Biocartis

H1 2017 results and business update

7 September 2017

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Today's presenters

Hilde Windels
Executive Director

Ewoud Welten
Chief Financial Officer

Herman Verrelst
Chief Executive Officer

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High precision diagnostics for personalized medicine

- Combining advantages of point-of-care testing with the quality of lab reference testing
  - High sensitivity
  - High levels of multiplexing
  - Unsurpassed ease of use
  - Fast time-to-result
  - Any clinical sample type (including FFPE[1])

- Fully automated sample-to-result allowing for 'first time right' results

1. FFPE = formalin-fixed and paraffin-embedded

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Key messages 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 59.0m
Guidance:	Full year guidance reiterated

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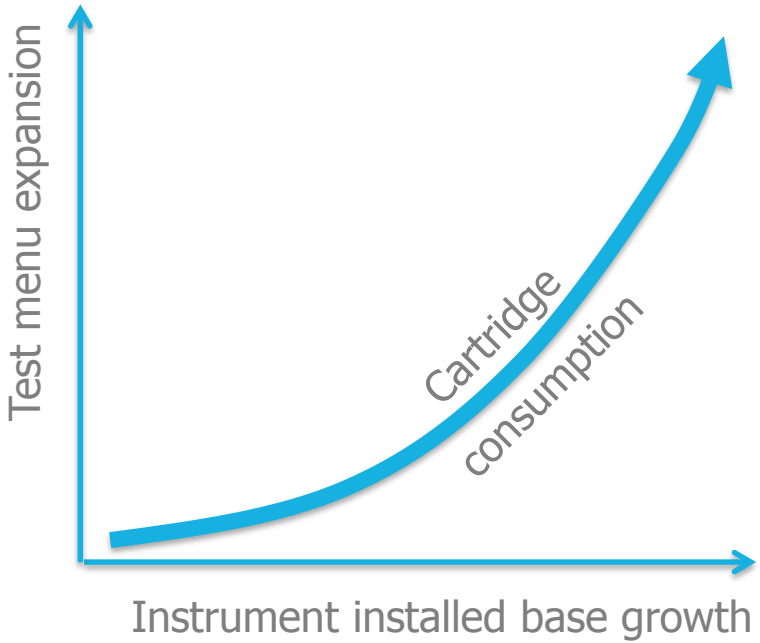
Idylla™ follows a razor-razorblade model



- Cartridge consumption on Idylla™ instruments will be the key value driver of Biocartis
- A broad installed base of Idylla™ instruments with expanding Idylla™ test menu facilitates cartridge consumption

- Focus H1 2017 on further growth of cartridge consumption through expansion of:
  - Idylla™ menu - internal and third party development
  - Commercial footprint - installed base growth in existing markets and launches in new markets

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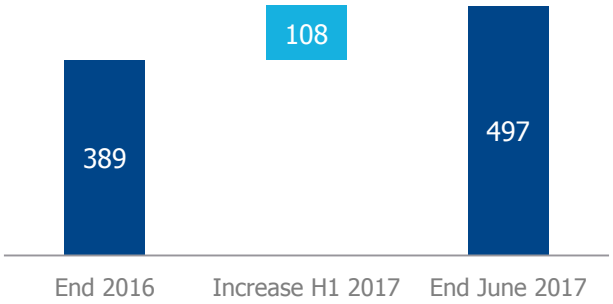
Idylla™ installed base close to 500 end H1 2017

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.

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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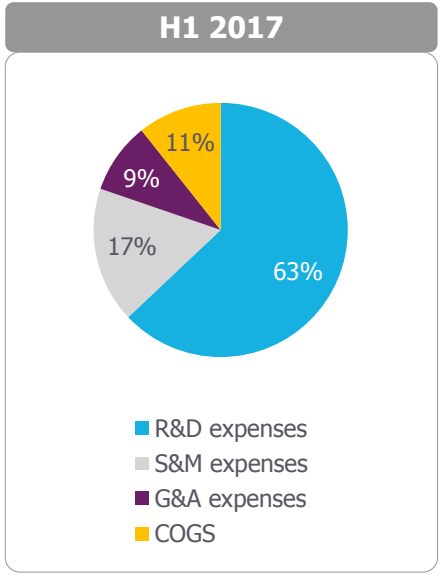
H1 2017 net result of EUR -24m

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



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: The 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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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 ✓

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

AMGEN

Collaboration aimed to offer Idylla™ RAS testing for rapid decentralized testing

MERCK

Collaboration aimed at improving patient access to ctRAS testing by leveraging the advantages of Idylla™

✓ Depicts assays that are launched.

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

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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. Aimed for launch 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

Test	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

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:
  - Is based on exclusively licensed biomarkers from the VIB[3]
  - Does not require sample control; only 1 FFPE slice per 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, to be presented as 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, to be presented as ESMO, 8-12 September 2017, Madrid, Spain

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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 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 $1.45B by 2020) and infectious disease (expected market size of $1.07B 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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Guidance 2017 reiterated

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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Expected menu newsflow 2017

- CE-marking Idylla™ EGFR Mutation Test ✓
- CE-marking Idylla™ NRAS Mutation Test ✓
- US FDA 510(k) approval 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.

Financial calendar 2017

• Extraordinary Shareholders Meeting Biocartis	11 September 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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Q&A

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