

# Biocartis H1 2018 results and business update

6 September 2018

# Today's presenters



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Chief Financial Officer



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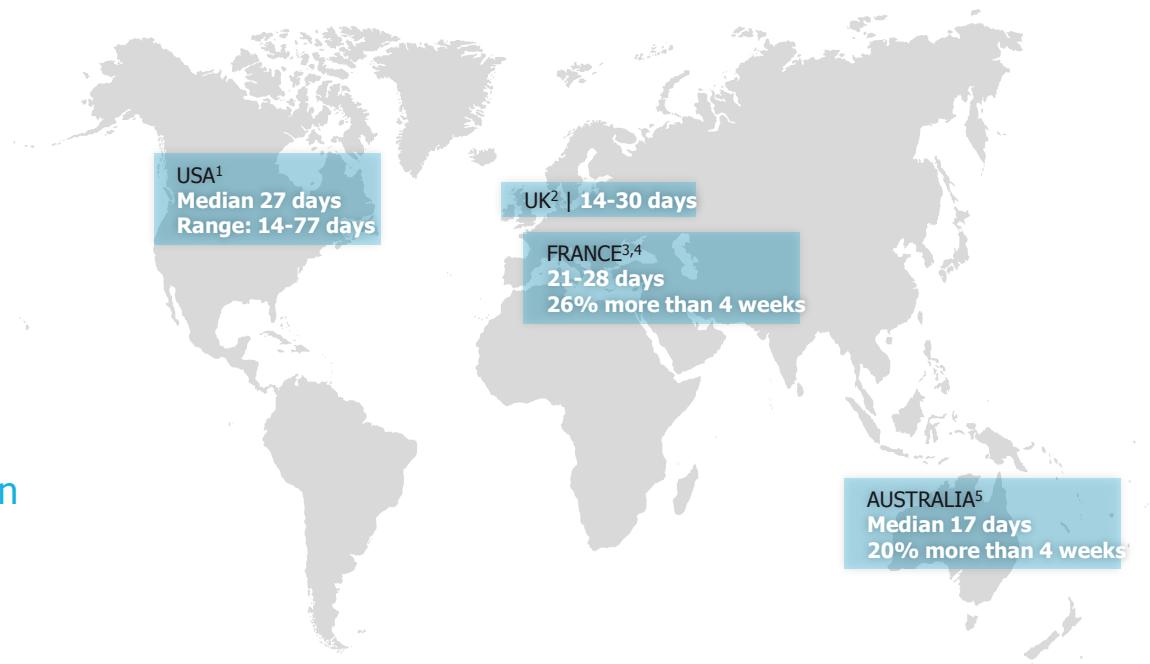
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# Agenda

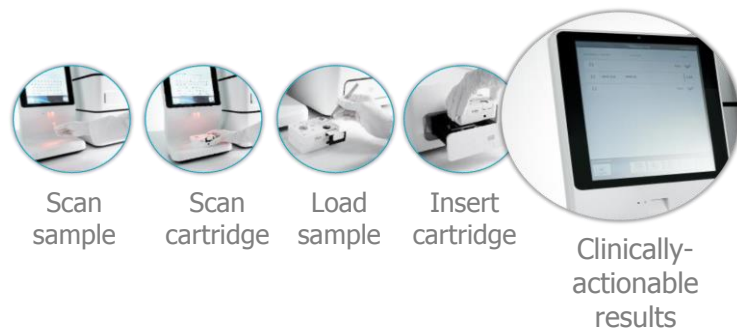
1. H1 2018 results
2. Business update
3. Outlook
4. Q&A

# Difficult access to molecular diagnostics information

- In the US, nearly **80%<sup>4</sup>** of cancer patients do **not have genetic mutation results available** at initial oncology consultation
- Up to **25%** of patients **begin treatment before receiving their results<sup>4</sup>**



# Fully automated molecular testing with Idylla™



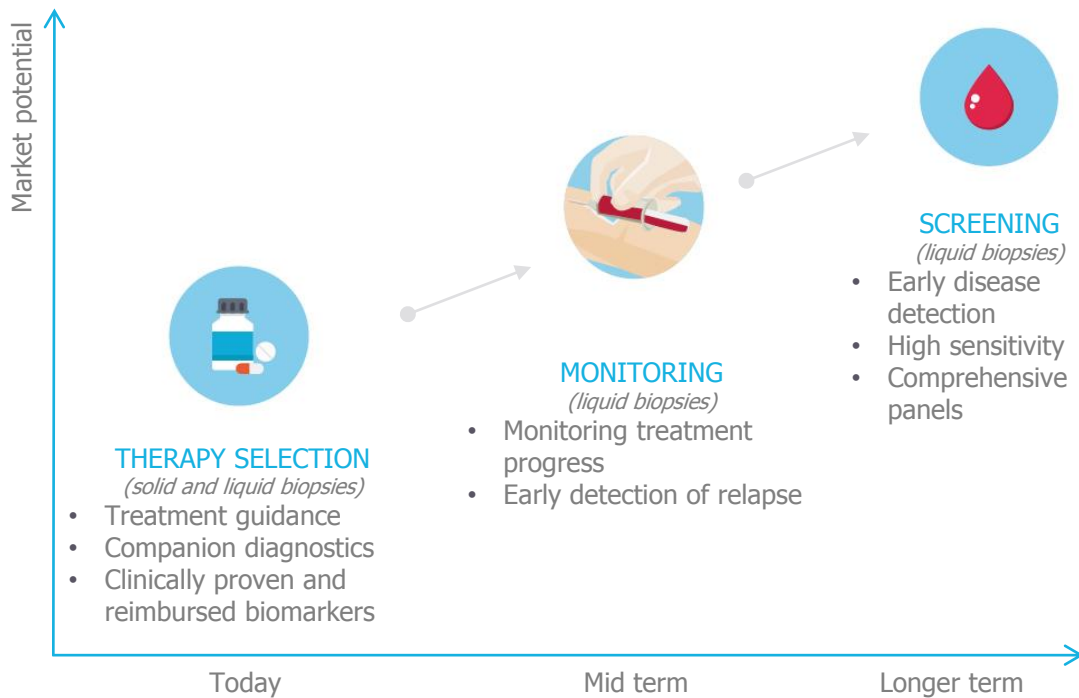
Superior sensitivity and ease-of-use, combined with sample to result turnaround time of 90 to 150\* minutes

# Menu focus on Oncology





## Idylla™ oncology USPs

- 1 Ability to combine advantages of point-of-care testing with **performance** of lab reference testing (i.e. enabling oncology 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:
  - o **Solid biopsies:** FFPE-slices\* and tumor tissue
  - o **Liquid biopsies:** blood, plasma and urine

## Expansion of the MDx application areas



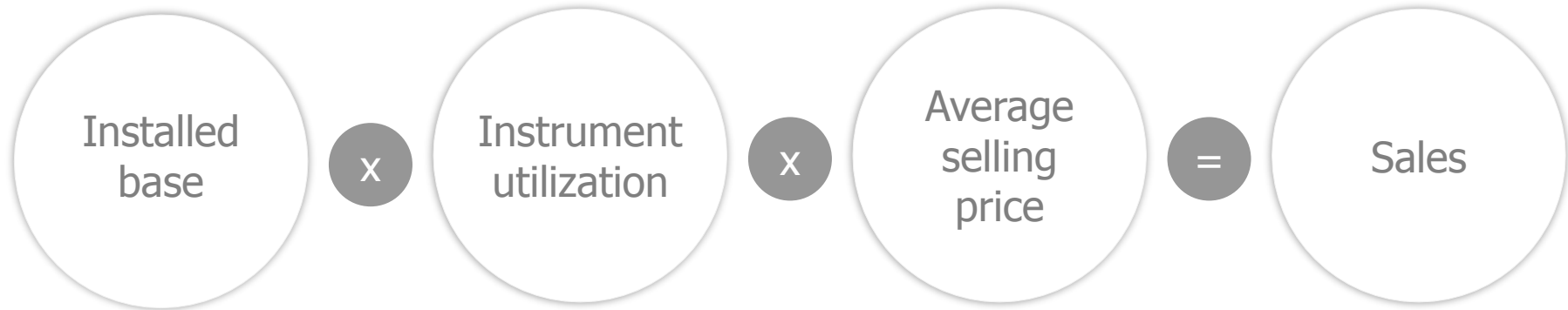
# Accelerated menu expansion with partners

	Pharma & biotech companies	Content partners	Development partners	
Focus	<ul style="list-style-type: none"> <li>(Joint) development of CDx<sup>1</sup> on Idylla™ platform</li> </ul>	<ul style="list-style-type: none"> <li>Porting of proprietary biomarker panels developed and validated by third parties on Idylla™ platform</li> </ul>	<ul style="list-style-type: none"> <li>Development Biocartis Idylla™ assays in partnership with research institutions</li> </ul>	
Benefit Biocartis	<ul style="list-style-type: none"> <li>Faster commercial adoption, higher market shares</li> </ul>	<ul style="list-style-type: none"> <li>Proprietary 3rd party content on Idylla™ platform</li> </ul>	<ul style="list-style-type: none"> <li>Lowered menu development costs</li> </ul>	
Benefit partners	<ul style="list-style-type: none"> <li>Better and faster selection of eligible patients for targeted therapies given faster TaT &amp; high sensitivity:               <ul style="list-style-type: none"> <li>Fast TaT: reduces competition with therapies not requiring a biomarker</li> <li>High sensitivity: more patients detected with relevant biomarkers</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Accelerated global roll-out of content</li> <li>No platform education needed: focus on content education</li> <li>Realization of cost efficiencies</li> </ul>	<ul style="list-style-type: none"> <li>Contribution to medical innovation</li> <li>Knowledge sharing and building</li> </ul>	
Partners				

1. CDx = Companion Diagnostics  
 2. On 15 June 2017, MRC Technology changed its name in LifeArc. LifeArc has been involved in helping deliver a number of therapies including Keytruda (pembrolizumab, marketed by MSD) which is an important immunotherapy treatment for various cancers  
 3. Partnership is with ETPL, the commercialization arm of A\*STAR



# Platform and consumable driven business model



## Key drivers

- Commercial footprint
- Commercialization partnerships

## Key drivers

- Menu of tests
- Regulatory registrations

## Key drivers

- Reimbursement
- Competitive advantage

## Gross margin driven by

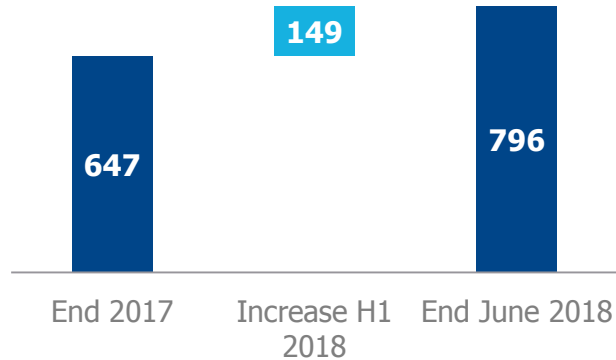
- Volume
- Manufacturing automation

# Key messages H1 2018

Installed base	+149 added to installed base, ~800 Idylla™ instruments end H1 2018
Cartridge consumption	More than doubled year-over-year to ~58k cartridges
Product revenues	Increased year-over-year with 68% to EUR 8.6m
Total operating income	Increased year-over-year with 83% to EUR 12.7m
Cash position	EUR 91.3m as per end of June 2018
Test menu	Accelerated development of the Idylla™ MSI Assay
New partnerships	Two new menu partnerships announced with Amgen and Immunexpress
Partnership pipeline	Advanced undisclosed pharma-sponsored feasibility projects
China	Finalized China strategy, resulting in a joint venture with Wondfo

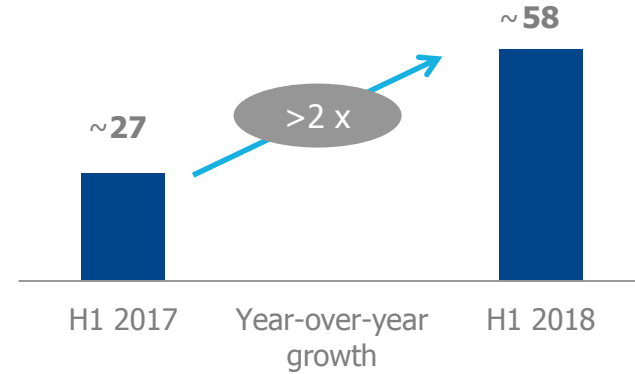
# Strong continued placements & volume growth

Installed base (in # instruments)



- Increase H1 2018 driven by higher than expected growth in **Europe** and strong placements in the **US**

Commercial cartridge volume (x 1,000)



- **Europe** followed by **RoW**<sup>1</sup> contributed most to the growth in commercial cartridge volume in H1 2018

# Delivering solid performance across markets

## Europe

- H1 2018 performance exceeded expectations
- Increased usage of Idylla™ in first line testing in amongst others:
  - UK
  - France
  - Germany
- Strong overall contribution from commercial pharma collaborations

## US

- Contributed to approx. 1/3 of installed base growth in H1 2018
- High profile customers added to the US client base
- Initial cartridge volume contribution in H1 2018
- Pending validation efforts at existing clients and ongoing expansion sales team to fuel growth of installed base and cartridge volume in H2 2018

## RoW

- Promising cartridge volume growth realized across key RoW<sup>1</sup> markets
- Additional market authorizations obtained for products:
  - Argentina
  - Brazil
  - Canada
  - Malaysia
  - Mexico
  - Uruguay
  - Singapore

# Total operating income increased with 83% in H1 2018

## Breakdown total operating income

In EUR 1,000	H1 2018	H1 2017
Product sales revenue	8,555	5,091
Collaboration revenue	3,535	716
Service revenue	251	104
<b>Total revenue</b>	<b>12,341</b>	<b>5,912</b>
Grants and other income	400	1,066
<b>Total operating income</b>	<b>12,741</b>	<b>6,978</b>

## Breakdown product revenues (in EUR 1,000)

By product	H1 2018	H1 2017
Idylla™ System Sales	1,952	1,821
Cartridge Sales	6,603	3,270
<b>Product sales revenue</b>	<b>8,555</b>	<b>5,092</b>

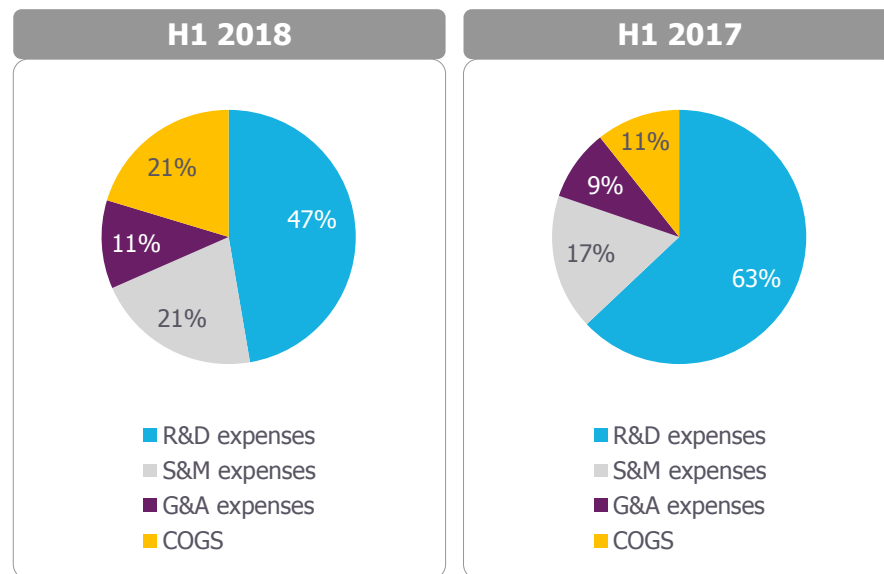
By type	H1 2018	H1 2017
Commercial revenue	7,950	5,024
R&D revenue	605	66
<b>Product sales revenue</b>	<b>8,555</b>	<b>5,091</b>

# H1 2018 net result of EUR -21.8m

## Condensed income statement

In EUR 1,000	H1 2018	H1 2017
<b>Total operating income</b>	<b>12,741</b>	<b>6,978</b>
COGS	(6,890)	(3,278)
R&D expenses	(16,029)	(19,320)
S&M expenses	(7,028)	(5,308)
G&A expenses	(3,933)	(2,781)
<b>Total operating expenses</b>	<b>(33,880)</b>	<b>(30,687)</b>
<b>Operating result</b>	<b>(21,139)</b>	<b>(23,709)</b>
Net financial result	(691)	(729)
Income taxes	70	456
<b>Net result</b>	<b>(21,760)</b>	<b>(23,982)</b>

## Breakdown operating expenses



# Cash position of EUR 91m end of H1 2018

## Condensed cash flow statement

In EUR 1,000	H1 2018	H1 2017
Result for the period	(21,760)	(23,982)
Depreciation and amortization	2,144	2,428
Working capital changes	(1,725)	(848)
Other adjustments	1,006	230
<b>CF operating activities</b>	<b>(20,335)</b>	<b>(22,172)</b>
<b>CF investing activities</b>	<b>(2,301)</b>	<b>(1,531)</b>
<b>CF financing activities</b>	<b>1,251</b>	<b>(1,531)</b>
<b>Total net cash flow<sup>1</sup></b>	<b>(21,385)</b>	<b>(24,182)</b>
<b>Cash and cash equivalents<sup>2</sup></b>	<b>91,269</b>	<b>59,042</b>
Financial debt	38,145	35,388

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 flow from operating activities** improved year-over-year as the result of:
  - An improved result for the period
  - Non-cash expenses for share based payments
  - Partially offset by higher investments in working capital
- **Cash flow from investing activities** in H1 2018:
  - Mainly related to capitalized Idylla™ systems placed with customers under (reagent) rental agreements and Idylla™ systems used for assay development needs
  - Note: investments for cartridge manufacturing expansion were directly paid for via lease financing
- **Cash flow from financing activities** in H1 2018 mainly related to the net proceeds from warrants exercises, partially offset by repayments of borrowings
- Total net cash flow in H1 2018 of EUR -21.4m, resulting in a **cash position** per end of June 2018 of **EUR 91.3m**. Note: no drawdowns made on the multiple purpose credit facility and facility from the EIB

# Accelerated launch Idylla™ MSI Assay in July 2018

## 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 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 Assay<sup>1</sup>



- Includes [novel set of 7 MSI biomarkers<sup>5</sup>](#), exclusively licensed to Biocartis<sup>2</sup> in 2013
- [Unique characteristics:](#)
  - Fast & reliable information on MSI status directly from FFPE tissue without the need for matched normal samples<sup>3</sup>
  - High concordance (> 95%) and lower failure rates compared to standard methods<sup>3</sup>
  - No control sample required
  - Provides accurate results for a variety of cancer types independent of ethnicities<sup>3</sup>
- Expected to overcome drawbacks of conventional MSI testing, making MSI testing available to a [larger patient population](#)

Once validated for diagnostic use, the Idylla™ MSI Assay<sup>1</sup> will further strengthen the colorectal cancer menu

<sup>1</sup> The Idylla™ MSI Assay was launched as a RUO (Research Use Only) Assay, not for use in diagnostic procedures

<sup>2</sup> 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)

<sup>3</sup> Maertens G. et al. Annals of Oncology (2017) 28 (suppl\_5): v22-v42; 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)>

<sup>4</sup> FFPE = formalin fixed, paraffin embedded

<sup>5</sup> Consisting of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2 genes



# Continued publication of performance studies support market adoption

## Idylla™ performance review

- Review of 18 Idylla™ performance studies published in Journal of Clinical Pathology<sup>1</sup>
- Included **2,482 Idylla™ tests** performed on tumor samples from 2,343 patients
- Idylla™ generated **valid result in 98.1%** of the cases
- Excellent concordance rate of 94.8% between Idylla™ and the reference methods

## Idylla™ ctRAS tests

- Abstract<sup>2</sup> on Idylla™ ctKRAS and ctNRAS-BRAF test performance published on AACR conference, Chicago (US)
- Included RAS concordance **comparison study** between **203 tumor tissue (FFPE) and blood plasma samples**
- Idylla™ provided a sensitive, reliable and fast solution for RAS-BRAF ctDNA (circulating tumor) testing
- **NGS comparison:** 90% overall RAS agreement with NGS on plasma, showing high clinical sensitivity

## Idylla™ MSI Assay<sup>4</sup>

- Two studies on the performance of Biocartis' MSI Biomarkers<sup>3</sup>
- First study<sup>3</sup>: used prototype Idylla™ MSI Assay in finalized design, showing **superior performance** versus reference methods
- Second study<sup>3</sup>: underlined potential of Biocartis' MSI Biomarkers to be used as a **companion diagnostic** to **predict immunotherapy outcome** in MSI-High endometrial and colorectal tumors

## Idylla™ EGFR Mutation Test

- Study on Idylla™ EGFR Mutation Test (CE-IVD) published in the Journal of Clinical Pathology<sup>5</sup>
- 68 NSCLC<sup>6</sup> archival DNA samples retested by Idylla™, incl. 25 samples unsuccessfully tested with NGS
- Idylla™ able to **rescue 80% of the FFPE samples unsuccessfully processed with NGS**
- 100% (43/43) Idylla™ concordance for samples with valid NGS result

1 Uguen A, Troncone G A review on the Idylla platform: towards the assessment of actionable genomic alterations in one day Journal of Clinical Pathology Published Online First: 14 June 2018. doi: 10.1136/jclinpath-2018-205189, available online on <https://jcp.bmj.com/content/early/2018/06/14/jclinpath-2018-205189> - 2 B Jacobs, B Claes, P Laurent-Puig, JP Bachet, S Tejpar, G Maertens, E Sablon, "Analytical and clinical validation of the Idylla™ ctKRAS and ctNRAS-BRAF Liquid biopsy tests", first presented at the 2018 AACR Annual Meeting in Chicago, US, 14-18 April 2018 - 3 Conducted with the Flemish Institute for Biotechnology (VIB). Sources: B. De Craene et al., "Detection of microsatellite instability (MSI) in colorectal cancer samples with a novel set of highly sensitive markers by means of the Idylla™ MSI Assay prototype", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, IL (US); 5 H. Zhao et al., "A novel set of 7 homopolymer indels for detection of MSI is associated with tumor mutation burden and total indel load in endometrial and colorectal cancers", ASCO Annual Meeting of the American Society of Clinical Oncology, 1-5 June 2018, Chicago, US. The methodology used for detection of the seven biomarkers, TMB (tumor mutation burden,) and indel load, was whole-exome sequencing - 4 RUO or research Use Only, not for use in diagnostic procedures - 5 Conducted by a.o. Prof. Giancarlo Troncone, Professor of Anatomic Pathology of the Department of Public Health, University of Naples Federico II (Naples, Italy) and Prof. Massimo Barberis, Director of Histopathology and Molecular Diagnostics Unit of the Division of Pathology and Laboratory Medicine, Istituto Europeo di Oncologia (Milan, Italy). De Luca et al, University of Naples Federico II, "The Idylla™ Assay and Next Generation Sequencing: an integrated EGFR mutational testing algorithm", Journal of Clinical Pathology, to consult online on <http://jcp.bmj.com/content/jclinpath/early/2018/05/24/jclinpath-2018-205197.full.pdf?ijkey=V8eBoaMdPkZ7t9N&keytype=ref>, 24 May 2018 - 6 Non-small cell lung cancer

# Strong progress in porting Oncotype DX<sup>®</sup> breast test to Idylla<sup>™</sup> platform

## Milestone study Oncotype DX<sup>®</sup> breast recurrence score test<sup>1</sup>

### TAILORx

The Trial Assigning Individualized Options for Treatment:  
*Transforming the Treatment of Breast Cancer*

- The **largest ever** breast cancer treatment trial (> 10k patients)
- Provided definitive evidence that the test identified **70 percent of early-stage breast cancer patients** who receive no benefit from chemotherapy
- Additionally, the trial established that chemotherapy may provide **life-saving benefit** to **30 percent** of patients
- Results are expected to be an important driver in **market adoption** of the test in Europe

## Development update H1 2018

1

### Full feasibility demonstrated

- During H1 2018, Genomic Health reached an important milestone in the development of the Idylla<sup>™</sup> IVD Oncotype DX Breast Cancer test by demonstrating full feasibility of that test on the Idylla<sup>™</sup> platform

2

### Access sites selected

- Furthermore, early access sites to conduct validation studies for the test were selected

3

### Launch H2 2019

- Aim to launch in the second half of 2019, beginning in France and Germany

# Expansion of menu partnerships

The Amgen logo is displayed in a blue, bold, sans-serif font within a rounded rectangular box with a blue border.

- **Second CDx partnership** with Amgen announced in January 2018
- Aimed at the development of Idylla™ CDx biomarker tests for a **novel oncology compound** to be used in the treatment of certain solid tumors
- The **first CDx partnership with Amgen** announced on 4 December 2017 is aimed at registering Idylla™ RAS biomarker tests with US FDA as a companion diagnostic (CDx) test for Vectibix® (panitumumab<sup>1</sup>)

The Immunexpress logo features a stylized 'X' icon composed of multiple parallel lines, followed by the word 'Immunexpress' in a grey, sans-serif font, all contained within a rounded rectangular box with a blue border.

- **Sepsis host response** partnership
- Aimed at development and commercialization of Immunexpress' SeptiCyte™ test for use on Idylla™
- This test aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS) systemic inflammation in critically ill patients
- SeptiCyte™ LAB test is 510(k) cleared for use on a manual PCR<sup>2</sup> instrument
- Parties will co-develop the SeptiCyte™ Idylla™ test
- Immunexpress will take the lead in commercialization, initial focus on US and Europe

# High volume cartridge manufacturing line operational by year end



- Provides an additional **annual capacity of over 1,000,000 cartridges**
- Fully **automated** assembly workstations (versus semi-automated on first line)
- Plastic parts manufactured with new **multi-cavity moulds** (versus single cavity on first line)
- Targeted to be operational by **end of 2018**
- Key driver in further **reduction of cartridge unit costs**

# Joint venture with Wondfo for Chinese market (1/2)

## Background Wondfo



- A **fast growing diagnostics leader** in China with a focus on POC<sup>1</sup> testing
- Listed on the **Shenzhen Exchange** (current market capitalization of USD ~1.7bn)
- Over **1,500 employees** and business activities in **over 100 countries** worldwide, serving more than 20,000 customers
- Revenues in 2017 of ~ USD 160m

## Background Chinese market



- Chinese MDx market **one of the fastest growing** in the world and expected to reach a total value of USD 1.5bn by the end of 2022<sup>2</sup>
- Growth is driven by a **rising cancer incidence** in China, with over 4 million diagnosed cancer cases in 2015<sup>3</sup>
- **Lung cancer** is most frequent cancer with close to 800,000 patients being diagnosed every year<sup>4</sup>
- Number of **targeted and immuno-oncology therapies** prescribed based on MDx results growing; already over 500 immuno-oncology clinical trials in China in 2016<sup>5</sup>

# Joint venture with Wondfo for Chinese market (2/2)

## Deal structure

### Ownership

- Joint Venture ('JV') based on a 50%-50% ownership structure

### Short term focus

- Initial activities focused on local manufacturing, commercialization & registration with the Chinese Regulatory Authorities (CFDA) of existing Idylla™ oncology tests

### Mid term focus

- In a next phase, the joint venture could develop new Idylla™ assays tailored to meet specific needs for the Chinese oncology market

### Funding

- A total of EUR 14m of capital, over several tranches, is committed to the JV

### License

- The joint venture will acquire from Biocartis a license to the Idylla™ platform

### Launch

- JV is expected to launch its operational activities towards the end of 2018

# Guidance 2018 full year



Installed base growth set at top end of 250-275 new instrument placements






Target of doubling year-over-year commercial cartridge volume in 2018



Targeted cash position in the range of EUR 50m – EUR 55m by 2018 year-end (excluding drawdowns on the Company's multiple purpose credit facility)

# Short term menu outlook (selection)

Area	Test	Timing	Partner
Colorectal cancer	<ul style="list-style-type: none"><li>• CE-marking of the <b>Idylla™ MSI Assay</b></li><li>• Submission of <b>Idylla™ RAS PMA<sup>2</sup></b> documentation with the US FDA, subject to feedback from US FDA interactions</li></ul>	<ul style="list-style-type: none"><li>• Q1 2019</li><li>• Q1 2019</li></ul>	
Lung cancer	<ul style="list-style-type: none"><li>• Launch of the <b>Idylla™ ctEGFR Assay (RUO<sup>1</sup>)</b></li></ul>	<ul style="list-style-type: none"><li>• H1 2019</li></ul>	
Breast cancer	<ul style="list-style-type: none"><li>• Launch of the <b>Idylla™ Oncotype DX® test</b> in Europe</li><li>• Launch of the <b>Idylla™ Resistance Monitoring Test (RUO<sup>1</sup>)</b></li></ul>	<ul style="list-style-type: none"><li>• H2 2019</li><li>• H2 2019</li></ul>	 



# Financial calendar 2018

- Q3 2018 business update 15 November 2018
- 2018 full year results 28 February 2019
- Capital Markets Day 28 February 2019
- Publication 2018 annual report 4 April 2019

# Q&A





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