

Business update and financial results for 2016

2 March 2017

Today's presenters



Rudi Pauwels
Founder and
Chairman Strategy Committee



Hilde Windels
Chief Executive Officer



Ewoud Welten
Chief Financial Officer

Agenda

1. 2016 results
2. Menu update
3. Outlook 2017
4. Q&A

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High precision diagnostics for high precision medicine



Idylla™



THERAPY SELECTION

- Treatment guidance
- Companion diagnostics

PATIENT MONITORING

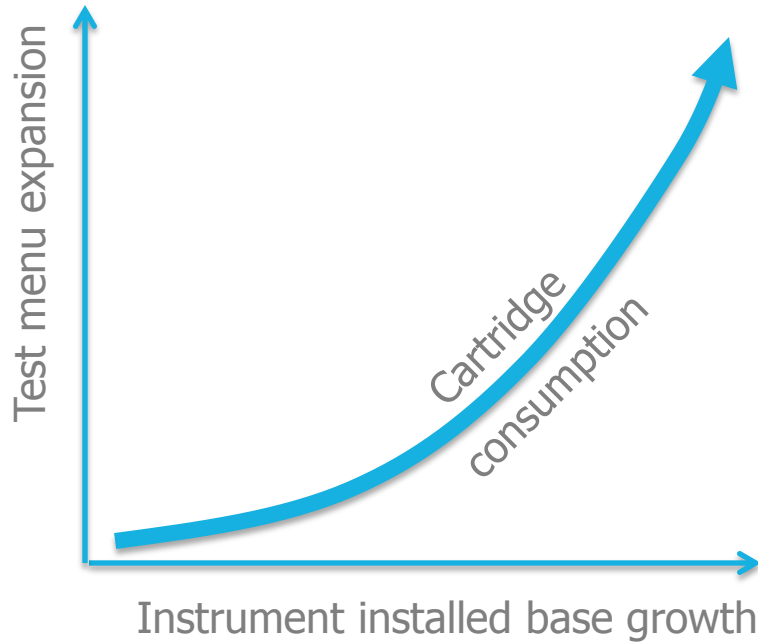
- Monitoring of treatment progress
- Early detection of relapse

EARLY DIAGNOSIS

- Rapid diagnosis
- High sensitivity
- Comprehensive panels

- 'First time right' molecular diagnostic system
- Combining advantages of **point of care** testing with **quality of lab reference testing**

Idylla™ follows a razor-razorblade model



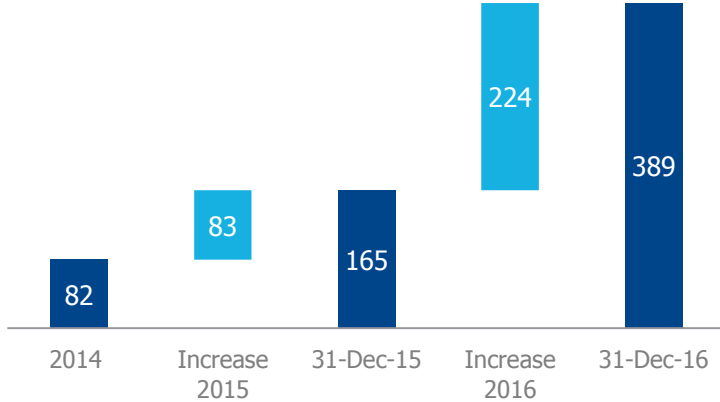
- Cartridge consumption on Idylla™ instruments will be the **key value driver** of Biocartis
- A **broad installed base** of Idylla™ instruments with expanding Idylla™ **test menu** facilitates cartridge consumption

An increasing installed base will:

- **Grow consumption** of existing Idylla™ tests
- **Accelerate market adoption** of new Idylla™ tests

Idylla™ installed base more than doubled to 389

Installed base development



2016 growth drivers

- 1 Continued menu expansion:
 - o Completion CE-marked offering for metastatic colorectal cancer (mCRC)
 - o Launch of lung cancer menu with Idylla™ EGFR Mutation Assay
- 2 Growing interest from pharmaceutical and biotech companies
- 3 Increased awareness by end customers on excellent performance Idylla™ technology as shown in recent performance studies

Exponential increase of cartridge volume in 2016

2015 end of the year



Installed base **165**



Idylla™ tests **5**



Of which
CE-marked tests **3**

2016 end of the year



Installed base **389**



Idylla™ tests **9**



Of which
CE-marked tests **4**

Cartridge volume

Commercial cartridge volume
2016 **over 7.5 times** 2015
volume

2016 volume approx. **25,000**
cartridges

Menu expansion 2016 focused on mCRC and lung cancer

mCRC



KRAS
Solid RUO
Solid CE
Liquid RUO
Liquid CE



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

- Completion of mCRC test offering for clinical use with CE-marking Idylla™ NRAS-BRAF Mutation Test:
 - Follows most recent clinical guidelines
 - Opens routes towards faster treatment selection

Lung cancer



EGFR
Solid RUO
Solid CE
Liquid RUO
Liquid CE

Melanoma



BRAF
Solid RUO
Solid CE
Liquid RUO
Liquid CE **

- First assay under Merck KGaA collaboration launched: Idylla™ ctKRAS Assay
- Launch first test lung cancer menu with Idylla™ EGFR Mutation Assay RUO: important addition to core menu

Excellent performance in comparative studies

Overview 2016 comparative studies*

By test



3x KRAS



2x BRAF



2x EGFR



1x NRAS

By channel



3x



1x



1x



1x

Key takeaways

- Superior **sensitivity** compared to competing NGS and qPCR technologies
- Unrivalled **ease of use**
- Shorter **turnaround times**
- Flexibility towards different **sample types**
- Suitable for both **solid** and **liquid** biopsies

Growing **interest** from pharmaceutical and biotech companies

Rationale

- Timely information on presence of mutations is critical in treatment selection; testing needed for patients to be eligible for targeted therapies
- In case of mCRC, testing of RAS genes is required for anti-EGFR therapies (e.g. Vectibix® of Amgen and Erbitux® of Merck)
- Technologies currently used are complex and often require several weeks¹
- This could result in situations where patients are not in the position to benefit from targeted therapies as oncologists often don't want to wait before initiating a treatment

Current collaborations



AMGEN

- Collaboration aimed to offer Idylla™ RAS testing for rapid decentralized testing
- Initiated in February 2016 with sites in 7 countries²
- Significantly expanded in Europe end of 2016 adding several dozen sites



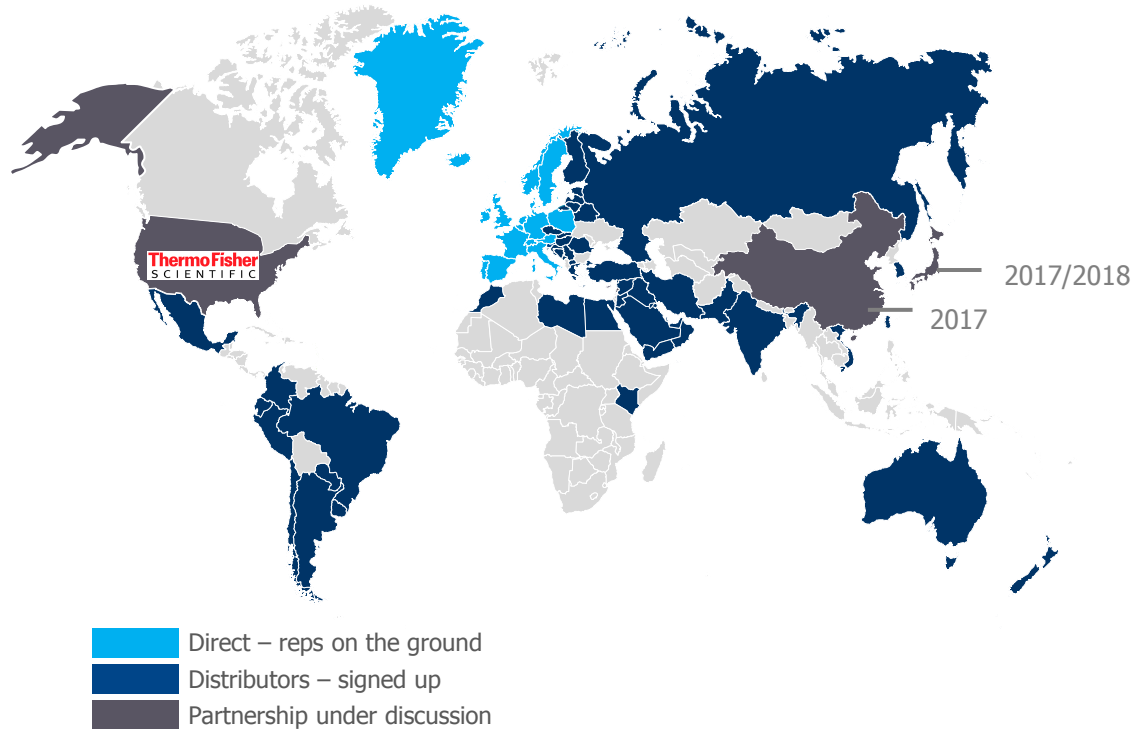
MERCK

- 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 world³

Continued expansion **global** commercial footprint*

Over **60 countries** covered through three sale channels:

- 1 Direct sales force** covering Western European countries
- 2 Distributor contracts** in place covering approx. 45 countries
 - US commercialization partnership signed in November 2016
 - Announcement commercialization strategy **China** in 2017
 - Announcement commercialization strategy **Japan** in 2017/2018
- 3 Global pharma collaborations** (e.g. Merck and Amgen)



US commercialization partnership with Thermo Fisher

Description partnership

- Partnership signed with **Fisher Healthcare**, a division of Thermo Fisher Scientific
- Thermo Fisher to act as **distributor in the US¹** Biocartis retains right to sell directly
- Initial focus on distribution of **Idylla™ oncology products**
- **5 year** initial term
- Biocartis to establish a US subsidiary and local team to support US commercialization in H1 2017 - commercial roll-out expected in H2 2017

Background Thermo Fisher Scientific³

ThermoFisher
S C I E N T I F I C

- World leader in serving science
- Annual revenues of approx. **\$17 billion**
- Approximately **50,000 employees in 50 countries**
- Experienced **nationwide sales team in place**

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

Product revenues increased with 88% in 2016

Breakdown total operating income

In EUR 1,000	2016	2015
Cartridge sales	4,015	1,294
Idylla™ system sales	2,752	2,299
Product sales revenue	6,767	3,593
R&D services	255	662
Upfront license revenues	4,691	5,025
Milestone revenues	332	4,000
Collaboration revenue	5,278	9,686
Service revenue	53	54
Total revenue	12,098	13,334
Grants and other income	1,674	1,617
Total operating income	13,772	14,951

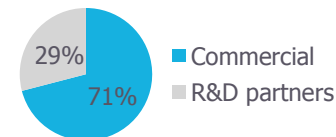
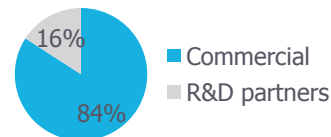
Remarks

- *Cartridge sales* increased with 210% and *system sales* with 20%
- *Collaboration revenues* decreased as EUR 4m one-off milestones were collected in 2015 (versus EUR 332k in 2016)
- *Grants and other income* consisted of recognized grant income for R&D project support

Cartridge sales by type

2016

2015



Net result of EUR (49.8)m in 2016

Condensed income statement

In EUR 1,000	2016	2015
Total operating income	13,772	14,951
COGS	(5,701)	(2,642)
R&D expenses	(42,091)	(36,554)
S&M expenses	(10,324)	(8,747)
G&A expenses	(5,827)	(6,662)
Total operating expenses	(63,943)	(54,606)
Operating result	(50,171)	(39,655)
Net financial result	(586)	(790)
Income taxes	980	648
Net result	(49,777)	(39,797)

Remarks

- Excluding cost of sales, operating expenses increased in 2016 with 12% to EUR 58.2m
- R&D: increased due to higher staff (and related) costs and increased R&D activities for test and platform development, partially offset by lower expenses for subcontracting
- S&M: increased due to an expansion of the S&M team and increased sales and promotional expenses
- G&A: decreased due to less expenses for external advice*, facilities & office and human resources, partially offset by increased staff costs
- Income taxes consist of research and development tax credits that Biocartis received in Belgium

Cash position end of 2016 of EUR 83.2m

Condensed cash flow statement			Remarks
In EUR 1,000	2016	2015 ²	
Result for the period	(49,777)	(39,797)	<ul style="list-style-type: none"> Cash flow from operating activities impacted by <ul style="list-style-type: none"> – A lower result for the period, predominantly due to higher operational expenses – Investments in working capital for 2016 versus significant positive movements in working capital for 2015 Cash flow from investing activities increased due to <ul style="list-style-type: none"> – Increased investments for the cartridge manufacturing expansion – Higher investments in intangible assets related to platform development Cash flow from financing activities includes <ul style="list-style-type: none"> – Net proceeds private placement November 2016 of approx. EUR 31m – Proceeds from new borrowing, partially offset by repayments of borrowing that were due end 2019 Financial debt (current portion of EUR 3.7m) includes <ul style="list-style-type: none"> – New subordinated loan of EUR 15m – Lease financing for cartridge manufacturing facilities
Depreciation and amortisation	5,055	5,094	
Other adjustments	109	(172)	
Operational burn rate	(44,613)	(34,875)	
Working capital changes	(8,699)	7,540	
CF operating activities	(53,312)	(27,335)	
CF investing activities	(9,342)	(5,436)	
CF financing activities	41,804	125,943	
Total net cash flow	(20,850)	93,172	
Cash and cash equivalents¹	83,247	104,087	
Financial debt	31,407	10,815	

1. Including EUR 1.2 million restricted cash related to KBC Leased financing

2. The presentation of the consolidated cash flow statement of the year ended 31 December 2015 has changed compared to what has been published in the annual report of 2015, predominantly related to activities for cartridge manufacturing expansion. The implemented changes were all qualified as reclassifications. Details will be included in the 2016 annual report

Menu update

Strong traction in oncology

Unique selling points

- FFPE*-based sample to result solutions
 - Solid and liquid biopsy testing on same platform
 - Reduction of time to result from weeks to hours
 - Superior performance data of Idylla™ tests
 - Proprietary assay content within immuno-oncology
 - Gateway to Next-Generation Sequencing (NGS)
- Customers
 - Installed base and cartridge volume growth
 - Deployment Idylla™ platform in research and clinical performance studies
 - Pharmaceutical/biotech companies
 - Commercial collaborations
 - Porting of proprietary assays to Idylla™
 - R&D collaborations
 - Companion diagnostics (CDx)

Increased focus on oncology

Objective

Turn positive momentum into strong market share and revenue growth

Menu perspective

- Menu expansion with initial focus on:
 - Colorectal
 - Lung
 - Melanoma
- Major oncology areas to be added, e.g.:
 - Breast
 - Urology
 - Immunotherapy
 - DNA repair*
- Establishment of CDx business

Commercialization perspective

- Additional collaborations with pharmaceutical and biotech companies aimed at:
 - Joint commercialization
 - Facilitating global access to targeted therapies by means of Idylla™ based testing
 - Seeking regulatory approvals

Valorization of Idylla™ platform in infectious diseases

Key features Idylla™ platform

- Large **syndromic panels** that include **quantitation**, **RNA and DNA combinations**
 - Ability to combine **short turn around times** with **ease of use** and **high sensitivity**
 - True **sample to result** (no pre-treatment needed of primary clinical samples)
 - Broad **sample type** and **volume** capabilities
 - **Sample enrichment technology** for sepsis and other bloodstream infections
- Infectious disease strategy going forward could include more partnership elements
 - Focus on Idylla™ based testing for syndromic panels and bloodstream infectious

Our Idylla™ menu

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

Area	On market end 2016	2017	2018	Focus as from 2019 (indicative)	
Oncology	Colorectal	KRAS CE	ctNRAS/BRAF/EGFR492 RUO	MSI	<ul style="list-style-type: none"> Additional assays to be launched for CRC and lung cancer menus Expansion into major oncology areas: <ul style="list-style-type: none"> Breast Urology Immunotherapy DNA repair* Additional NGS Prep Panels to be launched for number of pan-tumor indications
		NRAS-BRAF CE	NRAS CE		
		NRAS/BRAF/EGFR492 RUO	ctKRAS CE		
		ctKRAS RUO	ctNRAS-BRAF CE		
	Lung	EGFR RUO	EGFR CE	ctEGFR CE	
			ctEGFR RUO	GeneFusion Panel	
	Melanoma	BRAF CE			
		ctBRAF RUO			
	Other			MSI (immunotherapy)	
				NGS Hotspot Panel	
CDx		CDx signed	Additional CDx programs to be added		
Infectious diseases	IFV-RSV Panel CE+	IFV-RSV Panel 510k+	Syndromic panels (initial assay Respiratory MP++) and bloodstream infections (including sepsis)		
	Ebola EUA				

CE = CE-marked tests. RUO = Research Use Only. EUA = Emergency Use Authorization label + JnJ test ++ Fast-track Diagnostics development

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.

2017 Outlook

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**

Expected menu **newsflow** 2017

- CE-marking **Idylla™ EGFR Mutation Test** (Q2 2017)
- CE-marking **Idylla™ NRAS Mutation Test** (Q2/Q3 2017)
- CE-marking **Idylla™ ctKRAS Mutation Test** (H2 2017)
- CE-marking **Idylla™ ctNRAS-BRAF Mutation Test** (H2 2017)
- Launch **Idylla™ ctEGFR Mutation Assay** (RUO, H2 2017)
- **US FDA 510(k) approval of the Idylla™ platform** in conjunction with **Idylla™ IFV-RSV Panel Test**

Financial calendar 2017

- Publication annual report 2016 30 March 2017
- Q1 2017 business update 27 April 2017
- Annual General Meeting 12 May 2017
- H1 2017 results 7 September 2017
- Q3 2017 business update 16 November 2017

Q&A

