Biocartis

Corporate Presentation

October 2017

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Leader in oncology precision diagnostics

Differentiated technology	• Idylla™: first **fully automated** sample-to-result qPCR platform • Superior and validated **performance** versus competition • Enabling **global decentralization** of clinical molecular diagnostics
Attractive market	• Global MDx* market of USD 6.5bn; oncology fastest growing segment with **high double digit annual growth** rates • Large, global customer base & opportunity to add new **customer segments**, e.g. labs that want to step into MDx testing
Focus on oncology	• Unique platform features bring strong **competitive advantage in oncology testing** • Broad **test menu** (solid & liquid biopsies) for **therapy guidance**, later for patient monitoring & screening • Validation via **partnerships** with pharma (e.g. Amgen, Merck KGaA) and content partners (e.g. Genomic Health)
Proven commercial strategy	• Installed base over **500 instruments** • Present in **over 70 countries** • **US commercialization** via new subsidiary Biocartis Inc., with Thermo Fisher Scientific as distribution partner
Strong H1 2017 performance	• Year-over-year growth of commercial product revenues with **195%** • Accelerated cartridge consumption: **H1 2017 volume** greater than full year 2016 volume
Positioned for further growth	• Continued expansion **global commercial footprint** from current focus on Europe to US and other geographies • Rapidly **expanding test menu,** additional highly automated manufacturing line under construction, supporting volume growth & cost effectiveness • Strong pipeline of potential **partnerships** with leading pharma companies and content providers

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* MDx = molecular diagnostics

Fully automated molecular testing with Idylla™

Clinically-actionable results

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

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

Enabling decentralized testing

	Idylla™ workflow	Traditional workflow*
Instruments needed		
Lab consumables needed		
Lab infrastructure (# rooms)	1	3
Workflow	• Fully automated ('sample-to-result') and on demand	• Manual and batch-based testing, 1/week or biweekly
Turnaround time	• < 2.5hrs turnaround time per test • In 1-2 days to treatment initiation***	• 1-4 days turnaround time per test • On average 18 days** to treatment initiation***

Traditional workflow results in:

- Centralized testing (many labs send out samples) by specialized labs with experienced lab technicians
- Poor reproducibility of results (i.e. human errors)
- Long turnaround time (~ weeks)

Idylla™ enables:

- Decentralized testing by all labs (no geographical differences in quality)
- 'First-time-right' results
- Short turnaround time (~ 'same-day-result')

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* Based on a qPCR workflow
** Example for France, based on a survey conducted in 5 French regions by the French National Cancer Institute, January 2016 (http://en.e-cancer.fr)
*** Idylla™ CE IVD Tests are intended to aid in the assessment of patients with cancer for their mutation status and to facilitate treatment decisions with a multidisciplinary team

Comparative studies confirm superior performance

Comparative study organized by AstraZeneca

- Comparison of 13 different KRAS mutation detecting technologies:

6x NGS	ThermoFisher SCIENTIFIC, illumina, VELA DIAGNOSTICS, RainDance Technologies, CANCER RESEARCH UK
3x qPCR	BIOCARTIS, Roche, QIAGEN
2x mass spec.	Agena BIOSCIENCE
1x ddPCR	BIO-RAD
1x Sanger sequencing	ThermoFisher SCIENTIFIC

- Focused on detection of KRAS mutations in lung cancer based on blinded samples

Conclusions to the AstraZeneca study

Sensitivity

Technology	Overall sensivity
Idylla™ KRAS	**96%**
Other qPCR (cobas/therascreen)	46-52%
Mass-spectrometry	58-92%
NGS	48-100%
ddPCR	52-60%

Ease-of-use

- Highest score for Idylla™ KRAS technology:
  - Lowest number of manual handling steps in sample preparation (1 to 2 steps versus 3 to > 20 steps)
  - Requires lowest level of expertise (1 versus 2-4 for others*)

TaT**

- Highest score for Idylla™ KRAS technology on total turnaround time (2 to 4 hours versus 1 day to 3 weeks)

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Source: Sherwood JL, Brown H, Rettino A, et al. Key differences between 13 KRAS mutation detection technologies and their relevance for clinical practice. ESMO Open 2017;2:e000235. doi:10.1136/esmoopen-2017-000235).
NGS technologies included two technologies by Thermo Fisher Scientific. Mass spectrometry technologies included two technologies from Agena Bioscience

* One being the lowest level of expertise and four the highest
** TaT = total turnaround time

Oncology, an attractive market segment

Fast growing market

Oncology MDx market

- Represents 19% of the USD 6.5bn total MDx market in 2016[1]
- Fastest growing segment in MDx, expected to grow 26% per annum (doubling of market) to 2020[2]

Key growth drivers

- Growing global prevalence of cancer: ca. 2.5% per annum[3]
- Growth of MDx testing:
  - Clinical pipeline targeted therapies: in 2015, > 800 cancer treatments were in development in the US[4] of which 73% have the potential to be personalized medicines[5]
  - Availability of targeted therapies: increasing adoption in Western world; roll-out in developing countries due to patent expirations
- Growth of decentralized market

Significant underpenetrated customer potential

- Around 16,000 pathology laboratories worldwide[6]
- Significant number of hospitals not performing MDx today, table below shows situation US[7]:

Hospital Segment	Number	Performing MDx (total)	%
Small	3816	382	10%
Medium	988	632	64%
Large	420	353	84%

Sales approach:

- Initial focus on labs offering MDx testing (= **existing** market)
- Second phase focused on targeting labs that want to step into MDx testing (= **new** market)

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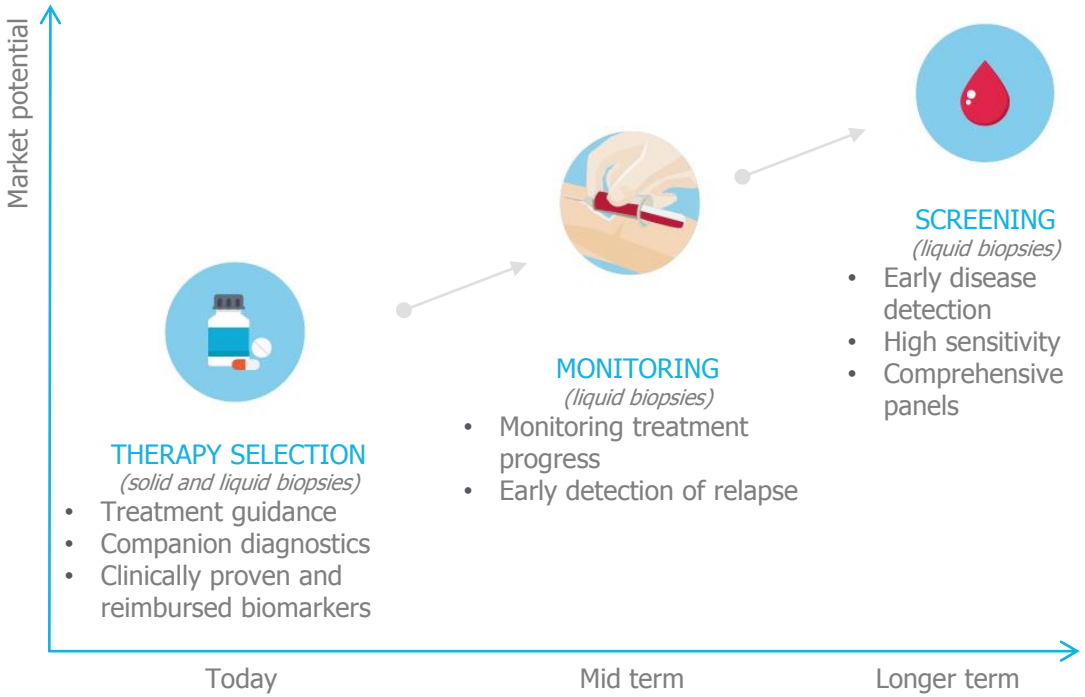
1. MarketsandMarkets, 2017; 2. Berenberg research; 3. Globocan 2012, Estimated cancer incidence, mortality and prevalence worldwide, WHO International Agency for Research on Cancer; 4. PhRMA, "Medicines in Development for Cancer," September 2015, http://phrma.org/sites/default/files/pdf/oncology-report-2015.pdf; American Association for Cancer Research. "Jose Baselga, MD, PhD" http://cancerprogressreport.org/2015/Pages/baselga.aspx; 5. PhRMA, Oncology Report 2015; 6. Management estimate; 7. Boston Strategic Market Research www.hospitalregisters.com 2014; American College of Surgeons 2000-2011; EMMES 2012, 2015 database

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

Rapidly expanding Idylla™ test menu

Onco Solid Biopsy | Idylla™ Retrieve
Onco Liquid Biopsy | CDx
On market assay

Area	On market end 2016	2017	2018	Focus as from 2019 (indicative)	
Colorectal	KRAS CE NRAS-BRAF CE NRAS/BRAF/EGFR492 RUO ctKRAS RUO	ctNRAS/BRAF/ EGFR492 RUO NRAS CE ctKRAS CE ctNRAS-BRAF CE	MSI	Expansion of existing assay menus: • CRC • Lung cancer • Melanoma	Expansion into major oncology areas: • Urology • DNA repair
Lung	EGFR RUO	EGFR CE ctEGFR RUO	ctEGFR CE GeneFusion Panel		
Melanoma	BRAF CE ctBRAF RUO				
Breast				Therapy selection+ Resistance monitoring++	Oncotype DX®+++ To be further expanded
Immunotherapy			MSI (immunotherapy)		
NGS			NGS Hotspot Panel	Additional NGS Prep Panels to be launched	
CDx		First CDx collaboration	Additional CDx programs to be added		
Infectious diseases	IFV-RSV Panel CE* Ebola EUA*	IFV-RSV Panel 510k*	Syndromic panels (initial assay Respiratory MP**) & bloodstream infections (incl. sepsis)		

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CE = CE-marked tests. RUO = Research Use Only + In collaboration with A*STAR ++ In collaboration with LifeArc +++ In collaboration with Genomic Health * JnJ test ** In collaboration with Fast-track Diagnostics
Note: overview is subject to changes in prioritization of test development driven by several factors such as commercial and operational considerations. Overview excludes regional expansion, life cycle management and potential partner tests

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	• Increased number 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.	LifeArc: UK based medical research charity[2] Agency for Science, Technology and Research: 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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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

- 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

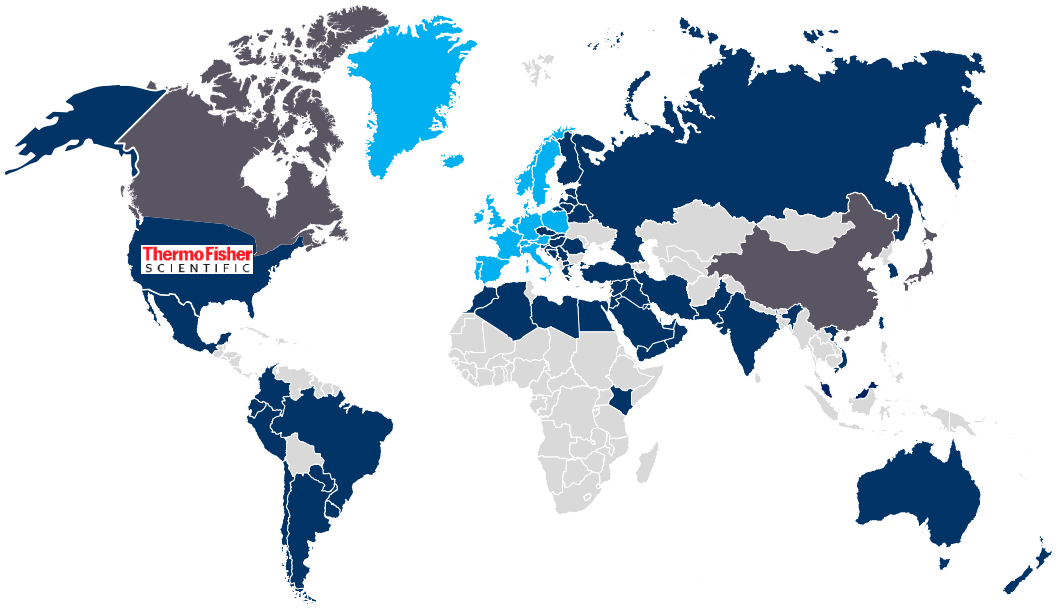
Continued expansion global commercial footprint*

Over 70 countries covered through three sale channels:

1. Direct sales force covering Western European countries

2. Distributor contracts in place covering 58 countries
   - US commercialization partnership signed in November 2016
   - Announcement commercialization strategy China in 2017/2018
   - Announcement commercialization strategy Japan in 2018/2019

3. Global pharma collaborations (e.g. Merck KGaA and Amgen)



Direct – reps on the ground
Distributors – signed up
Partnership under discussion

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* Situation as per 30 June 2017

US commercialization launched

Commercialization update

- US General Manager and core US support team hired ✓
- Sales force training Thermo Fisher Scientific ongoing ✓
- US subsidiary established ✓
- US FDA 510k exemption Idylla™ instrumentation and first (infectious disease) test cleared by US FDA ✓
- First US commercial placements concluded ✓

Partnership Thermo Fisher Scientific

ThermoFisher SCIENTIFIC

- Partnership signed with Fisher Healthcare, a division of Thermo Fisher Scientific Inc.
- Thermo Fisher to act as distributor in the US[1], Biocartis retains right to sell directly
- Initial focus on distribution of Idylla™ oncology products
- 5 year initial term

US expected to account for the largest proportion of the MDx market for oncology (expected market size of USD 1.45bn by 2020, > 45% of the global market) and infectious disease (expected market size of USD 1.07bn by 2020)[2]

[1] Exclusive for Biocartis' Idylla™ assays; non-exclusive for Idylla™ instruments
[2] MarketsandMarkets, Molecular Diagnostics Market - Forecast to 2020

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Platform and consumable driven business model

Installed base

x

Instrument utilization

x

Average selling price

=

Sales

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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Strong H1 performance: H1 2017 results

Commercial product revenues:	Year-over-year growth of 195%
Commercial cartridge consumption:	Exceeded full year 2016 volume
Installed base:	Close to 500 Idylla™ instruments per end H1 2017
Menu of tests:	Two new CE-markings and launch third liquid biopsy
Cash position:	EUR 59m
Guidance:	Full year guidance reiterated

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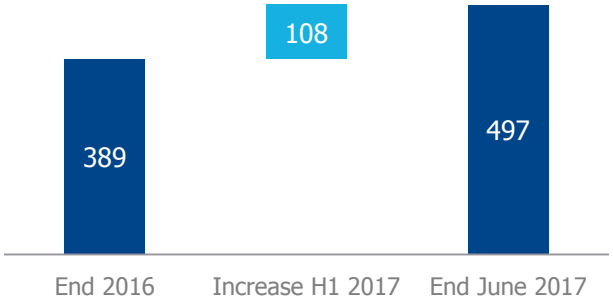
Idylla™ installed base close to 500 end H1 2017

Installed base development



Remarks

- Key drivers H1 2017 installed base growth:
  - Fully CE-marked solid biopsy RAS offering for mCRC on market since end 2016
  - CE-marking Idylla™ EGFR Mutation Test in June 2017
- Strong placements in both the European and RoW[1] markets

1. RoW = Rest of the World. RoW is defined as the world, excluding Europe, US, China and Japan

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Continued accelerated growth of cartridge volume

End June 2016

Installed base 271

Idylla™ tests 7

Of which
CE-marked tests 3

End June 2017

Installed base 497

Idylla™ tests 12

Of which
CE-marked tests 6

Cartridge volume

H1 2017 commercial volume increased to approx. 27,000 cartridges

Volume H1 2017 exceeded the total volume for the full year 2016

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Commercial product revenues increased 195% in H1 2017

Breakdown product revenues (in EUR 1,000)

By type	H1 2017	H1 2016
Commercial revenue	5,024	1,705
R&D revenue	67	1,006
Product sales revenue	**5,092**	**2,711**

By product	H1 2017	H1 2016
Idylla™ System Sales	1,821	988
Cartridge Sales	3,270	1,723
Product sales revenue	**5,092**	**2,711**

Breakdown total operating income

In EUR 1,000	H1 2017	H1 2016
Product sales revenue	5,092	2,711
Collaboration revenue	716	3,377
Service revenue	104	20
Total revenue	**5,912**	**6,109**
Grants and other income	1,066	641
Total operating income	**6,978**	**6,750**

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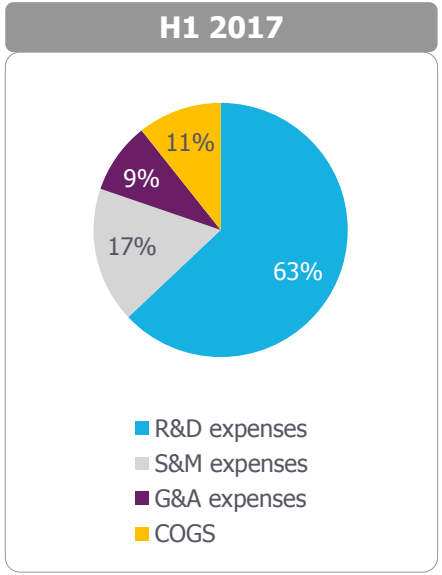
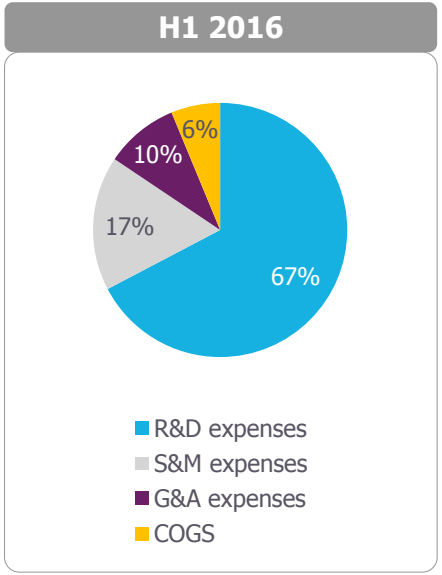
H1 2017 net result of EUR -24m

Condensed income statement

In EUR 1,000	H1 2017	H1 2016
Total operating income	**6,978**	**6,750**
COGS	(3,278)	(1,921)
R&D expenses	(19,320)	(20,699)
S&M expenses	(5,308)	(5,259)
G&A expenses	(2,781)	(2,874)
Total operating expenses	**(30,687)**	**(30,754)**
Operating result	**(23,709)**	**(24,003)**
Net financial result	(729)	(282)
Income taxes	456	501
Net result	**(23,982)**	**(23,784)**

Breakdown operating expenses





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Cash position of EUR 59m end of H1 2017

Condensed cash flow statement

In EUR 1,000	H1 2017	H1 2016
Result for the period	(23,982)	(23,784)
Depreciation and amortisation	2,428	2,393
Other adjustments	230	235
Operational burn rate	**(21,324)**	**(21,156)**
Working capital changes	(848)	(4,189)
CF operating activities	**(22,172)**	**(25,345)**
CF investing activities	**(1,531)**	**(6,912)**
CF financing activities	**(479)**	**3,919**
Total net cash flow	**(24,182)**	**(28,338)**
Cash and cash equivalents[1]	**59,042**	**75,757**
Financial debt[2]	33,279	16,544

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 year-over-year stable operational burn rate
  - Modest investments in working capital for H1 2017 compared to material movements in working capital for H1 2016
- Cash flow from investing activities in H1 2017:
  - Mainly related to capitalized Idylla™ systems placed with customers under (reagent) rental agreements and Idylla™ systems used for internal needs
  - Note: EUR 1.8m investments for cartridge manufacturing expansion in H1 2017 were directly paid via lease financing
- Cash flow from financing activities in H1 2017 relates to repayment of borrowings
- Total net cash flow in H1 2017 of EUR -24.2m

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Expected menu newsflow 2017

- CE-marking Idylla™ EGFR Mutation Test ✓
- CE-marking Idylla™ NRAS Mutation Test ✓
- US FDA 510(k) clearance of the Idylla™ Respiratory (IFV-RSV) Panel[1] ✓
- CE-marking Idylla™ ctKRAS Mutation Test (Q4 2017) ○
- CE-marking Idylla™ ctNRAS-BRAF Mutation Test (Q4 2017) ○
- Launch Idylla™ ctEGFR Mutation Assay (RUO, Q4 2017) ○

1. Note: In July 2017, the US FDA published a final list of devices that it has exempted from 510(k) premarket notification requirements. The product codes applicable to the Biocartis Idylla™ Instrument and Idylla™ Console are included on this list

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Guidance 2017

250 - 275 expected installed base expansion in 2017

Forecasted total installed base of Idylla™ instruments around 640 by year-end

Commercial cartridge volume in 2017 to be at least three times 2016 volume

Guidance target cash position by end 2017 of around EUR 40m

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Shareholders, stock performance and coverage

BCART LISTED EURONEXT

Shareholder overview *(as per 21 Sept 2017)*

Shareholder >3% table	# shares	% shares
Johnson & Johnson Innovation	6,107,518	13.7%
Debiopharm Diagnostics	4,749,707	10.6%
RMM	3,989,058	8.9%
Sycomore Asset Management	2,394,179	5.4%
Capfi Bank Delen Asset Management	2,236,901	5.0%
PMV-TINA	1,840,861	4.1%
Participatie-Maatschappij Vlaanderen	501,484	1.1%
Topbio1	1,804,644	4.0%
Hitachi Chemical	1,417,346	3.2%
Other institutional and retail investors	19,606,407	43.9%
Total outstanding shares (non-diluted)	**44,648,105**	**100.0%**

Note: see website Biocartis for more details

Share performance last 12 months*

Coverage

KBC Securities · Kempen · Degroof Petercam · BERENBERG

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* Source: Euronext

Financial calendar 2017

• Q3 2017 business update	16 November 2017
• 2017 full year results	1 March 2018
• Publication 2017 annual report	5 April 2018

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Appendix

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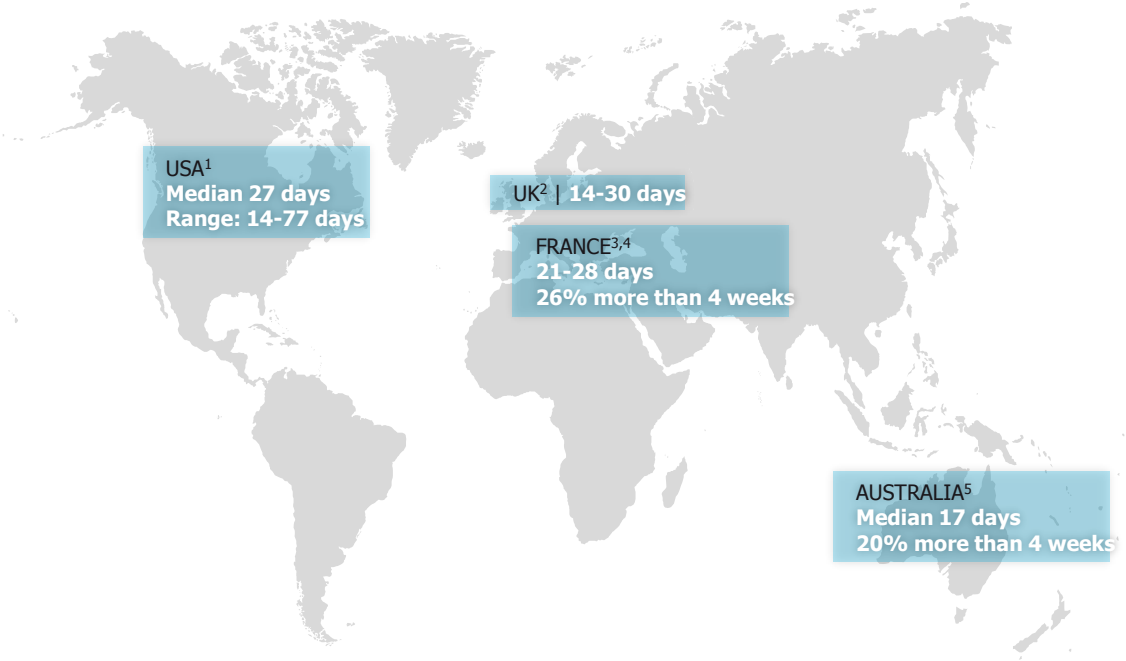
Difficult access to molecular diagnostics information

- In the US, nearly 80%[4] 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[4]



Source: 1 Schwaederle et al. (2014) Oncologist 19, 631 – 636; 2 Saunders et al. ESMO 2016, Abstract #; 3 INCa 2012 Survey, 3 Etude FLASH RAS 2014; 4 JMD, May 2017; 5 Scott et al. (2014) Asia Pac J Clin Oncol. 10(3):261-5.

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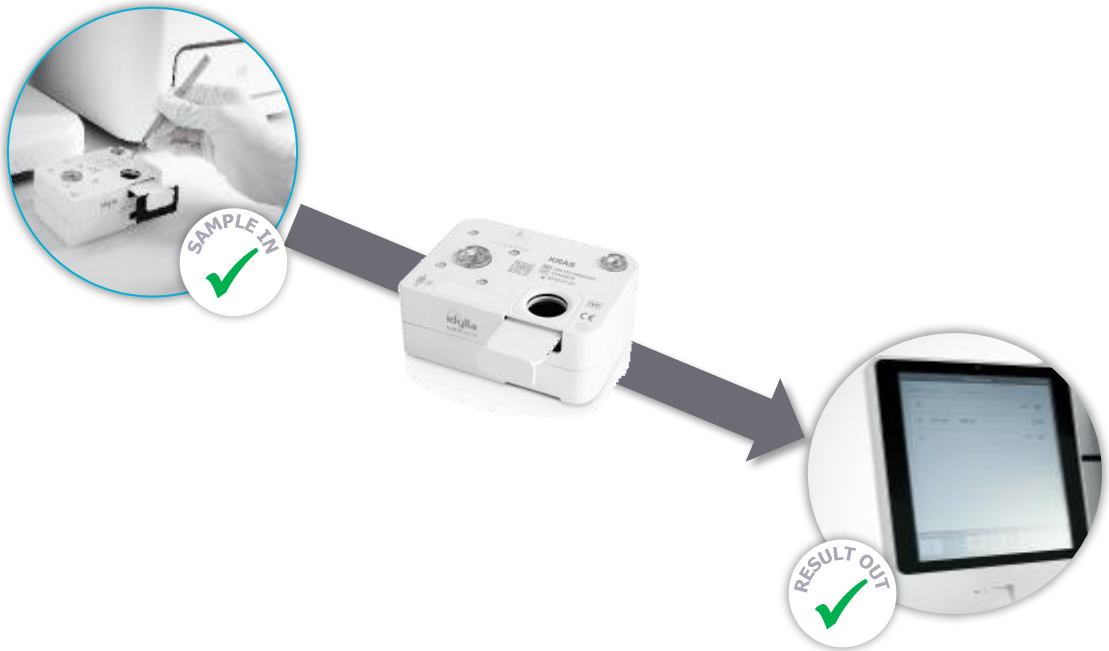
Limitation of erroneous results due to standardized cartridge

- Virtually any sample type
- No sample pre-treatment
- All reagents on board
- No PCR lab infrastructure
- No cold chain
- Stable at room temperature



Offering potential for CLIA waiver

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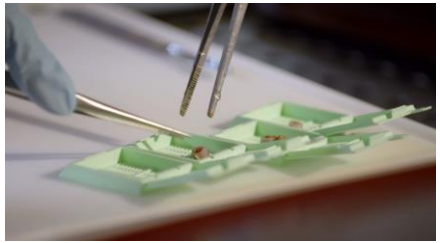
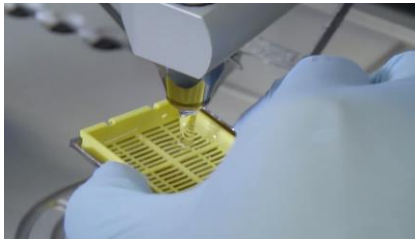
FFPE (formalin-fixed and paraffin-embedded) sample

Step 1: tissue macroscopy	Step 2: formalin-fixing	Step 3: paraffin-embedding	Step 4: microtome cutting
			
• A laboratory technician cuts the tissue into smaller pieces	• This incubate overnight in formalin for optimal conservation while maintaining the fixation of the morphology	• The next day, the tissue is embedded in fluid paraffin	• The paraffin block is then cut into thin slices (tissue sections), suitable for (microscopic) analysis

FFPE is the gold standard sample type within oncology

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Broad offering for colorectal cancer

Overview

KRAS
- Solid RUO ✓
- Solid CE ✓
- Liquid RUO ✓
- Liquid CE ○

NRAS-BRAF
- Solid RUO* ✓
- Solid CE ✓
- Liquid RUO* ✓
- Liquid CE ○

NRAS
- Solid RUO* ✓
- Solid CE ✓

✓ Depicts assays that are launched

Background

- CRC is the second most common cancer worldwide, estimated incidence of over 1.36 million new cases annually[1]
- Complete mCRC test offering for clinical use: most recent clinical guidelines recommend extended RAS/BRAF testing[2]
- Ability to enable same-day results could open routes towards faster treatment selection for mCRC patients

Pharma collaborations IdyllaTM RAS tests

AMGEN

- Collaboration aimed to offer Idylla™ RAS testing for rapid decentralized testing
- Initiated in February 2016 with sites in 7 countries[3]
- Significantly expanded in Europe end of 2016 adding several dozen sites

MERCK

- Collaboration aimed at improving patient access to ctRAS testing by leveraging the advantages of Idylla™
- Development of CE-IVD Idylla™ liquid biopsy tests for KRAS and NRAS/BRAF tests
- Subsequent implementation of tests in numerous medical centers across the world[4]

CE = CE-marked tests. RUO = Research Use Only, not for diagnostic procedures. Depicted products are not for sale in the USA and Canada

1. Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality
2. Jean-Yves Douillard, M.D., Ph.D., Kelly S. Oliner, Ph.D., Salvatore Siena, M.D., et al. Panitumumab–FOLFOX4 Treatment and RAS Mutations in Colorectal Cancer. N Engl J Med 2013;369:1023-34

3. Focused on selected reference hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey
4. US, China and Japan are excluded from this collaboration. Commercialization of assays under the collaboration is on a non-exclusive basis

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Powerful tests for lung cancer

Lung cancer testing

- Lung cancer is most common cancer worldwide accounting for 13% of all cancer types[1], 85% of lung cancers are non-small cell lung cancers (NSCLC)[2]
- Today, EGFR mutation testing is recommended in all patients with advanced NSCLC of a non-squamous subtype[3]
- Current molecular testing of lung cancer samples is a complex process:
  - Can take up to several weeks[4]
  - Samples are often small, with a limited amount of available lung tumor tissue
  - Laboratories send out samples for testing, causing long waiting times

Idylla™ EGFR Mutation Test

- Solid biopsy test
- CE-marked in June 2017
- Only on market fully automated CE-IVD test detecting all relevant EGFR mutations according to international guidelines

Idylla™ ctEGFR Mutation Assay

- Liquid biopsy test, under development. RUO launch aimed for end of 2017
- Same panel as solid biopsy test (51 EGFR mutations)
- Operates directly from plasma

1. Navani et al. Lancet Respir Med (2015)
2. American Cancer Society. Global Cancer Facts & Figures 2nd Edition (2011)
3. NCCN Clinical Practice Guidelines in Oncology – NSCLC – Version 6.2017. Novello S. et al. Metastatic non-small-cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 2016
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)

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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

Promising MSI test to be launched in 2018

Background

- Microsatellite instability (MSI) is the consequence of errors in the body's so-called DNA mismatch repair system, resulting in potential tumor growth

- Initial target markets for MSI testing:
  - Recommended in several guidelines[1] for CRC (present in several other tumor types as well, such as gastric cancer)
  - Could be the sole independent factor to predict a patient's response to certain immunotherapies[2] for oncology
- Biocartis' MSI test:
  - Based on exclusively licensed biomarkers from the VIB[3]
  - No sample control required; only 1 FFPE slice/patient required

Performance data licensed MSI Biomarkers[3] (Reference method ('RM') is Promega MSI analysis)

In CRC samples[4]

- Included 870 samples
- 94% overall agreement with RM (discordance testing showed that MSI Biomarkers detected 6% more MSI-high status)
- 12% of the tests performed with RM failed, even after repeat testing, compared to 4% with MSI Biomarkers

In gastric samples[5]

- Included 150 samples (study in collaboration with Merck KGaA)
- 100% overall agreement with RM for valid results
- 11% of samples tested with RM failed, even after repeat testing, MSI Biomarkers generated a result in 100% of the tests

1. NCCN Guidelines Colon Cancer version 2017.1; and, Van Cutsem et al. (2016) ESMO Consensus Guidelines for the management of patients with mCRC. Annals of Oncology 27, 1386–1422
2. Recent data have shown that advanced CRC patients with an MSI-high status respond particularly well to certain immunotherapies (Xiao Y et al. (2015)
3. Exclusive license agreement with the Flemish Institute for Biotechnology (VIB) for rt-PCR compatible MSI markers (the "MSI Biomarkers')
4. Maertens et al., "Detection of microsatellite instability (MSI) in colorectal cancer samples with the automated Idylla™ MSI Test", 2017, presented at ESMO, 8-12 September 2017, Madrid, Spain
5. De Craene et al., "Detection of microsatellite instability (MSI) with a novel panel of biomarkers in gastric cancer samples", 2017, presented at ESMO, 8-12 September 2017, Madrid, Spain

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NGS sample and library preparation revisited

Typical NGS workflow

	sample prep	NGS library prep	sequencing
	• Isolate genomic material from clinical sample • Quantify genomic material via qPCR	• Target amplification via PCR • Indexing and tagging via PCR • Purification	• Pool libraries • Sequencing • Data analysis
hands-on	2.5h	3.5h	
TaT*	5h	7h	

Full NGS prep summary

4 #labs	6 #auxilliary devices	6h hands-on
3 #PCR reactions	18 #samples/ batch	12h Turnaround time

Idylla™ NGS Prep Panels:

- Standardization and automation of key sample and library preparatory steps
- Any sample type
- Reduction of total hands-on and turnaround time of 50%-75%**

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* TaT: total turnaround time
** Based on common NGS workflows and management estimates

Increasing biomarker-based therapies requiring CDx tests

What is Companion Diagnostics (CDx)?

- A CDx Test is used as a companion to a therapeutic drug[1] that helps predict if a patient is likely to respond to a treatment or not[2].
- CDx are most useful in the field of targeted therapy and immunotherapy.
- The Personalized Medicine Coalition counted 132 personalized medicines[3] or drugs that point to specific biomarker(s) in their labels to direct use, currently on the market.
- Analysts estimate the market value for drugs reliant on CDx at over $25 billion in 2015[3].
- A recent survey by the Tufts Center for the Study of Drug Development showed that 42 % of the drugs in the development pipeline now include biomarkers in their R&D design[3].

Growing global market for CDx

The global companion diagnostic market is expected to reach USD 6.5 billion by 2022 from USD 2.6 Billion in 2017, at a growth rate (CAGR[4]) of 20%[5].

Rationale CDx partnerships for Biocartis

- Increased number eligible patients for their targeted therapies given faster TaT[6] and high sensitivity of tests:
  - Fast TaT: less competition with therapies not requiring a biomarker
  - High sensitivity: more patients detected with relevant biomarkers

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1. 'Companion Diagnostics' FDA. Retrieved 26 September 2016. ; 2. Duffy, MJ; Crown, J (October 2013). "Companion biomarkers: paving the pathway to personalized treatment for cancer.". Clinical chemistry. 59 (10): 1447–56. PMID 23656699; 3. "The Personalized Medicine Report", 2017, Opportunity, Challenges and the Future, The Personalized Medicine Coalition; 4. CAGR = Compound Annual Growth Rate; 5. MarketsandMarkets, 2016, "Companion Diagnostics Market by Technology (PCR, IHC, NGS, ISH), Indication (Breast cancer, NSCLC, Colorectal cancer, Neurological disorders, Infectious Diseases), End User (Pharmaceutical & Biopharmaceutical Companies, Reference Lab) - Global Forecast to 2022"; 6. TaT = Total Turnaround Time

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