid & easy to use technology for fast actionable results in first line testing ('1') and the use of a large panel NGS for comprehensive genomic coverage in 2nd line testing

CONSISTENT PERFORMANCE IN EU & ROW MARKETS

Europe

- Good & consistent installed base & cartridge volume performance
- Driven by continued growing Idylla[™] use in 1st line testing, predominately by larger laboratory customers in Western Europe
- Solid expansion into the medium-sized lab segment amongst others in South-EU

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Solid performance in cartridge volume growth

RoW¹

- New instrument placements
 exceeded expectations
- Performance driven by active commercialization in + 50 countries
- Strong network of local distribution partners, supported by pharma partners collaborations

- Joint venture established with Wondfo² in China³
- Completion of closing of the establishment of the JV in Q1 2019 led to first capital contributions & license payment to Biocartis
- Initial focus JV: local manufacturing & product registrations

Commercialization agreement with Nichirei Biosciences⁴

Japan

- Completion of registration of Idylla[™] Instrumentation with PMDA in Japan⁵ in October 2019
- Nichirei Biosciences can now offer Idylla[™] platform & RUO assays to local pathology labs, while progressing IVD registration preparations for the Idylla[™] assays



China

26 IDYLLA™ PUBLICATIONS & MULTIPLE STUDY ABSTRACTS IN 2019

Europe

- 19 new Idylla [™] performance publications¹, of which 5 Idylla[™] study abstracts were selected for publication at ESMO² congress and multiple study abstracts were selected for national conferences
- All studies published at ESMO demonstrated excellent performance of Idylla[™] compared to other methods, in combination with ease of use and fast turnaround time of Idylla[™] platform
- Studies included, amongst others, Idylla[™] MSI Assay (RUO³) and prototype of the Idylla[™] ctEGFR Mutation Assay (RUO)

US

- 5 new Idylla[™] publications and 6 study abstracts were selected for publication at the USCAP congress
- One study abstract was selected for ASCO⁴ congress
- Five study abstracts were selected for AMP⁵ congress:
 - All study abstracts showed a strong performance of Idylla[™] assays (RUO) compared to other methods including IHC⁶ and NGS⁷ in terms of concordance⁸, ease of use, workflow automation and turnaround times
 - Some studies researched Idylla[™]'s capability to analyze different sample types and smaller sample quantities



1 Not including two publications of which the epub version was published in 2019, ahead of the print version in 2020

2 The European Society for Medical Oncology ('ESMO') congress that took place between 27 September and 1 October 2019 in Barcelona (Spain) 3 RUO = Research Use Only, not for use in diagnostic procedures 4 The American Society of Clinical Oncology (ASCO') Annual Meeting took place between 30 May and 4 June 2019 in Chicago (IL), US 5 The Association for Molecular Pathology (AMP) conference took place between 7 and 9 November 2019 in Baltimore, Maryland, US 6 Immuno-histochemistry is often used to assess the MSI status. MSI is useful for screening patients for Lynch syndrome, and has become a predictive marker for response to immunotherapy

7 Next-Generation Sequencing or NGS is a technology for determining the sequence of DNA or RNA to study for example specific genetic alterations in patients with cancer. Source: NCBI, Jan-Dec 2018, last consulted on 3 March 2020 8 For more details, we refer to the abstracts for more details on https://doi.org/10.1016/S1525-1578(19)30391-5

SOLID COMMERCIAL KPI's

Product sales	 Product sales revenues increased year-over-year with 29% to EUR 24.2m Of which cartridge revenues EUR 18.0m & instrumentation revenues EUR 6.2m
Cartridge ASP ¹	 Intrinsic commercial selling prices for assay remained stable in US & RoW, moderate decrease in EU Overall cartridge ASP impacted by market seeding campaigns in Europe, volume ramp-up in RoW & customer implementation support in the US
Instrument throughput	 Average annual cartridge throughput per instrument is stable, despite fast growing installed base
Collaboration revenue	 Increased year-over-year with 49% to EUR 12.5m driven by growing partner ecosystem
Total operating income	 Increased year-over-year with 32% to EUR 37.7m





Business review 2019



B TARGETED THERAPIES: 2 IDYLLA™ ASSAY LAUNCHES IN 2019∗

Idylla™ MSI Test (CE-IVD)

- CE-marking announced 28 February 2019
- Key addition to Idylla[™] CRC test menu as MSI detection (Micro Satellite Instability¹) is currently recommended for all CRC² patients
- MSI is present in several other tumor types (e.g. gastric & endometrial cancer) as well. It is also an independent factor that may predict a patient's response to certain immunotherapies²
- Includes a novel set of 7 MSI biomarkers³, fully automated, fast & accurate information on MSI status directly from FFPE⁴ tissue without the need for matched normal samples⁵
- Expected to overcome drawbacks of conventional MSI testing, making MSI testing available to a larger patient population

Idylla[™] ctEGFR Mutation Assay⁵ (RUO)

- Launch was announced on 25 October 2019
- Allows for the detection of 49 EGFR mutations
- Directly from 2 ml of blood plasma
- Provides results within 160 minutes



* The title of the slide 'targeted therapies' refers to one of the strategic pillars of Biocartis' strategy. We refer to the specific product labeling for applicable intended use for each individual Biocartis product.

1 MSI is the result of inactivation of the body's DNA mismatch repair (MMR) system. This contributes to tumor growth & evolution as DNA replication errors are no longer corrected; 2 NCCN Guidelines, https://www.nccn.org/patients/guidelines/colon/22/, last consulted on 3 March 2020; 3. Consisting of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2 genes. The biomarkers were exclusively licensed to Biocartis in 2013 from VIB, the life sciences research institute in Flanders (Belgium), and originated from the research of the group of Prof. Diether Lambrechts (VIB-KU Leuven, Belgium); 4. FFPE = formalin fixed, paraffin embedded; 5 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)>; 5 RUO = Research Use Only, not for use in diagnostic procedures



B TARGETED THERAPIES: NUMEROUS ONGOING PARTNERSHIPS*

AstraZeneca



LifeArc



- Partnership broadened on 22 January 2020
- Enables collaborative development & commercialization of Idylla[™] tests in support of AstraZeneca's pharmaceutical products, such as CDx¹ development projects
- Specifics new agreement:
 - Ongoing European prospective study Idylla[™] EGFR Mutation Test extended to additional countries within & outside Europe
 - New: study to evaluate if liquid biopsy testing using the Idylla[™] ctEGFR Mutation Assay (RUO²) could provide further benefits to tissue-based EGFR testing

- LifeArc is a co-development partner, focused on developing an Idylla[™] breast cancer test
- Due to emerging pipeline of targeted drugs in advanced breast cancer ('ABC'), Biocartis & LifeArc decided to strengthen positioning of the assay under development
- Idylla[™] ABC Panel now targets a multi-gene panel of predictive and resistance-inducing mutations based on an FFPE⁴ sample

BIOCARTIS

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1 CDx = companion diagnostics; 2 RUO = Research Use Only, not for use in diagnostic procedures; 3 On 15 June 2017, MRC Technology changed its name in LifeArc. LifeArc has been involved in helping to deliver a number of therapies including Keytruda (pembrolizumab, marketed by MSD) which is an important immunotherapy treatment for various cancers; 4 FFPE = Formalin Fixed, Paraffin Embedded

PAN-TUMOR: ASSESSING APPLICABILITY OF IDYLLA™ ASSAYS*

- Therapy selection increasingly driven by genetic make-up of the tumor rather than tissue of origin
- Idylla[™] assays increasingly assessed for pan-tumor testing, potentially expanding applicability of current Idylla[™] assay menu. Examples of research into new applications include:
 - KRAS mutations detected in FFPE lung samples¹
 - KRAS mutations detected in pancreatic cyst fluid samples²
 - NRAS and BRAF mutations detected in FFPE melanoma samples¹
 - NRAS and BRAF mutations detected in thyroid Fine Needle-Aspirates (FNA) samples³







 Various efforts ongoing to demonstrate feasibility of the Idylla[™] MSI Test in other cancer types than colorectal cancer: over 30 Idylla[™] MSI studies initiated worldwide in 2019⁴



* The title of the slide 'pan-tumor' refers to one of the strategic pillars of Biocartis' strategy. We refer to the specific product labeling for applicable intended use for each individual Biocartis product.

1 Huang et al. J Mol Diagn. 2019 Sept; 2 The use of the IdyllaTM ctKRAS Mutation Assay directly on pancreatic cyst fluid was researched as a solution for direct, rapid KRAS mutation testing, which is especially helpful in cases where cellular content and fluid volume of pancreatic cysts are suboptimal for other routine testing (Al-Turkmani M et al. Pancreatic cyst fluid harboring a KRAS mutation. Cold Spring Harb Mol Case Study 5.(2) Apr 2019. Available online on https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6549572/; 3 The IdyllaTM BRAF Assay and the IdyllaTM NRAS-BRAF Assay (RUO) were used to research the direct use of thyroid FNA samples as a Rapid On site Molecular Evaluation (ROME) solution for the rapid and easy detection of NRAS and BRAF mutations without having to specialized, centralized labs (De Luca Pointadion). Glauary 2020, doi: 10.1002/dc.24378. Epub ahead of print. Available online on https://www.ncbi.nlm.nih.gov/m/pubmed/31904908/) ; 4 Many of these demonstrate importance of pan-tumor MSI testing in non-colorectal cancers (CRC) with microsatellite instability (MSI)



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GENE SIGNATURES: TWO ADVANCED ASSAY DEVELOPMENTS*

Exact Sciences

EXACT SCIENCES

- Exact Sciences Corp. (NASDAQ: EXAS) acquired Genomic Health on 8 November 2019¹
- During 2019, EXAS progressed the development of the Idylla[™] Oncotype DX IVD Breast Recurrence Score[®] test
- Idylla[™] instruments placed in Q4 2019 at early access sites in Europe, beginning with France & Germany, as a preparation for the start of the validation studies
- Start of validation studies expected in 2020





- Agreement² for development & commercialization of Immunexpress' SeptiCyte[™] test on Idylla[™]
- The SeptiCyte[™] LAB³ test received 510(k) clearance from the US FDA for use on a manual PCR instrument
- Immunexpress currently works on achieving US FDA 510(k) clearance of an Idylla[™] SeptiCyte[™] RAPID test as the first 1hour, direct-from-blood, host-response assay that will aid in the diagnosis of sepsis in critically ill patients²



* The title of the slide 'gene signatures' refers to one of the strategic pillars of Biocartis' strategy. We refer to the specific product labeling for applicable intended use for each individual Biocartis product. 1 The partnership with Genomic Health (now Exact Sciences) was announced on 13 September 2017; 2 The agreement with Immunexpress Pty Ltd, a host response molecular diagnostic company, was announced on 24 January 2018; 3 The test aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS) systemic inflammation in critically ill patients on their first day of their admission in the ICU (intensive care unit)



BMS

Bristol-Myers Squibb OPDIVO

- Agreement¹ focused on MSI testing in connection with IO therapies²
- Allows for joint developments & registrations of Idylla[™] MSI Test for use in a variety of indications, commercial settings & geographies
- Initial focus is CDx registration of the Idylla[™] MSI test in the US

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Kite A GILEAD Company A GILEAD Company

Kite/Gilead

- Master development & commercialization agreement aimed at development of assays on Idylla[™] supportive to Kite's therapies
- Speed & ease-of-use of Idylla[™] could enable regular, rapid monitoring of patients under cell therapies in a near-patient setting, which is expected to help optimize patient management
- Cell & checkpoint blockade therapies are expected to cover a wide range of complementary indications in solid & hematological tumors, and may be used depending on the tumor's immune activity status

* The title of the slide 'immuno-oncology/liquid biopsy' refers to one of the strategic pillars of Biocartis' strategy. We refer to the specific product labeling for applicable intended use for each individual Biocartis product.

1 The agreement with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company, was announced on 12 March 2019; 2 OPDIVO® (nivolumab) plus low-dose Yervoy (ipilimumab) is the first immuno-oncology combination treatment approved by US FDA for MSI-High or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with fluoropyrimidine, oxaliplatin and irinotecan. Note that OPDIVO® is also approved in the US as as a single agent, for the treatment of adult and pediatric patients 12 years and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. OPDIVO® generated USD 7.2m of global revenues in 2019 (Source: https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-reports-fourth-quarter-and-full-year-fi-1, last consulted on 3 March 2020); 3 Kite's YescartaTM (Axicabtagene Ciloleucel) was the first CAR-T therapy approved by the US FDA for treatment of adult patients with relapsed or refractory large B-cell lymphoma. Biocartis announced its partnership with Kite/Gilead on 1 June 2019



NEW PROJECT UNDER COLLABORATION Bristol-Myers Squibb REGISTRATION IDYLLA™ MSI TEST IN CHINA



- On 5 March 2020, Biocartis announced to pursue registration of Idylla[™] MSI test as a CDx test in metastatic colorectal cancer (mCRC) in the People's Republic of China
- New project under existing immuno-oncology collaboration with BMS
- Biocartis' joint venture Wondfo-Cartis will commercialize the Idylla[™] MSI test in the People's Republic of China upon obtaining regulatory approval





Financial results 2019



TOTAL OPERATING INCOME INCREASED TO EUR 38M IN 2019

Breakdown total operating income

In EUR 1,000	2019	2018
Product sales revenue	24,224	18,843
Collaboration revenue	12,451	8,329
Service revenue	769	639
Total revenue	37,444	27,811
Grants and other income	288	840
Total operating income	37,732	28,651

Additional details (in EUR 1,000)

Product sales revenue	2019	2018
Idylla™ system sales	6,220	4,185
Idylla™ cartridge sales	18,004	14,658
Product sales revenue	24,224	18,843
Collaboration revenue	2019	2018
R&D services	9,026	4,338
License fees	2,517	3,158
Milestones	908	833
Collaboration revenue	12,451	8,329



OPERATING RESULT OF EUR -55.6M IN 2019

Condensed income statement

2019	2018
37,732	28,651
(21,328)	(15,349)
(39,844)	(36,842)
(18,011)	(15,349)
(14,151)	(7,971)
(93,334)	(75,511)
(55,602)	(46,860)
(7,934)	(1,402)
-631	0
99	109
(64,068)	(48,153)
	37,732 (21,328) (39,844) (18,011) (14,151) (93,334) (55,602) (7,934) -631 99

Comments

- OPEX amounted to EUR 93.3m (y-o-y increase of 24%) in 2019 driven by higher:
 - COGS increased product volumes & higher operational costs for cartridge manufacturing
 - *R&D expenses* increased depreciation & amortization charges, employee benefit expenses and laboratory & cartridge costs.
 Partially offset by decreased facilities, office and a one-off impairment charge in 2018
 - S&M expenses increased due to additional operational expenses incurred in relation to the expansion of S&M team
 - G&A expenses increased due to overall organizational growth & a general cost allocation that is shifting more towards a commercial stage organizational structure
- Net financial result amounted to EUR 7.9m and included:
 - EUR 5.2m in relation to the Company's convertible bond (of which EUR 2.2m non-cash debt appreciation)
 - $_{\odot}$ EUR 1.1m in relation to the repaid subordinated loan
 - \circ Commitment fees for the multiple purpose credit
- Net result equaled to EUR -64.1m in 2019



STRONG CASH POSITION END OF 2019

Condensed cash flow statement

In EUR 1,000	2019	2018
Result for the period	(64,068)	(48,153)
Depreciation and amortization	9,719	4,273
Impairment losses	476	3,456
Working capital changes	(48,788)	(41,679)
Taxes & interests paid	(5,466)	(314)
CF operating activities	(54,254)	(41,993)
CF investing activities	(5,496)	(5,820)
CF financing activities	(175,023)	(1,507)
Total net cash flow ¹	115,274	(49,320)
Cash and cash equivalents ²	178,726	63,539
Financial debt	166,578	35,335

1. Excludes effects of exchange rate changes on the balance of cash held in foreign currencies

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

Remarks

- Cash burn from operating activities increased as result of:
 - A higher operating loss for the period
 - o Increased investments in working capital
 - Partial offset by increased non-cash adjustments
- Cash flow from investing activities included:
 - $\circ~$ Capital contribution made to China joint venture
 - Capitalized Idylla[™] systems and investments in laboratory & manufacturing equipment
- Cash flow from financing activities included:
 - EUR 55.5m capital raise in January 2019
 - $\circ~$ EUR 150m convertible bond issue in May 2019
 - EUR 23.7m repayments of borrowings (predominantly the Company's subordinated loan)
- Net cash flow of EUR 115.3m, resulting in a cash position of EUR 179m as per end of December 2019





Outlook 2020



GUIDANCE 2020



Targeting a year-over-year commercial volume growth in the range of 30%, representing a volume of Idylla[™] cartridges in the range of 228k



Targeting an installed base growth in the range of 300-350 new instrument placements



Targeted cash position in the range of EUR 110m by 2020 year end

Impact COVID-19 outbreak: The guidance for 2020 assumes a moderate impact of the ongoing worldwide COVID-19 outbreak as well as a stabilization of the situation around the April 2020 timeframe



MENU OUTLOOK

Area







Test

- US FDA 510(k) submission Idylla[™] MSI Test
 o Together with partner Bristol-Myers Squibb
 o Subject to further feedback from US FDA interaction, expected by end 2020
- US FDA PMA² application submission for Idylla[™] RAS tests

 Together with partner Amgen
 Subject to further feedback from US FDA interaction, expected by Q1 2021



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 Start of clinical validation studies of Idylla[™] IVD Oncotype DX Breast Recurrence Score[®] test in France & Germany expected in 2020



FINANCIAL CALENDAR 2020

5 March 2020Full year results 20192 April 2020Publication Annual Report 201923 April 2020Q1 2020 Business Update8 May 2020Annual and Extraordinary General Meeting Biocartis Group NV3 September 2020H1 2020 results12 November 2020Q3 2020 Business Update



After the summer of 2020, Biocartis will organize a Capital Markets Day for financial analysts, media & institutional investors to provide an update of its Idylla™ product strategy (date to be confirmed)





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