

# 2015 mid-year update

September 11, 2015



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# Agenda

- Today's presenters
- Strategy recap
- Review H1 2015
- Outlook 2015
- Financial calendar
- Q&A



# Today's presenters

## CEO



- Rudi Pauwels continues to lead the Company in the role of CEO
- Primary focus on research and innovation to drive long-term future growth

## Deputy CEO



- Hilde Windels assumes new role of Deputy CEO
- Will continue to work closely alongside CEO
- Primary focus on execution of strategy and steering of the different teams

## CFO



- Ewoud Welten joins Biocartis as CFO from Kempen & Co
- Primary focus on finance, business plan monitoring and implementation
- Will also have a key role in Investor Relations

# High precision diagnostics for high precision medicine

Adding significant value to all stakeholders



# Towards evidence based medicine

Biocartis aims to become a global leading player in MDx by providing innovative, personalized healthcare solutions, enabling fast and effective diagnosis, treatment selection and treatment monitoring



## EARLY DIAGNOSIS

Biocartis brings...

- More rapid diagnosis of disease
- More sensitive identification of mutations
- Comprehensive panels of pathogens in infectious disease



## THERAPY SELECTION

Biocartis brings...

- Identification of the right treatment for the right patient
- Companion diagnostics to test alongside new drugs



## PATIENT MONITORING

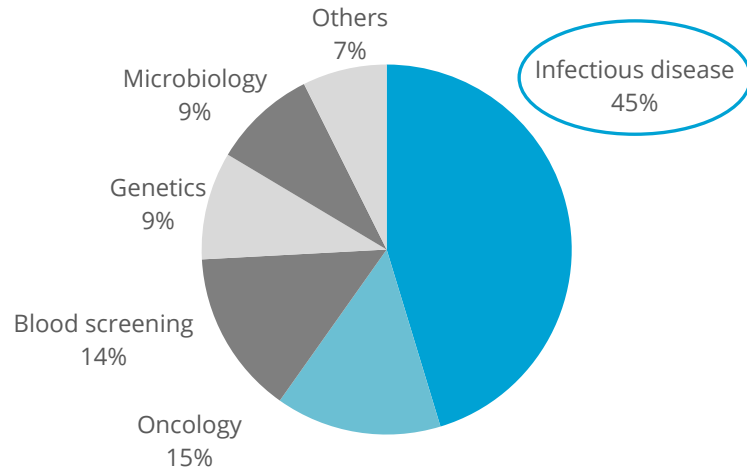
Biocartis brings...

- Monitoring of treatment progress
- Early detection of relapse

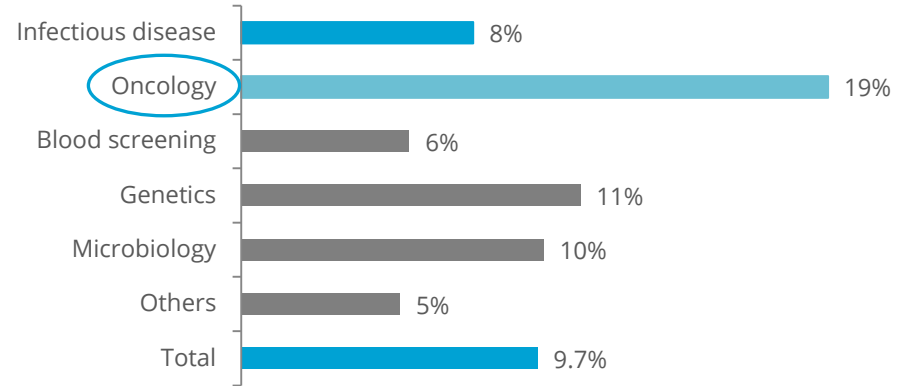


# Focus on largest and fastest growing MDx markets<sup>1</sup>

MDx market  
(estimated at \$5.0 bn in 2013)\*



Growth MDx market segments  
(CAGR '13 - '18)



Supported by an increasing use of companion diagnostics to determine patient response based on genetic characteristics, thereby preventing ineffective and potential harmful therapies and enhancing efficient use of medical care

1. Source: Markets and Markets – Molecular Diagnostics Market, Global Forecast to 2018 (August 2014)  
\* Numbers do not add up to 100% due to rounding

# Clear menu strategy

## ONCOLOGY

### USPs

- Sample prep ability to directly process FFPE
- **Sensitivity levels enabling to pick up low tumor content in tissue or blood**

## INFECTIOUS DISEASES

- **Highly sensitive** testing
- Ability to test infection syndromes by means of **multiplex testing**
- **Short turn around times**
- **Sample enrichment platform for sepsis application**

### FOCUS

- Focus on **solid biopsies**:
    - Existing biomarkers (e.g. BRAF, KRAS, etc.)
    - New proprietary biomarkers such as MSI
  - Followed by **liquid biopsies** (initially same oncogenes as solid)
- Focus on:
    - **Syndromic panels** (e.g. respiratory tract panel assays)
    - **Sepsis**
    - **Viral load assays**

## PARALLEL MENU EXPANSION

### Strategic partnerships

**Johnson & Johnson**

Initial tests include Flu-RSV

**Abbott**  
Molecular

Focus on CDx development

### Diagnostic app developer partnerships





**Microbiome**

**A \* S T A R**

**fast-track** >>>  
DIAGNOSTICS  
TRUE POSITIVES. TRUE NEGATIVES.

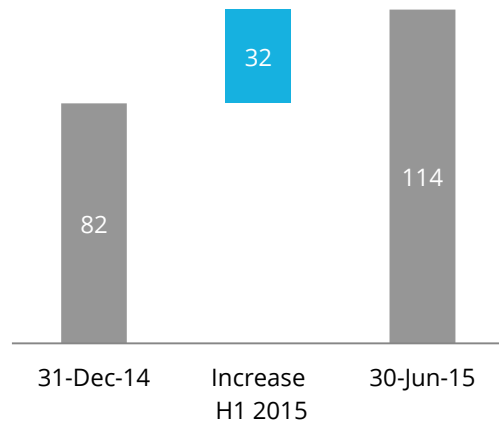


# Key achievements H1 2015

- 32 Idylla™ instruments sold in H1 2015 
- Continued strong ramp up of global commercial footprint, now covering 50 countries 
  - Nine new distribution contracts signed in H1 2015, bringing the total number of distributors to 17 as of 30 June 2015
- Significant progress in test menu development: 
  - CE-IVD mark KRAS Mutation Test for colorectal cancer in June 2015
  - Intensified efforts on liquid biopsy based tests (initiation of cfBRAF test)
  - Acceleration of first infectious disease test (Influenza-RSV test)
  - Three new collaborations signed with development partners for further menu expansion in oncology and infectious diseases
- Solid cash position of EUR 128m at end of H1 2015, primarily driven by successful EUR 115m IPO in April 2015 

# 32 Idylla™ Instruments sold in H1 2015

Increased installed base

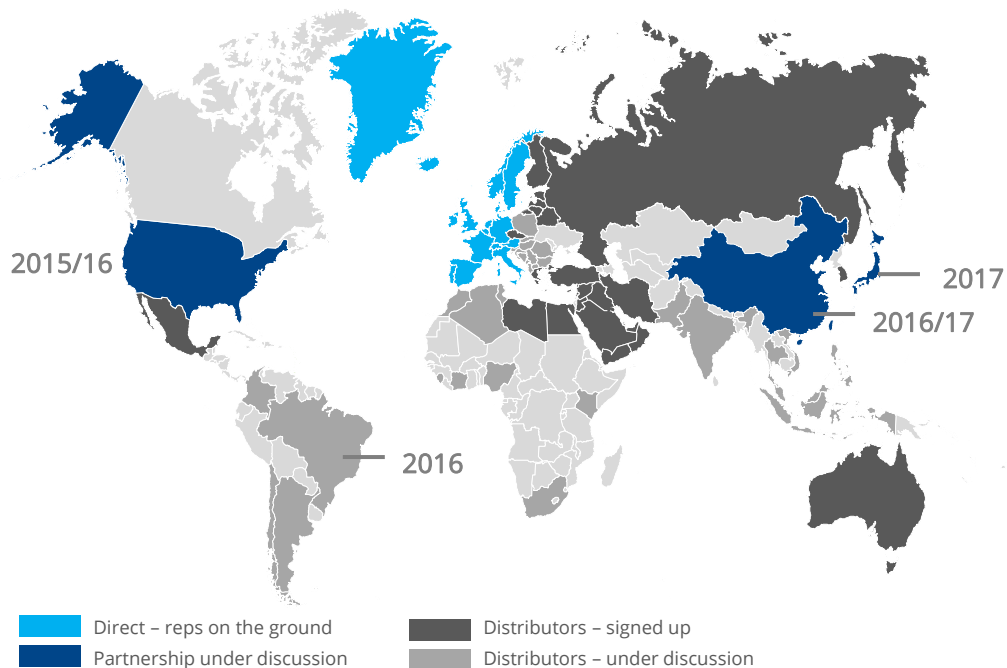


- Installed base of Idylla™ instruments of 114 as per 30 June 2015
- Instruments placed with clients worldwide



# Continued expansion **global** commercial footprint

- > 50 countries covered through direct and indirect sales channels
- Direct sales force covering 16 European countries
- Nine new distribution contracts signed in H1 2015:
  - 12 additional countries
  - Minimum purchase obligations > 100 Idylla instruments over coming 3 years



Status as of 30 June 2015

# Launch of CE-IVD KRAS mutation test

- On 24 June 2015, Biocartis' KRAS Mutation Test received CE-IVD marking
- First fully-automated test for routine use that detects all clinically relevant driver mutations (21 in total) of the KRAS oncogene in tissue of colorectal cancers
- Sensitivity of 5% for the most prevalent markers as recommended according to ESMO<sup>1</sup>, NCCN<sup>2</sup>, and the recently issued CAP/AMP/ASCO guidelines<sup>3</sup>
- Results in an unprecedented timeframe of approximately two hours
- Hands-on time is less than two minutes



1. E. Van Cutsem, B. Nordlinger & A. Cervantes. On behalf of the ESMO Guidelines Working Group. Advanced colorectal cancer: ESMO clinical practice guidelines for treatment. Annals of Oncology 21 (Supplement 5): v93-v97, 2010  
2. NCCN Clinical Practice Guidelines Colon Cancer, vs. 2, 2015  
3. [http://www.amp.org/committees/clinical\\_practice/documents/20150327CRCMMDraftRecommendationsforOCP-UPDATEDfinaldraft\\_001.pdf](http://www.amp.org/committees/clinical_practice/documents/20150327CRCMMDraftRecommendationsforOCP-UPDATEDfinaldraft_001.pdf)

# Significant progress made in our oncology menu...

## BRAF

- Continued acceleration of commercialization of Idylla™ BRAF Test with, amongst others, support of key opinion leaders in H1 2015
- On 27 July 2015, Dr. Filip Janku, MD from MD Anderson published a research study that showed that the Idylla™ BRAF Mutation Test is rapid and has high concordance with other routinely used but more complex BRAF mutation-detecting tests<sup>1</sup>

## NRAS

- Continued development of extended NRAS panel that detects 19 mutations in the NRAS gene
- In combination, the KRAS and NRAS enable testing of an extended set of 40 clinically actionable RAS mutations for colorectal cancer
- Development NRAS/BRAF test as well as NRAS/BRAF/EGFR492 along same timelines

## Liquid biopsies

- Intensified efforts on liquid biopsy based tests
- Biocartis presented positive results of a research study at ASCO<sup>2</sup>, demonstrating that BRAF mutant tumor DNA levels circulating in blood of metastatic melanoma patients were associated with disease progression
- Launch of a BRAF liquid biopsy test (RUO) is anticipated by the end of 2015

1. The Idylla™ System and Idylla BRAF Test are currently not available in the USA  
2. American Society for Clinical Oncology, in collaboration with Prof. Bart Neyns from the University Hospital Brussels

## ...as well as our infectious diseases menu

### IFV-RSV

- Test is being developed by Janssen Diagnostics in collaboration with Biocartis and aimed at detection of influenza in nasopharyngeal swabs from patients
- Test aimed at the detection of influenza A, influenza B, RSV A (respiratory syncytial virus) and RSV B
- Janssen Diagnostics has agreed to appoint Biocartis as a worldwide co-exclusive distributor of the IFV-RSV test

### Ebola

- Emergency Use Authorization (EUA) submission process to the FDA for the Idylla™ platform and Rapid Ebola Virus Triage Test has been initiated
- Studies with live Ebola viruses are ongoing in the highest biosafety level laboratories of the National Institute of Health (NIH), part of the U.S. Department of Health and Human Services

# Three key strategic agreements signed

Infectious Disease

Microbiome

- Worldwide license and collaboration agreement aimed at developing a test for the rapid detection of bloodstream infections, such as sepsis
- Test is aimed to be used in conjunction with Biocartis Idylla™-Enrich platform, a dedicated pre-enrichment platform for bloodstream infections that is under development by Biocartis

fast-track  
DIAGNOSTICS  
TRUE POSITIVES. TRUE NEGATIVES.

- Strategic partnership aimed at development of broad range of Idylla™ infectious disease tests
- Based on new approach 'syndromic multiplex testing', allowing the identification of a broader range of disease pathogens in a single test

Oncology

A\*STAR

- Partnership agreement (signed on 17 July 2015<sup>1</sup>) to jointly develop a range of proprietary tests for the Idylla™ platform with a main focus on cancer biomarkers
- Biocartis has access to novel biomarkers (including those discovered within A\*STAR's research institutes) from the Diagnostics Development Hub



# Successful IPO raising EUR 115m



- On 28 April 2015, Biocartis raised gross proceeds of EUR 115m in a successful IPO on Euronext Brussels
- IPO was in a 6.5x oversubscribed (i.e. more than EUR 650 million in demand)
- IPO attracted a wide interest from a mix of long-term, specialist investors across continental Europe, the UK and the US
- Banking syndicate consisted of KBC, Kempen & Co and Petercam



# Solid cash position of EUR 128m per 30 June 2015

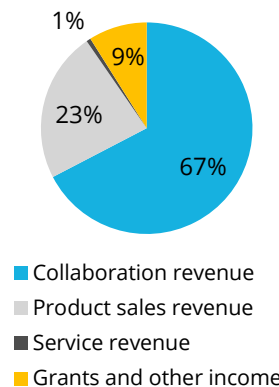
## Key financials H1 2015

<i>In EUR 1,000</i>	H1 2015	H1 2014
Revenue	6,578	1,124
Total operating income	7,224	2,503
Operating expenses	-24,047	-18,066
Operating result	-16,823	-15,563
Net result	-16,915	-19,746 <sup>2</sup>
Net cash flow	117,579	-19,410 <sup>2</sup>
Cash position <sup>1</sup>	128,477	9,585

## Revenue breakdown H1 2015

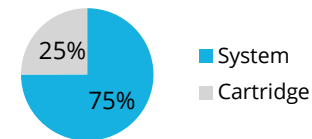
### Total operating income

100% is EUR 7.2m

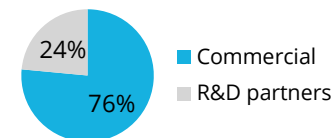


### Product sales revenue

By product (100% is EUR 1.7m)



By type (100% is EUR 1.7m)



# Strong news flow expected for remainder 2015

## Oncology menu

- RUO launch of NRAS solid biopsy test
- RUO launch of BRAF liquid biopsy test

## Infectious diseases menu

- CE-IVD marking Influenza-RSV test
- Final submission of Idylla™ platform and Rapid Ebola Virus Triage Test for EUA approval

## Operational

- Instrument manufacturing outsourced

Guidance for 75 instruments to be sold in 2015 reiterated

# Financial calendar

- Q3 2015 business update Thursday 19 November 2015
- Publication 2015 full year results Thursday 17 March 2016



# Q&A

