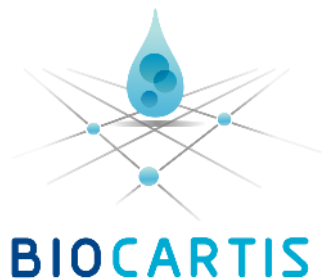


5 SEPTEMBER 2019

Biocartis H1 2019 results & business update

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TODAY'S PRESENTERS



Ewoud Welten
Chief Financial Officer



Herman Verrelst
Chief Executive Officer

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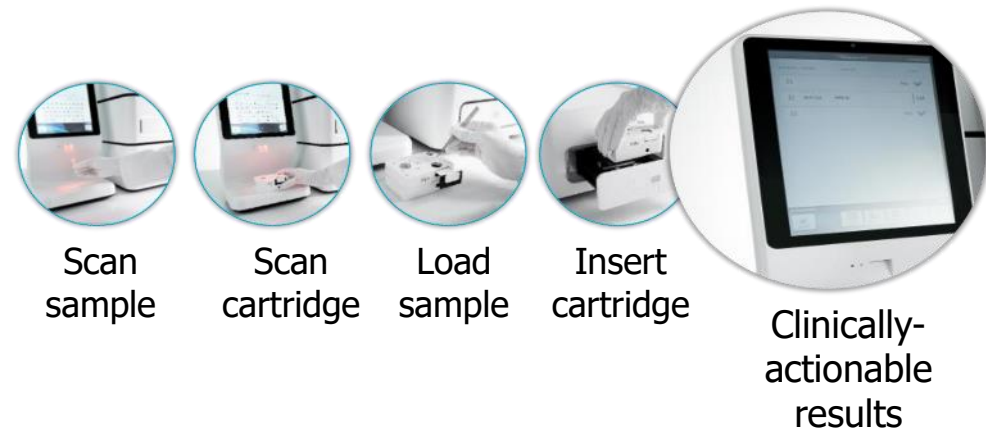
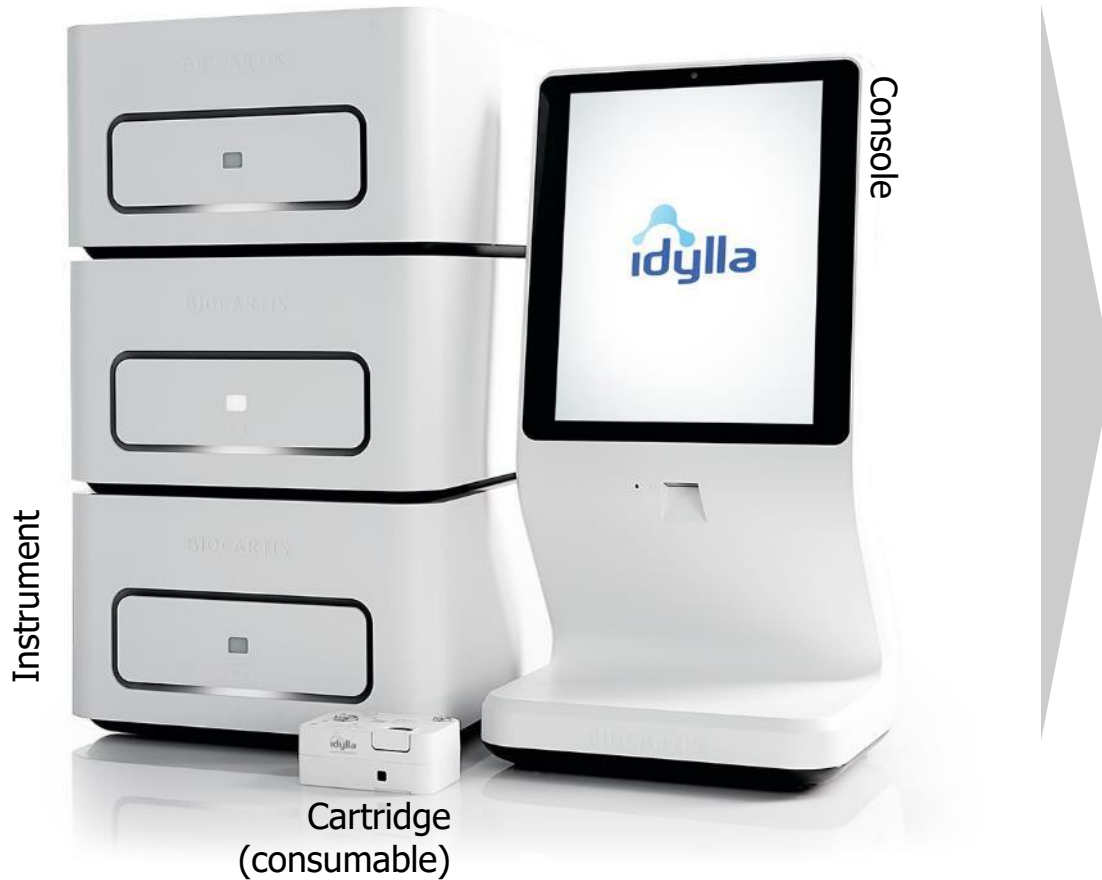
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AGENDA

1. H1 2019 results
2. Business update
3. Outlook
4. Q&A

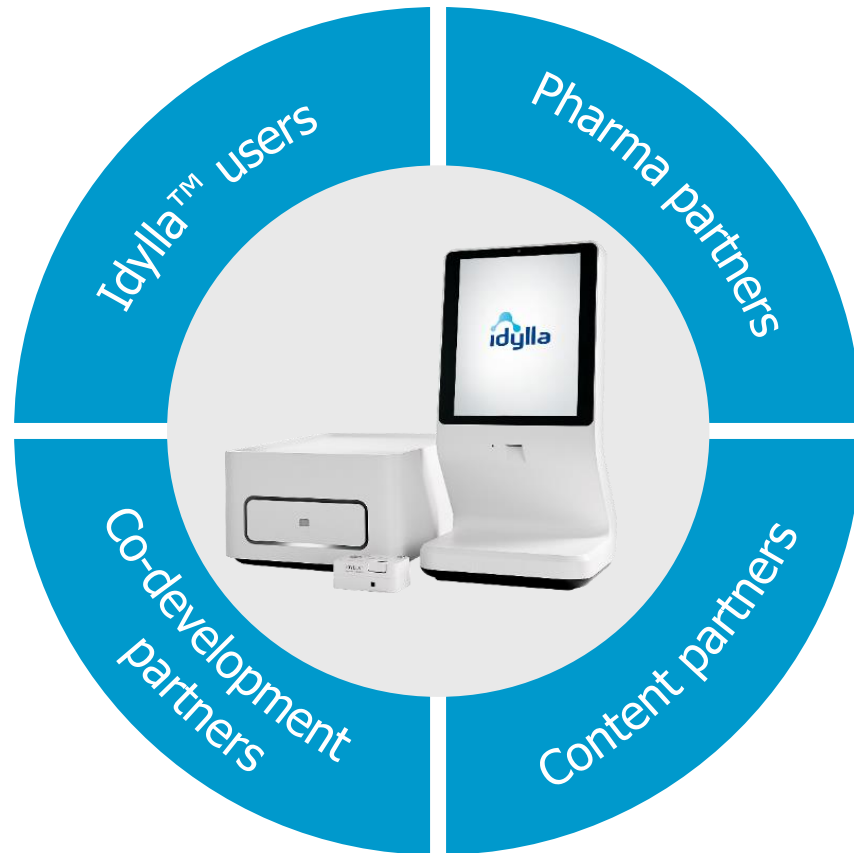
FULLY AUTOMATED MOLECULAR TESTING WITH IDYLLA™



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

TOWARDS AN IDYLLA™ ECOSYSTEM



Selected partners:

AMGEN

MERCK

Johnson & Johnson

AstraZeneca 

 **Kite**
A GILEAD COMPANY

Bristol-Myers Squibb

 **Genomic Health**
LIFE, CHANGING.

lifeArc

COVANCE

PHILIPS

KEY MESSAGES H1 2019

Commercialization

Installed base

+ 156 instruments added

Cartridge volume

72k cartridges, +24% year-over-year growth. Slower pick-up in US cartridge volumes

Commercial footprint

Japanese commercialization agreement signed. Termination US distribution agreement Fisher Healthcare.

Menu and partnerships

Colorectal cancer (CRC) menu

Successful CE-IVD launch MSI Test

Immuno-oncology (IO)

Two IO assay development projects initiated

Partnership business

Partnerships signed with BMS, Kite and Covance

Financials

Total operating income

+36% year-over-year to EUR 17.3m

Funding events

EUR 55.5m equity raise and EUR 150m convertible bond issue

Cash position

Cash and cash equivalents of EUR 209m end H1 2019

SOLID CONTINUED GROWTH IN EUROPE & ROW¹ MARKETS

Europe

- Continued growth in cartridge volumes and installed base growth **exceeded expectations**
- Driven by **increased usage of Idylla™ in first line testing** in amongst others UK, France and Italy, as well as strong overall contribution from pharma collaborations

RoW¹

- Solid performance with new instrument placements **exceeding expectations** and significant continued cartridge volume growth
- Driven by **strong customer base expansion** in Canada, Asia, Eastern Europe and North Africa and **new market authorizations** for products in amongst others Colombia and Thailand



ACTIONS TAKEN TO BOOST US COMMERCIALIZATION

H1 2019 update

- Further expansion of the US customer base with **new high profile customers**
- Cartridge volume pick-up below expectations due to **more gradual increase of cartridge orders** after Idylla™ instrument implementation
- Variety of **reasons** driving delayed pick-up, including:
 - Education on amended standard operational procedures
 - Gradual switch from current testing methodologies to Idylla™

US outlook

- On 5 September 2019, Biocartis and Fisher Healthcare announced **termination of US distribution agreement**
- Going forward, Biocartis' **US direct sales team** will drive US commercialization
- A number of US customers is currently **completing Idylla™ implementation** which is expected to drive volume ramp-up in H2 2019
- Accelerate **growth of US customer base** expected once:
 - **Transition** from Fisher Healthcare is completed
 - **Expansion** of Biocartis US direct sales team is further progressed

~30 IDYLLA™ PERFORMANCE STUDIES PUBLISHED IN H1 2019

Publications at ASCO (30 May-4 June 2019)

- **Multi-centered study¹** on the performance of the Idylla™ MSI Test (CE IVD) in **comparison with the Promega MSI test** ('Promega MSI Test')
- Selected for **publication** at the renowned ASCO (American Society of Clinical Oncology) Annual Meeting
- Study showed **high performance and a low invalid rate** of the Idylla™ MSI Test
- Demonstrated the possibility of rapid, fully automated MSI testing with Idylla™

Publications at USCAP² (16-21 March 2019)



- A hairy cell leukemia focused study³ using different sample types including stained smear slides, blood & bone marrow without pre-extraction



- A colorectal cancer focused prospective study⁴ and a melanoma focused study⁵ with comparison to next-generation sequencing (NGS)



- A colorectal cancer focused study⁶ with comparison to PCR & IHC for Microsatellite Instability Status, and a multiple cancers focused study⁷ using challenging FFPE samples not suitable for conventional sanger & NGS testing



- A melanoma focused study⁸ using pigmented melanomas

1 Pauwels P. et al, 'The Idylla™ MSI Test multi-center concordance study: microsatellite instability detection in colorectal cancer samples', first published at ASCO Annual Meeting of the American Society of Clinical Oncology, 30 May – 4 June 2019, Chicago (IL), US

2 The USCAP (United States and Canadian Academy of Pathology) Annual Meeting took place in Maryland, US, from 16-21 March 2019. All abstracts can be found on <https://www.xcdsystem.com/uscap/program/2019/index.cfm?pgid=131&qfixed=1&sessiontype=Poster%20Presentation>. All Idylla™ assays sold in the US are for Research Use Only, not for use in diagnostic procedures

3 'Sensitive and Ultra-Rapid BRAF V600E Mutation Assessment in Hairy Cell Leukemia From Stained Smear Slides, Blood and Bone Marrow Without Pre-Extraction', Memorial Sloan Kettering Cancer Center,

4 'Evaluation of a fully automated system for use in somatic mutation testing in colorectal cancer: A prospective study with comparison to next-generation sequencing', Dartmouth Hitchcock Medical Center

5 'Rapid Detection of BRAF and NRAS Mutations in Melanoma Using a Fully Automated System: A Comparison with Next Generation Sequencing', Dartmouth Hitchcock Medical Center

6 'Evaluation of a fully automated system for use in somatic mutation testing in colorectal cancer: A prospective study with comparison to next-generation sequencing', Medical College of Wisconsin

7 'Rapid Detection of BRAF and NRAS Mutations in Melanoma Using a Fully Automated System: A Comparison with Next Generation Sequencing', Medical College of Wisconsin

8 'Fully automated biomarker analysis on samples challenging for traditional molecular methods', Wake Forest Baptist Health

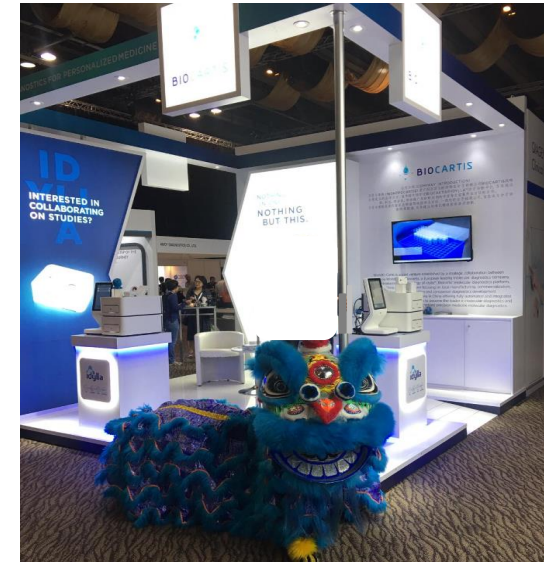
CHINA AND JAPAN COMMERCIALIZATION FURTHER PROGRESSED

China

- Joint venture established with **Wondfo**¹, a fast growing diagnostics leader in China²
- Completion of **closing of joint venture** in Q1 2019 resulted in **first capital contributions** and **license payment** to Biocartis

Japan

- Commercialization agreement signed with **Nichirei Bioscience**³ for Japanese market⁴ in January 2019
- Partners **further progressed registration preparations** for the Idylla™ instrumentation and assays in H1 2019



1 Wondfo is listed on Shenzhen Exchange (current market capitalization of USD ~1.3bn) with revenues in 2017 of ~ USD 160m

2 China is one of fastest growing MDx markets in the world. Source: DataMintelligence, "Global Molecular Diagnostics Market 2018-2025"

3 Part of Nichirei Corporation (TYO: 2871), a holding company with an annual turnover of ~¥ 550 billion (source: Nichirei Bioscience website and company information). The agreement was announced on 7 January 2019

4 Japanese MDx market is one of the largest MDx markets in the world, representing ~ 10% of the global MDx market. Source: DataMintelligence, "Global Molecular Diagnostics Market 2018-2025"

LAUNCH IDYLLA™ CE-IVD MSI TEST

Background MSI

- MSI is the abbreviation of Micro Satellite Instability
- MSI is the result of inactivation of the body's so-called 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, such as gastric & endometrial cancer
- MSI is also 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:](#)
 - Fully automated
 - Fast and accurate information on MSI status in colorectal cancer directly from FFPE⁴ tissue without the need for matched normal samples³
 - High concordance (> 97%) and lower failure rates compared to standard methods³
 - 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](#)

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, DDO1, MRE11, RYR3, SEC31A and SULF2 genes.

IMMUNO-ONCOLOGY COLLABORATION WITH Bristol-Myers Squibb

Background collaboration

- Collaboration focused on **MSI testing** in connection with immuno-oncology therapies
- Allows for **joint developments** and registrations of the **Idylla™ MSI test** for use in a variety of indications, commercial settings and geographies
- Initial focus under agreement is expected to be registration in the **US** of Idylla™ MSI test as a **companion diagnostic test**
- Bristol-Myers Squibb Company (NYSE: BMY) is a global biopharmaceutical company that amongst others markets **OPDIVO®**
- Financial details are not disclosed

Background OPDIVO®



- OPDIVO® (nivolumab) plus low-dose Yervoy+ (ipilimumab) is the **first immuno-oncology combination treatment** approved by the US FDA for **MSI-High** or mismatch repair deficient (dMMR) metastatic colorectal cancer (**mCRC**) that has progressed following treatment with certain chemotherapies*
- OPDIVO® generated USD **4.9bn** of **global sales** in 2017~

+ 3 mg/kg Opdivo plus 1 mg/kg Yervoy.

* Treatment with fluoropyrimidine, oxaliplatin and irinotecan. Note that OPDIVO® is also approved in the US 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 (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

~ Source: 2017 annual report BMS.

DEVELOPMENT & COMMERCIALIZATION AGREEMENT WITH



Background Kite

- Biopharmaceutical company that was acquired by **Gilead Sciences** (Nasdaq: GILD) for USD 11.9bn¹ in 2017
- Active in **innovative cancer immunotherapies**: harnessing power of a patient's own immune system to effectively target & attack cancer cells
- Has **industry-leading pipeline** of CAR² and TCR² product candidates to address hematological (blood-based) & solid cancers¹
- Kite's **Yescarta™** (Axicabtagene Ciloleucel) was the first CAR-T therapy approved by US FDA for treatment of adult patients with relapsed or refractory large B-cell lymphoma³

Details collaboration

- **Master development and commercialization agreement** aimed at development of molecular-based assays on the Idylla™ platform that are 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.
- This partnership is Biocartis' **2nd immunotherapy assay development agreement**

1 Source: <https://www.kitepharma.com/>, last consulted on 29 May 2019

2 Chimeric Antigen Receptor (CAR) and T cell receptor (TCR)

3 After two or more lines of systemic therapy. Source: <https://www.kitepharma.com/>, last consulted on 29 May 2019

GLOBAL STRATEGIC COLLABORATION WITH



Background

- In 2018, over 1,100 cancer treatments were in development in the US¹, 42% of new approved therapies represented a personalized medicine approach²
- **Clinical studies** for targeted therapies, which include testing that is performed in global laboratories such as those of Covance, **require rapid & standardized biomarker MDx testing platforms**
- **Covance** has been involved in development of all of the current **top 50 drugs** as measured by sales revenue, and collaborated on **more than 90%** of the **novel drugs approved by the FDA** in 2018, including most of the novel oncology drugs

Details

- Covance, LabCorp's Drug Development business, has the **leading central laboratory network** serving the biopharma industry, with a specific focus on precision medicine
- Agreement announced on 23 April 2019, aimed at **offering the Idylla™ platform** and its existing Idylla™ oncology assay menu³ to **Covance's customer base**
- Several Idylla™ instruments have already been placed at Covance sites in the US and China
- The agreement provides for additional placement of **Idylla™ instruments at Covance sites globally** to support customer needs for **clinical trials** and, when appropriate, to validate and implement companion diagnostic applications

¹ Source: <https://www.statista.com/statistics/268805/number-of-cancer-drugs-in-development-since-2005/>, last consulted on 19 April 201

² Source: PMC, 'Personalized Medicine at FDA', A progress and outlook report', 2018

³ Idylla™ Assays currently available in the USA and China are for Research Use Only, not for use in diagnostic procedures. Any support of clinical trials in the USA, China, or other locations will follow applicable regulations

TOTAL OPERATING INCOME INCREASED TO EUR 17.3M

Breakdown total operating income

In EUR 1,000	H1 2019	H1 2018
Product sales revenue	9,980	8,555
Collaboration revenue	6,816	3,535
Service revenue	351	251
Total revenue	17,147	12,341
Grants and other income	151	400
Total operating income	17,298	12,741

Additional details (in EUR 1,000)

Product sales revenue	H1 2019	H1 2018
Idylla™ system sales	2,499	1,952
Idylla™ cartridge sales	7,481	6,603
Product sales revenue	9,980	8,555

Collaboration revenue	H1 2019	H1 2018
R&D services	4,350	2,626
License fees	2,467	75
Milestones	0	833
Collaboration revenue	6,816	3,535

OPERATING RESULT OF EUR -29.7M

Condensed income statement

In EUR 1,000	H1 2019	H1 2018
Total operating income	17,298	12,741
Cost of sales	(8,742)	(6,890)
R&D expenses	(20,031)	(16,029)
S&M expenses	(8,811)	(7,152)
G&A expenses	(6,399)	(3,809)
Total operating expenses	(43,983)	(33,880)
Operating result	(26,685)	(21,139)
Net financial result	(2,822)	(691)
Share in result JV	-181	0
Income taxes	18	70
Net result	(29,670)	(21,760)

Comments

- OPEX increased 30% y-o-y to EUR 44.0m in H1 2019
- Increase in OPEX driven by:
 - Increased COGS due to higher commercial product volumes
 - Increased R&D expenses due to addition of menu partnerships
 - Increased S&M expenses due to expansion of US sales force
 - Increased G&A expenses due to overall organizational growth & general cost allocation that is shifting more towards a commercial stage organizational structure
- Net financial result increased to EUR 2.8m of which:
 - EUR 1.1 m relates to accrued interest of the convertible bonds
 - EUR 1.0m relates to interest and repayment of the Company's subordinated loan

RECORD CASH POSITION OF EUR 209M

Condensed cash flow statement

In EUR 1,000	H1 2019	H1 2018
Result for the period	(29,670)	(21,760)
Depreciation and amortization	3,713	2,144
Impairment losses	202	0
Working capital changes	(4,568)	(1,665)
Taxes & interests paid	(1,842)	(110)
CF operating activities	(28,357)	(20,335)
CF investing activities	(5,267)	(2,301)
CF financing activities	179,465	1,251
Total net cash flow ¹	145,841	(21,385)
Cash and cash equivalents ²	209,200	91,269
Financial debt	166,731	38,145

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** slightly higher as result of:
 - A higher operating loss for the period
 - An increase in investments in working capital
 - Higher interest and other financial expenses
- **Cash flow from investing activities**
 - Increase driven by initial capital contribution made to China joint venture
 - Includes capitalized Idylla™ systems
- **Cash flow from financing activities** included:
 - EUR 55.5m capital raise in January 2019
 - EUR 150m convertible bond issue in May 2019
 - EUR 19.4m repayments of borrowings (predominantly the Company's subordinated loan)
- **Net cash flow** of EUR 145.8m, resulting in a **cash position** of EUR 209m as per end of June 2019

STRONG FINANCIAL POSITION

EUR 55.5m capital raise - January 2019

- Gross proceeds of **EUR 55.5m** by means of a private placement via an accelerated bookbuild offering
- Participation 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

EUR 150m convertible bond issue - May 2019

- EUR 150 million senior **unsecured convertible bonds** due 9 May 2024
- Participation from a renowned group of **international and local institutional investors**
- Bonds bear a **coupon of 4.00%** per annum and can be converted into shares at an **initial conversion price of ~EUR 12.90** (representing a 25% conversion premium*)
- Application will be made to list the bonds on the regulated market of Euronext Brussels by no later than 1 December 2019

* Above the reference price of EUR 10.3130

UPDATED GUIDANCE FULL YEAR 2019



Guidance for full year installed base growth is now set in the range of **325-350** new Idylla™ instrument placements
(initial guidance was 350 new instrument placements)







Guidance for full year commercial Idylla™ cartridge volume growth is decreased and now set in the range of **30% - 35%**
(initial guidance was growth of around 60%-70%)



Guidance for cash position now set in the range of **EUR 170m-175m** by year-end
(initial guidance was in the range of EUR 55m – EUR 65m)

SHORT TERM MENU OUTLOOK (SELECTION)

Area	Test	Timing
	<ul style="list-style-type: none"> • Launch Idylla™ ctEGFR Assay (RUO²) • Launch Idylla™ GeneFusion Panel 	<ul style="list-style-type: none"> • Q4 2019 • 2020
	<ul style="list-style-type: none"> • CE-marking Idylla™ MSI Assay • US FDA submission Idylla™ MSI Test • US FDA submission Idylla™ RAS PMA¹ documentation 	<ul style="list-style-type: none"> • Q1 2019  • 2020 • 2020
	<ul style="list-style-type: none"> • Placement of Idylla™ instruments at European sites for the clinical validation studies of the Idylla™ Oncotype DXi IVD Breast Recurrence Score™ test in H2 2019 	<ul style="list-style-type: none"> • H2 2019

¹ PMA = Pre-Market Approval

² RUO = Research Use Only, not for use in diagnostic procedures

FINANCIAL CALENDAR

- Special Shareholders Meeting 27 September 2019
- Q3 2019 Business Update 14 November 2019
- 2019 full year results 27 February 2020
- 2019 annual report publication 2 April 2020

Q&A





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