Biocartis
H1 2016 results

6 September 2016

BIOCARTIS

Today's presenters

Ewoud Welten

Chief Financial Officer

Rudi Pauwels

Chief Executive Officer & Founder

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Agenda

1. Strategy recap
2. H1 2016 highlights
3. Outlook 2016
4. Q&A

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High precision diagnostics for high precision medicine

Idylla™

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

EARLY DIAGNOSIS

- Rapid diagnosis
- High sensitivity
- Comprehensive panels

THERAPY SELECTION

- Treatment guidance
- Companion diagnostics

PATIENT MONITORING

- Monitoring of treatment progress
- Early detection of relapse

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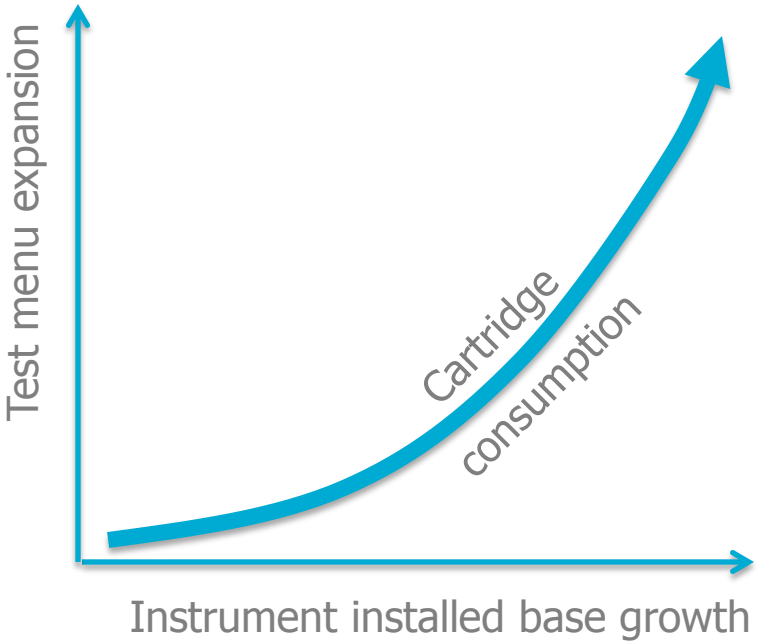
Idylla™ best-in-class

- Accurate results at right sensitivity
- Fully automated sample-to-result
- Any clinical sample type
- High levels of multiplexing
- Short turnaround time
- Modular and scalable
- Data connectivity

Idylla™ follows a 'razor-razorblade' model

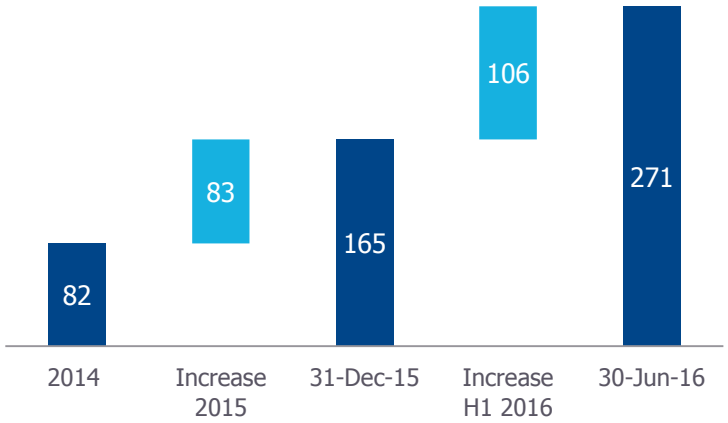


- Cartridge consumption on Idylla™ instruments is key value driver of Biocartis
- A broad installed base of Idylla™ instruments with expanding Idylla™ test menu facilitates cartridge consumption

An increasing installed base will:
- Grow consumption of existing Idylla™ tests
- Accelerate market adoption of new Idylla™ tests

106 Idylla™ instruments added to installed base

Installed base development



Remarks

- Key drivers behind growth H1 2016:
  - Oncology menu expansion end 2015 (doubling number of oncology tests to four)
  - Launch of Idylla™ EGFR Mutation Assay* end Q2 2016
- Significant number of new installations placed with customers towards end of Q2 2016
- Majority of new placements in H1 2016 with customers in Europe

* The Idylla™ EGFR Mutation Assay is intended for Research Use Only, not for diagnostic procedures. Not for sale in the USA and Canada.

Razor-razorblade approach in numbers

30 June 2015

Installed base Idylla™ instruments: 114

Number Idylla™ tests on market: 2

30 June 2016

Installed base Idylla™ instruments: 271

Number Idylla™ tests on market: 7

Cartridge volume

Commercial cartridge volume H1 2016 > 2x volume 2015 full year

Idylla™ KRAS Mutation Test top selling product in H1 2016, followed by Idylla™ BRAF Mutation Test

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Two new Idylla™ tests in H1 2016

In total 7 tests per 30 June 2016

Oncology

Idylla™ EGFR Mutation Assay

- Lung cancer
- Solid biopsy (1 FFPE° tumour slice)
- Research Use Only*
- Over 50 mutations
- Minimal tumour sample or DNA input requirements
- Sensitivity of < 5%
- TaT** approx. 2.5 hours
- HoT⁺ < 2 minutes

Easiest and fastest test for EGFR mutations available

Infectious disease

Idylla™ Ebola Virus Triage Test

- For detection of the Ebola Zaire virus in patients with signs and symptoms of Ebola virus disease
- Co-developed by Biocartis NV, Janssen Diagnostics (a division of Janssen Pharmaceutica NV) and the Belgium Institute of Tropical Medicine
- EUA (Emergency Use Authorization)~
- Sample type: blood
- TaT** around 100 min

Allows for rapid deployment in both developed and emerging market countries

* The Idylla™ EGFR Mutation Assay is intended for Research Use Only, not for diagnostic procedures. Not for sale in the USA and Canada.
** Total turnaround time ⁺ Hands on Time ° Formalin Fixed Parrafin Embedded

~ This test was granted EUA by the US FDA but has not been FDA cleared or approved.

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Towards a critical mass for oncology

BRAF (melanoma)

Solid biopsy ✓
CE-marking ✓
Liquid biopsy ✓

EGFR (lung)

Solid biopsy ✓
CE-marking ○
Liquid biopsy ○

KRAS (colon)

Solid biopsy ✓
CE-marking ✓
Liquid biopsy ○

NRAS (colon)

Solid biopsy ✓
CE-marking ○
Liquid biopsy ○

Idylla™ EGFR Mutation Assay important addition to menu

CE-marking required on all solid biopsy tests to enable wide spread clinical use

Development liquid biopsy versions (RUO) of Idylla™ KRAS Mutation Test and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, part of collaboration signed with Merck KGaA, will significantly expand liquid biopsy offering

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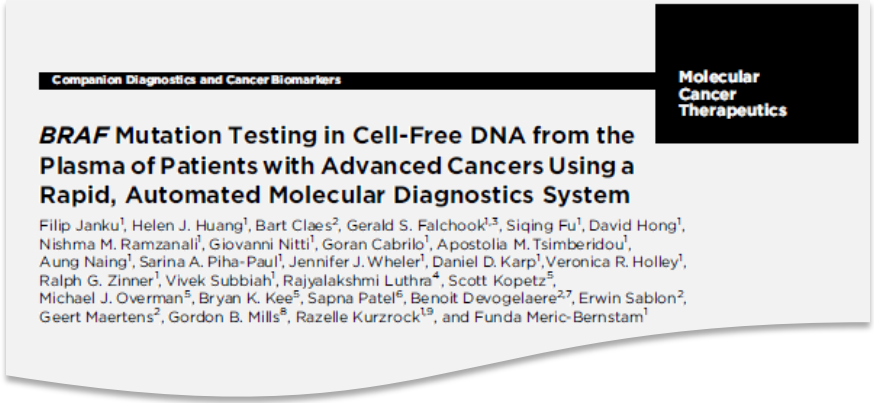
Publications continue to demonstrate high quality of Idylla™ tests

Idylla™ ctBRAF Mutation Assay



Companion Diagnostics and Cancer Biomarkers

Molecular Cancer Therapeutics

***BRAF* Mutation Testing in Cell-Free DNA from the Plasma of Patients with Advanced Cancers Using a Rapid, Automated Molecular Diagnostics System**

Filip Janku[1], Helen J. Huang[1], Bart Claes[2], Gerald S. Falchook[1,3], Siqing Fu[1], David Hong[1], Nishma M. Ramzanali[1], Giovanni Nitti[1], Goran Cabrilo[1], Apostolia M. Tsimberidou[1], Aung Naing[1], Sarina A. Piha-Paul[1], Jennifer J. Wheler[1], Daniel D. Karp[1], Veronica R. Holley[1], Ralph G. Zinner[1], Vivek Subbiah[1], Rajyalakshmi Luthra[4], Scott Kopetz[5], Michael J. Overman[5], Bryan K. Kee[5], Sapna Patel[6], Benoit Devogelaere[2,7], Erwin Sablon[2], Geert Maertens[2], Gordon B. Mills[8], Razelle Kurzrock[1,9], and Funda Meric-Bernstam[1]

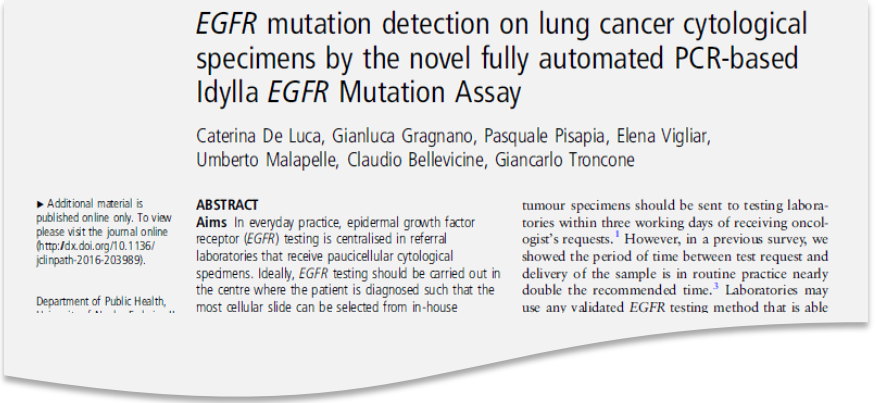
Dr. Filip Janku*, PhD, MD Anderson, US (June 2016)

Takeaways:

- Can act as a faster and minimally invasive substitute for invasive tissue biopsy testing in advanced cancers such as melanoma or colorectal cancers
- High concordance (up to 90%) with solid biopsy testing
- Perfectly suited for treatment monitoring

* Janku et al. BRAF Mutation Testing in Cell-Free DNA from the Plasma of Patients with Advanced Cancers Using a Rapid, Automated Molecular Diagnostics System. Mol Cancer Ther (2016) 15(6): 1–8.

Idylla™ EGFR Mutation Assay



***EGFR* mutation detection on lung cancer cytological specimens by the novel fully automated PCR-based Idylla *EGFR* Mutation Assay**

Caterina De Luca, Gianluca Gragnano, Pasquale Pisapia, Elena Vigliar, Umberto Malapelle, Claudio Bellevicine, Giancarlo Troncone

▸ Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/jclinpath-2016-203989).

Department of Public Health,

ABSTRACT

Aims In everyday practice, epidermal growth factor receptor (*EGFR*) testing is centralised in referral laboratories that receive paucicellular cytological specimens. Ideally, *EGFR* testing should be carried out in the centre where the patient is diagnosed such that the most cellular slide can be selected from in-house

tumour specimens should be sent to testing laboratories within three working days of receiving oncologist's requests.[1] However, in a previous survey, we showed the period of time between test request and delivery of the sample is in routine practice nearly double the recommended time.[3] Laboratories may use any validated *EGFR* testing method that is able

De Luca et al.**, ASCO conference (June 2016)

Takeaways:

- Assay yielded valid results in 97.3% of samples tested, detecting all the mutant cases identified by standard techniques
- In addition, Idylla™ detected two low abundance EGFR exon 19 deletions and two G719X exon 18 point mutations, not covered by the standard reference method

** De Luca et al. J Clin Pathol, published online first: ASCO 2016, doi:10.1136/jclinpath-2016-203989

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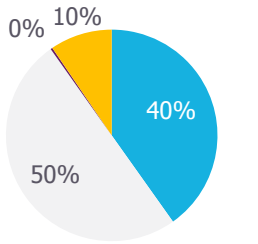
Increase in product revenues of 63%

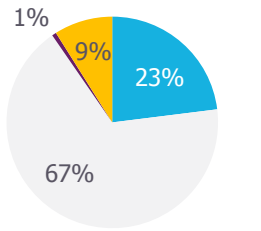
Breakdown total operating income

In EUR 1,000	H1 2016	H1 2015
Idylla™ System Sales	988	1,246
Cartridge Sales	1,723	416
Product sales revenue	**2,711**	**1,663**
Collaboration revenue	**3,377**	**4,866**
Service revenue	20	48
Total revenue	**6,109**	**6,577**
Grants and other income	641	646
Total operating income	**6,750**	**7,224**

H1 2016



H1 2015



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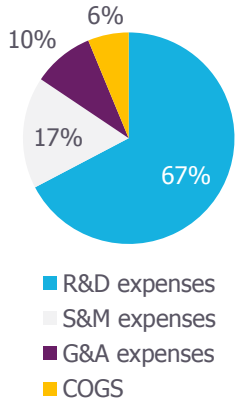
H1 2016 net result of EUR -24m

Condensed income statement

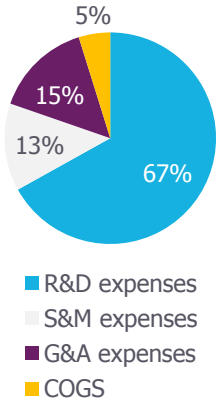
In EUR 1,000	H1 2016	H1 2015
Total operating income	**6,750**	**7,224**
COGS	(1,921)	(1,158)
R&D expenses	(20,699)	(16,092)
S&M expenses	(5,259)	(3,219)
G&A expenses	(2,874)	(3,578)
Operating expenses	**(30,754)**	**(24,047)**
Operational result	**(24,003)**	**(16,823)**
Net financial result	(282)	(429)
Income taxes	501	337
Net result	**(23,784)**	**(16,915)**

Breakdown operating expenses

H1 2016



H1 2015



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Cash position of EUR 76m end of H1 2016

Condensed cash flow statement

In EUR 1,000	H1 2016	H1 2015
Result for the period	(23,784)	(16,915)
Depreciation & amortisation	2,393	2,417
Working capital changes	(4,189)	5,653
Other adjustments	235	126
CF operating activities	**(25,345)**	**(8,719)**
CF investing activities	**(6,912)**	**(1,679)**
CF financing activities	**3,919**	**127,977**
Total net cash flow	**(28,338)**	**117,579**
Cash and cash equivalents	**75,757**	**128,477**
Financial debt	16,544	10,815

Remarks

- Cash flow from operating activities – increased negative cash flow as the result of:
  - Higher operating expenses
  - Investments in working capital for H1 2016 compared to significant positive movements in working capital for H1 2015
- Cash flow from investing activities: increase principally driven by increased capital expenditure for cartridge manufacturing expansion
- Cash flow from financing activities:
  - Driven by proceeds of obtained lease and bank financing for cartridge manufacturing equipment
  - H1 2015 cash flow impacted by inflow from the IPO (EUR 107.0m) in April 2015 and second tranche of the series F round (EUR 21.5m) in January 2015
- Total net cash flow in H1 2016 of EUR -28.3m

EUR 55m non-dilutive financing announced in July 2016

Element	Providers	Background	Inclusion
Lease financing (EUR 15m)	KBC Lease Group	• To fund the equipment of a second Idylla™ cartridge manufacturing line	• ~ EUR 5m drawn as per 30 June 2016
Credit lines (EUR 25m)	KBC; GIGARANT PMV-GROEP	• To fulfil certain future financing needs in, amongst others, working capital • Consisting of a EUR 15m rollover credit line and EUR 10m working capital credit line • Partially guaranteed by Gigarant+	• Not included in H1 2016 accounts as signed after 30 June 2016
Subordinated loan (EUR 15m)	PMV* DOE- EN DURFBEDRIJF; sfpi fpim~	• To refinance the company's current subordinated loan of EUR 5m (excluding accrued interest charges) due end of 2016	• Not included in H1 2016 accounts as signed after 30 June 2016

* Flemish Investment Company 'ParticipatieMaatschappij Vlaanderen'
~ Belgian 'Federal Holding and Investment Company' (FPIM)
+ Guarantee by Flemish Government through Gigarant

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Guidance 2016

Guidance installed base expansion in 2016 of 150-175 reiterated, yet at the top end of the range
Forecasted total installed base of around 340 Idylla™ instruments by year end

Guidance for launching at least four new tests in 2016 reiterated

€

Guidance target cash position by end 2016 in the range of EUR 45m to EUR 55m reiterated

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News flow remainder of 2016

Menu expansion

- Expected new test launches for H2 2016:
  - Liquid biopsy version of the Idylla™ KRAS Mutation Assay (RUO)
  - Liquid biopsy version of the Idylla™ NRAS-BRAF Mutation Assay (RUO)

Regulatory

- CE-marking of Idylla™ NRAS Mutation Test and Idylla™ NRAS-BRAF Mutation Test solid biopsy tests
- US FDA 510k submissions for the Idylla™ Respiratory (IFV-RSV) Panel and the Idylla™ Instrument and Idylla™ Console

Expected publication

- Publication expected by renowned pharma company on KRAS Mutation detection technologies, incl. the Idylla™ KRAS Mutation Test, at upcoming ESMO* meeting in October 2016

* European Society for Medical Oncology

Financial calendar

- Q3 Business Update 17 November 2016
- Full year results 2016 2 March 2017

Key messages H1 2016 results

General	Initial validation of Biocartis' razor-razorblade business model as increased installed base Idylla™ instruments and broadened menu Idylla™ tests are resulting in accelerated growth of cartridge consumption
Cartridge volume	Commercial cartridge volume H1 2016 more than twice the volume for 2015FY
Installed base	106 Idylla™ instruments added to the installed base in H1 2016, bringing total to over 270 as per 30 June 2016
Menu	Continued menu expansion with launch of the Idylla™ EGFR Mutation Assay and the granting of Emergency Use Authorization (EUA) for the Idylla™ Ebola Virus Triage Test
Financial	Product revenues +63% to EUR 2.7m in H1 2016 Cash and cash equivalents 30 June 2016 amounted to EUR 75.8m


Q&A