Biocartis 2017 results and business update

1 March 2018

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Today's presenters

Ewoud Welten
Chief Financial Officer

Herman Verrelst
Chief Executive Officer

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Agenda

1. 2017 results
2. Business update
3. Outlook 2018
4. Q&A

Fully automated molecular testing with Idylla™

- Fully automated sample-to-result qPCR platform
- Superior and validated performance versus competition
- Combining advantages of point-of-care testing with quality of lab reference testing enables:
  - Decentralized testing by all labs
  - 'First-time-right' results
  - Short turnaround times (~ 'same-day-result')

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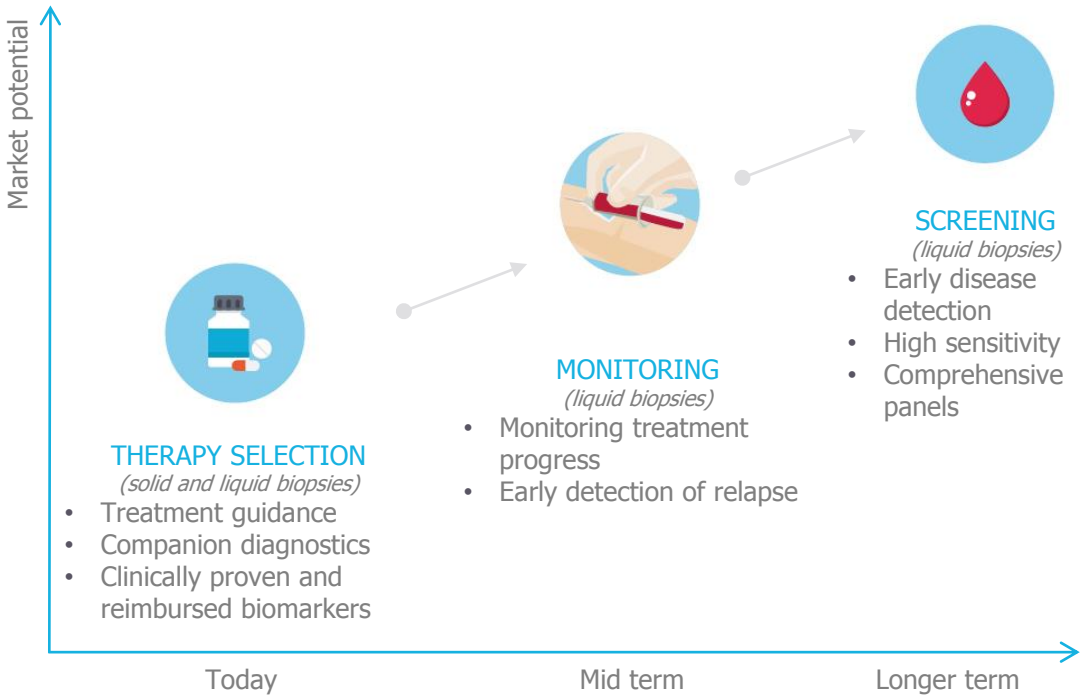
Menu focus on oncology

Idylla™ oncology Unique Selling Points

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:
   - Solid biopsies: FFPE-slices* and tumor tissue
   - Liquid biopsies: blood, plasma and urine

Expansion of the MDx application areas



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* FFPE = Formalin-fixed, parrafin embedded

Accelerated menu expansion with partners

	Pharma & biotech companies	Content partners	Development partners
Focus	• (Joint) development of CDx[1] on Idylla™ platform	• Porting of proprietary biomarker panels developed and validated by third parties on Idylla™ platform	• Development Biocartis Idylla™ assays in partnership with research institutions
Benefit Biocartis	• Faster commercial adoption, higher market shares	• Proprietary 3rd party content on Idylla™ platform	• Lowered menu development costs

Benefit partners	• Better and faster selection of eligible patients for targeted therapies given faster TaT & high sensitivity:
	  ○ Fast TaT: reduces competition with therapies not requiring a biomarker
	  ○ High sensitivity: more patients detected with relevant biomarkers
		• Accelerated global roll-out of content
		• No platform education needed: focus on content education
		• Realization of cost efficiencies
			• Contribution to medical innovation
			• Knowledge sharing and building

Partners	Johnson & Johnson, AMGEN, MERCK	Genomic Health LIFE, CHANGING., Immunexpress	LifeArc: UK based medical research charity[2]; Agency for Science, Technology and Research (Singapore): Singapore's Agency for Science, Technology and Research[3]

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

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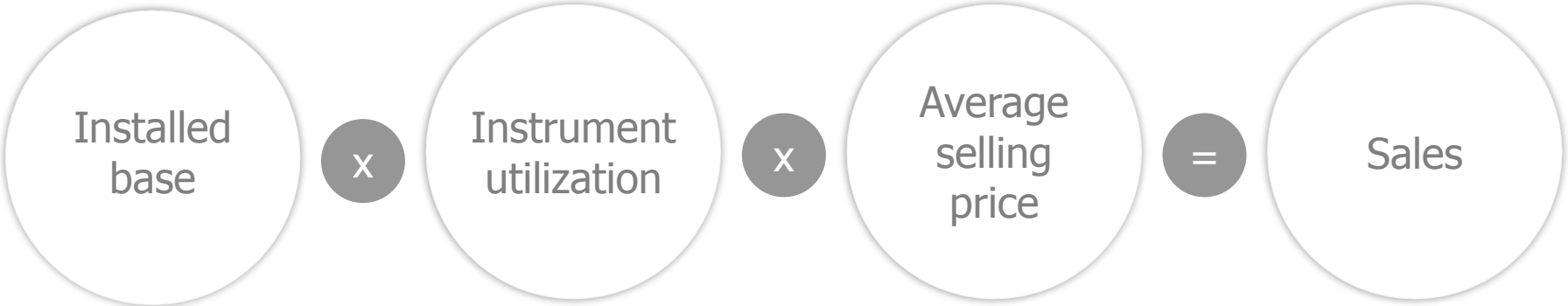
Platform and consumable driven business model



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

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Key messages FY 2017 results

Installed base	+258 to installed base, close to 650 Idylla™ instruments at year-end
Cartridge consumption	x2.8 times 2016 volume to over 71k Idylla™ cartridges
Commercial product revenues	Increased year-over-year with 124% to EUR 12.7m
Total operating income	Increased year-over-year with 68% to EUR 23.1m
Cash position	EUR 112.8m per year-end
Test menu	4 new CE-IVD tests for our oncology menu. First test cleared with US FDA
Partnerships	Four new menu partnerships announced in 2017
Commercial footprint	US commercialization initiated

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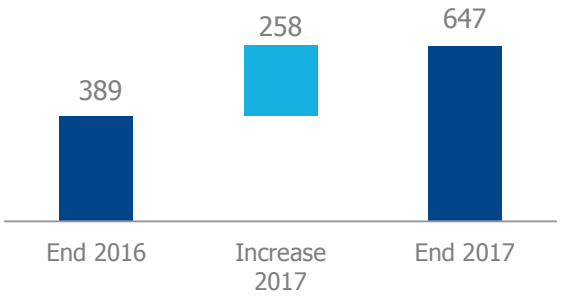
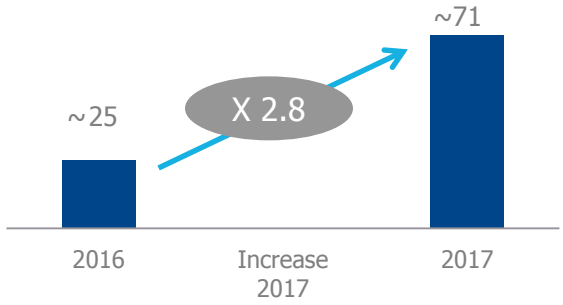
Strong installed base & cartridge volume growth

Installed base



- Strong new placements in both European and RoW distribution markets: contributed to majority of overall installed base growth
- Growth was complemented by initial placements in the US market during H2 2017

Commercial cartridge volume (x 1,000)



- Driven by continued test menu expansion and installed base growth
- Strong performance in European direct markets, overall volume slightly below expectations driven by a slower take-up in RoW distribution markets

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Commercial product revenues increased with 124% in 2017

Breakdown product revenues (in EUR 1,000)

By type	2017	2016
Commercial revenue	12,748	5,691
R&D revenue	187	1,076
Product sales revenue	**12,936**	**6,767**

By product	2017	2016
Idylla™ System Sales	4,620	2,752
Cartridge Sales	8,316	4,015
Product sales revenue	**12,936**	**6,767**

Breakdown total operating income

In EUR 1,000	2017	2016
Product sales revenue	12,936	6,767
Collaboration revenue	7,739	5,278
Service revenue	282	53
Total revenue	**20,957**	**12,098**
Grants and other income	2,153	1,674
Total operating income	**23,110**	**13,772**

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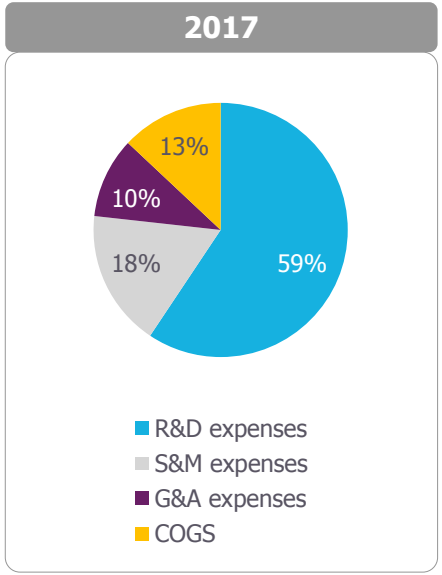
2017 net result of EUR -42m

Condensed income statement

In EUR 1,000	2017	2016
Total operating income	**23,110**	**13,772**
COGS	(8,673)	(5,701)
R&D expenses	(39,594)	(42,091)
S&M expenses	(11,600)	(10,324)
G&A expenses	(6,832)	(5,827)
Total operating expenses	**(66,699)**	**(63,943)**
Operating result	**(43,589)**	**(50,171)**
Net financial result	(1,736)	(586)
Income taxes	3,365	980
Net result	**(41,960)**	**(49,777)**

Breakdown operating expenses



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Cash position of EUR 113m end of 2017

Condensed cash flow statement

In EUR 1,000	2017	2016
Result for the period	(41,960)	(49,777)
Depreciation and amortization	5,096	4,848
Working capital changes	(3,403)	(8,699)
Other adjustments	(1,138)	316
CF operating activities	**(41,405)**	**(53,312)**
CF investing activities	**(4,320)**	**(9,342)**
CF financing activities	**75,256**	**41,804**
Total net cash flow	**29,531**	**(20,850)**
Cash and cash equivalents[1]	**112,765**	**83,247**
Financial debt[2]	35,388	31,407

1. Including EUR 1.2 million restricted cash related to KBC Lease financing
2. Current portion of EUR 4.0m

Remarks

- Cash flow from operating activities improved year-over-year as the result of:
  - A higher result for the period
  - Modest investments in working capital for 2017 compared to material movements in working capital for 2016
- Cash flow from investing activities in 2017:
  - Mainly related to capitalized Idylla™ systems placed with customers under (reagent) rental agreements and Idylla™ systems used for assay development needs
  - Note: most investments for cartridge manufacturing expansion were directly paid for via lease financing
- Cash flow from financing activities in 2017 mainly related to the net proceeds from the private placement in November 2017
- Total net cash flow in 2017 of EUR 29.5m, resulting in a cash position per year-end of EUR 112.8m. Note: per year-end no drawdowns made on the multiple purpose credit facility

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Four new CE-IVD oncology tests and first US FDA clearance

Oncology

NRAS Mutation Test

- CE-IVD
- **Colorectal cancer**

- 18 NRAS mutations, , directly on 1 FFPE[1] tissue
- TaT[2]: Approx. 120 minutes sample-to-result
- < 2 minutes hands-on time

ctKRAS Mutation Test

- CE-IVD
- **Colorectal cancer**

- 21 mutations, directly on 1 ml plasma
- TaT[2]: Approx. 130 minutes sample-to-result
- < 1 minute hands-on time

ctNRAS-BRAF Mutation Test

- CE-IVD
- **Colorectal cancer**

- 18 NRAS mutations and 5 BRAF mutations, directly on 1 ml plasma
- TaT[2]: Approx. 110 minutes sample-to-result
- < 1 minute hands-on time

EGFR Mutation Test

- CE-IVD
- **Lung cancer**

- 51 mutations, directly on 1 FFPE[1] tissue
- TaT[2]: Approx. 150 minutes sample-to-result
- < 2 minutes hands-on time

Infectious disease

Respiratory (IFV-RSV) Panel

- US FDA 510(k) clearance
- **Intended for detection of various strains of Influenza Virus (IFV) and Respiratory Syncytial Virus (RSV)**

- TaT[2]: Approx. 50 minutes sample-to-result
- < 2 minutes hands-on time

1. FFPE = Formalin fixed, parrafin embedded
2. TaT = Turnaround Time

Initiated breast cancer menu development with partners

	Description	Partner	Partnership structure
Resistance monitoring test	• Liquid biopsy test • Monitoring of metastatic breast cancer patients for resistance to hormone therapy	LifeArc UK based medical research charity[1]	• Development multiple Idylla™ tests • LifeArc acts as development contractor • Biocartis responsible for commercialization under own label
Therapy selection test	• Solid biopsy test • Supporting optimal therapy selection decisions for breast cancer patients	Agency for Science, Technology and Research SINGAPORE Singapore's Agency for Science, Technology and Research[2]	• Parties will co-invest in development of selected Idylla™ tests • A*STAR acts as development partner • Biocartis responsible for commercialization under own label
Oncotype Dx Breast Recurrence Score® test	• Solid biopsy test • Tailoring treatment of breast cancer patients based on the biology of their individual disease	Genomic Health® LIFE. CHANGING. US based provider of genomic-based diagnostic tests in cancer	• Genomic Health to develop Idylla™ versions of proprietary Genomic Health tests • Genomic Health responsible for commercialization under own label • Biocartis acts as supplier of tests

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1. 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
2. Partnership is with ETPL, the commercialization arm of A*STAR

Strategic collaboration with Genomic Health® LIFE, CHANGING.

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

Background Genomic Health

- A leading provider of genomic-based diagnostic tests in cancer with revenues of USD 328m in 2016
- Based in California (US) and listed on NASDAQ (GHDX) with a market cap of approx. USD 1bn
- On-market tests for breast, prostate and colon cancer, currently offered through own service laboratories

Oncotype Dx Breast Recurrence Score® test

oncotype DX® Breast Recurrence Score

- Provides personalized information for tailoring treatment of breast cancer patients based on the biology of their individual disease
- Predicts the likelihood of chemotherapy benefit as well as the chance of cancer recurrence in early-stage breast cancer patients
- Included in all major cancer guidelines worldwide and considered as standard of care for women with early-stage breast cancer

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Source: company website and financial reporting Genomic Health

AMGEN CDx agreements

CDx Vectibix®

- Aimed at registering Idylla™ RAS biomarker tests with US FDA as a companion diagnostic (CDx) test for Vectibix® (panitumumab[1])
- Biocartis will pursue a premarket approval (PMA[2]) for the Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF Mutation Test with the US FDA
- Amgen will provide financial and operational support to Biocartis for the PMA process

CDx novel oncology compound

- Aimed at the development of Idylla™ CDx biomarker tests for a novel oncology compound to be used in the treatment of certain solid tumors

CDx agreements further build on Biocartis' and Amgen's collaborations[3] in Europe focused on accelerating results of RAS biomarker testing from up to one month to, in principle, same-day results for mCRC patients

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1. Vectibix® is the first and only fully human monoclonal anti-epidermal growth factor receptor (EGFR) antibody indicated for certain mCRC patients with wild-type RAS (defined as wild-type in both KRAS and NRAS genes)
2. PMA is the US FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. PMA is the most stringent type of device marketing application required by the US FDA. PMA approval is based on a determination by the US FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)
3. Biocartis and Amgen announced a first collaboration on 3 February 2016, aimed at accelerating access to RAS biomarker information for mCRC patients in a number of selected countries worldwide (Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey) and expanded their collaboration on 22 December 2016 to additional selected hospitals in Europe

US commercialization initiated

Commercialization approach

- Distribution agreement in place with Fisher Healthcare: focus on distribution of Idylla™ oncology products[2]
- Hybrid sales approach:
  - Distributor sales through fisher healthcare [1]
  - Direct sales through Biocartis' US sales team (also providing support to Fisher Healthcare team)
- US FDA 510(k) exemption Idylla™ instrumentation and first test cleared by US FDA, the Idylla™ Respiratory (IFV-RSV) Panel
- Successful placement of first Idylla™ instruments with US customers

US Idylla™ performance data

- Idylla™ performance data presented at annual AMP[4] meeting on 15 November 2017
- Dr. Tsongalis presented results from an internal study comparing the performance of the Idylla™ KRAS, NRAS and BRAF tests to the internal Standard of Care methods at the Dartmouth Hitchcock Medical Center, in this case based on a NGS technology
- Study[5] indicated full concordance of Idylla™ KRAS, NRAS and BRAF test with internal Standard of Care method in terms of sensitivity, specificity and predictive value
- Dr. Gregory J. Tsongalis, BS, MS, PhD is Professor of Pathology at Dartmouth Hitchcock Medical Center, New Hampshire, US

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1. A division of Thermo Fisher Scientific Inc.
2. Exclusive for Biocartis' Idylla™ assays; non-exclusive for Idylla™ instruments
3. MarketsandMarkets, Molecular Diagnostics Market - Forecast to 2020, February 2017
4. Association for Molecular Pathology (AMP), 15 November 2017
5. The study was performed on 53 archived formalin-fixed paraffin-embedded (FFPE) colorectal cancer samples in the Dartmouth Hitchcock Medical Center. Compared to the NGS technology, Idylla™ scored 100% on sensitivity, specificity and positive & negative predictive value. Study results were first presented at the Biocartis Corporate Workshop held at the Association for Molecular Pathology (AMP) 2017 Annual Meeting, 15 November 2017, US.
6. Next Generation Sequencing

Business update

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Establishment of a US R&D center

- Rationale US R&D center (Raritan, New Jersey):
  - Support execution of strategy to accelerate menu expansion through predominantly CDx collaborations and assay content partnerships
  - Have access to a US pool of R&D talent
- Establishment result of transfer of R&D staff members (approx. 10 FTEs) from Janssen Diagnostics to Biocartis[1]
- Development experts joining Biocartis have in-depth Idylla™ IVD assay development expertise: successfully developed, amongst others, the Idylla™ Respiratory (IFV-RSV) Panel
- Furthermore, agreement includes:
  - Two-year transitional lease of laboratory and office space from Janssen
  - Acquisition of laboratory equipment
  - Ownership transfer of the Idylla™ Respiratory (IFV-RSV) Panel to Biocartis (including regulatory authorizations)

Impression lab facilities Biocartis US R&D center

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1. Janssen Diagnostics is a division of Janssen Pharmaceuticals, Inc.

Rapidly expanding Idylla™ test menu (1/2)

	Test	Development[1]	RUO[2]	Validation[3]	CE[4]	PMA[5]	CDx[6]	Disclosed partnerships
CRC	KRAS		✓		✓	Submission 2018E[7]		• Amgen
	NRAS-BRAF		✓		✓	Submission 2018E[7]		• Amgen
	NRAS		✓		✓			
	ctKRAS		✓		✓			• Merck
	ctNRAS-BRAF		✓		✓			• Merck
	MSI	2018E						
Lung	EGFR		✓		✓			
	ctEGFR	2018E		2019E				
	BRAF		✓	2018E				
	GeneFusion	2019E						
	NGS Prep Panel Lung	2019E						
Mel.	BRAF		✓		✓			
	ctBRAF		✓					
Breast	Therapy selection	2019E						• A*Star
	Oncotype DX®	2019E						• Genomic Health
	Resistance monitoring	2018E						• LifeArc
CDx	Novel compound							• Amgen
	Undisclosed CDx							• Undisclosed partner

completed | ongoing | = solid biopsy | = liquid biopsy

1. Generally includes analytical validation. 2. Research Use Only 3. Clinical validation. 4. CE-IVD. 5. Premarket approval process with US FDA. 6. Companion Diagnostic. 7. Submission of the Idylla™ RAS PMA (Pre-Market Approval) documentation with the US FDA around year-end, subject to feedback from US FDA interactions. Note: Launch dates are indicative. Overview is subject to change in amongst others prioritization of test development by Biocartis and/or partners driven by commercial, partnering and operational considerations

Rapidly expanding Idylla™ test menu (2/2)

Further expansion oncology menu

- Continued menu expansion through own developments and partnerships:

1 Menu expansion within current cancer areas focused on, e.g.:
  - Complementary novel assays (including NGS Prep Panels)
  - Companion Diagnostics of existing and novel tests
  - (Exclusive) third party diagnostic content

2 Into additional:
  - Cancer indications (e.g. bladder and prostate cancer)
  - Treatment options (e.g. immuno-oncology)

Infectious disease menu

- On market tests:
  - Idylla™ IFV-RSV Panel (CE-IVD, RUO[1] and 510k[2])
  - Ebola (EUA[3])

- Sepsis host response partnership with Immunexpress
  - Aimed at development and commercialization of Immunexpress' SeptiCyte™ test[4] for use on Idylla™
  - SeptiCyte™ LAB test, recently received 510(k) clearance for use on a manual PCR instrument
  - Parties will co-develop the SeptiCyte™ Idylla™ test
  - Immunexpress will take the lead in commercialization, initial focus on US and Europe

- Further menu expansion with focus on syndromic panels & bloodstream infections tests that are to be (co-)developed and commercialized through partnerships

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1. Research Use Only. 2. US FDA 510(k) clearance. 3. EUA = Emergency Use Only. 4. The SeptiCyte™ test aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS, Systematic inflammatory response syndrome) systemic inflammation in critically ill patients on their first day of their admission in the ICU (intensive care unit)

Up to EUR 24m provided by the EIB financing facility for infectious disease projects

Facility details

- Up to EUR 24m debt financing facility. Can be used to part-finance up to 50% of further investments in infectious diseases diagnostics solutions on Idylla™
- Consisting of two tranches, each with a minimum of EUR 6m
- First tranche to drawn within 12 months following signing and second tranche within 18 months from disbursement first tranche
- Duration of up to six years as of the disbursement of the first tranche. Biocartis is entitled to forgo drawdowns on the facility
- Facility enjoys a senior ranking and security position comparable to the Company's existing multi-purpose credit facility
- Supported by InnovFin – EU Finance for Innovators' Infectious Diseases Finance Facility, with the financial backing of the European Union under Horizon 2020 Financial Instruments

European Investment Bank

European Commission

EIB Vice-President Ambroise Fayolle, reacted:
"R&D is an indispensable part of the healthcare sector, but also the one with the highest risk, which can sometimes make it challenging to finance. Thanks to the support of the European Commission under the InnovFin program, the European Investment Bank is very glad to provide financing to Biocartis in rolling out their Idylla™ technology that has the potential to significantly speed up the identification and diagnosis of infectious diseases, enabling amongst others faster and better treatment decisions. This is what European innovation is all about."

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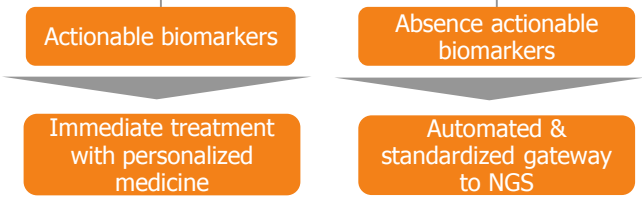
NGS Prep Panel Lung completes lung menu

Idylla™ lung menu	Application
EGFR ctEGFR	• Panel of >50 EGFR mutations as included in clinical guidelines • Solid and liquid biopsy version required as tumor tissue is often not available • Clinical guidelines[1] recommend EGFR testing for all NSCLC patients[1]
GeneFusion Panel[3]	• Clinical guidelines[1] recommend ALK and ROS1 testing for all NSCLC patients[2]
BRAF	• Panel of 7 BRAF mutations • Clinical guidelines[1] recommend BRAF testing for patients who are negative for EGFR, ALK and ROS1
NGS Prep Panel Lung	• A multiplexed sequencing panel for additional/infrequent markers • Becoming accepted by international societies and increasingly mentioned in guidelines[1]

- **Complete menu** for lung cancer testing from clinically **actionable** to clinically **oriented** targets starting from a **minimal sample input**



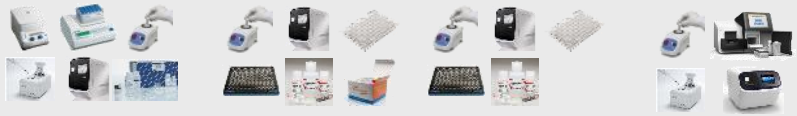
- **Fastest time-to-therapy** for frequent 'actionable mutations' as recommended by clinical guidelines

1. ESMO guidelines, CAP/IASLC/AMP guidelines
2. For all non-small cell lung cancer (NSCLC) patients with advanced/recurrent disease
3. Panel includes amongst others ALK and ROS1

NGS sample prep & target enrichment on Idylla™

Traditional NGS workflow

sample prep → target enrichment → library prep → sequencing



- Isolate genomic material from clinical sample
- Quantify genomic material via qPCR

- Target amplification via PCR

- Sample indexing and tagging
- Purification

- Pool libraries
- Sequencing
- Data analysis

Summary traditional workflow

4 #labs	6 #auxilliary devices	6h Hands-on time[1]
3 #PCR reactions	18 #samples/ batch	12h Turnaround time[1]

Idylla™ NGS Prep Panels:

- **Standardization** and **automation** of FFPE sample prep and target enrichment workflow
- **Compatible** with mainstream desktop sequencers
- **Minimization** of required amount **FFPE sample input**
- Maintains **sample pooling flexibility**
- Biocartis NGS panel design makes overall NGS workflow more **cost-effective**
- Offers **partnership possibilities** for third party NGS panel content and CDx

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1. Estimates are based on analysis of traditional NGS workflows

2018 Outlook

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Guidance 2018

Maintain installed base growth at 250-275 new instrument placements, to a total of around 900-925 Idylla™ instruments by year-end 2018

Target of doubling commercial cartridge volume in 2018

Targeted cash position in the range of EUR 50m – EUR 60m by 2018 year-end (excluding drawdowns on the Company's multiple purpose credit facility)

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Menu newsflow 2018

Area	Test	Timing	Partner
Colorectal cancer	• Launch of the Idylla™ MSI Assay (RUO[1]) • Submission of Idylla™ RAS PMA[2] documentation with the US FDA, subject to feedback from US FDA interactions	• H2 2018 • Around year-end	AMGEN
Lung cancer	• Launch of the Idylla™ ctEGFR Assay (RUO[1]) • CE-marking of the Idylla™ BRAF Mutation Test[3]	• H2 2018 • H2 2018	
Breast cancer	• Launch of the Idylla™ Resistance Monitoring Test (RUO[1])	• H2 2018	LifeArc

1. RUO = Research Use Only
2. PMA = Pre-Market Approval
3. Validated for therapy selection in BRAF positive non-small cell lung cancer patients

Financial calendar 2018

- Publication annual report 2017 — 5 April 2018
- Q1 2018 business update — 26 April 2018
- Annual General Meeting — 11 May 2018
- H1 2018 results — 6 September 2018
- Q3 2018 business update — 15 November 2018

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Q&A

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