2015 Results Presentation

17 March 2016

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Today's presenters

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Agenda

- Strategy recap
- 2015 results
- Menu update
- 2016 outlook and news flow
- Q&A

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High precision diagnostics for high precision medicine

Idylla™

- 'First time right' molecular diagnostic system
- In close time and space proximity where patients and healthcare professionals interact and make therapeutic decisions

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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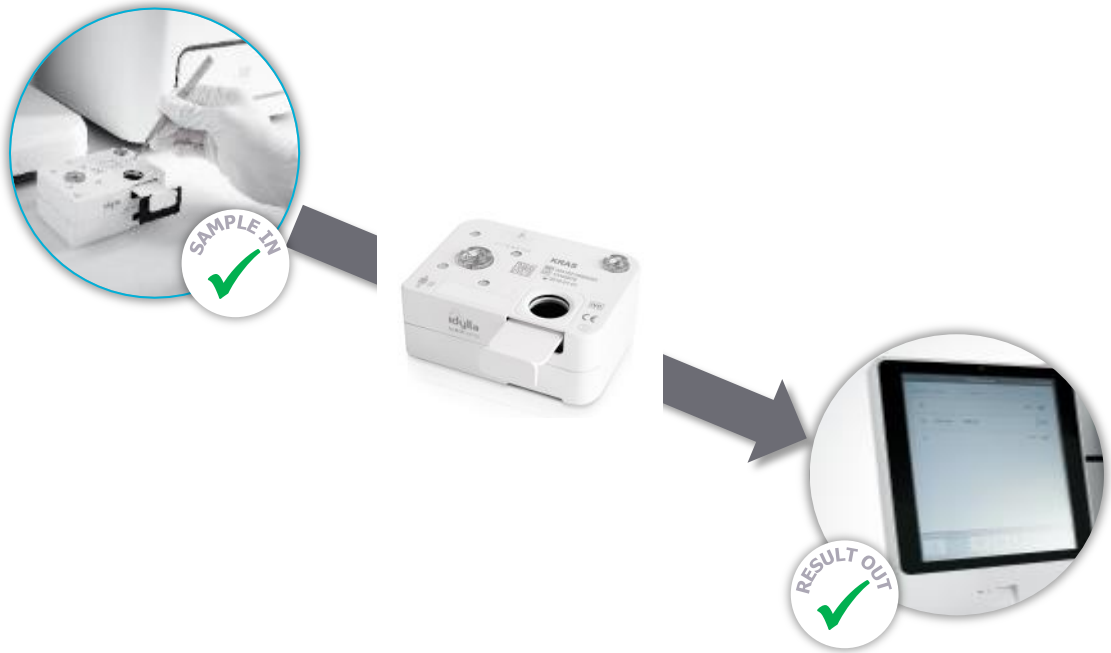
Idylla™ best-in-class

- Fully automated sample-to-result
- Accurate results at right sensitivity
- High levels of multiplexing
- Short turnaround time
- Modular
- Connectivity

Limitation of erroneous results due to standardised cartridge

- 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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Menu for oncology and infectious diseases

	Oncology	Infectious diseases
	Fastest growing segment of the MDx market[1] - CAGR of 17% between 2015-2020	**Largest segment** of the MDx market[1] – 44% of total in 2015
USPs	• Direct processing of FFPE[2] tumour slices • Highly sensitive detection of a vast range of mutations from tissue or blood	• Ability to offer syndromic panels that include quantitation • Short turn around times combined with high sensitivity • Sample enrichment platform for sepsis application
Focus	• Solid biopsies and liquid biopsies • First wave of tests based on clinically proven and reimbursed biomarkers • Second wave to include new proprietary biomarkers	• Syndromic panels (e.g. respiratory tract panel assays) • Disease surveillance • 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*STAR

fast-track DIAGNOSTICS

TRUE POSITIVES. TRUE NEGATIVES.

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1. Source: Markets & Markets: In Vitro Diagnostics (IVD) Market by Product Technology (Immunoassay, Clinical Chemistry, Molecular Diagnostics, Hematology) by Application (Diabetes, Cancer, Cardiology, Autoimmune Diseases) - Forecast to 2020
2. FFPE is abbreviation of Formalin-Fixed Paraffin Embedded

2015 Results

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Key messages 2015 results

Commercialisation

- Successful initial market adoption of the Idylla™ platform by adding 83 instruments: exceeding 2015 target of 75
- Total installed base of 165 Idylla™ instruments by the end of 2015
- Commercial footprint covering over 55 countries worldwide end of 2015

Test menu

- Significant progress made in further building the Idylla™ menu by adding four new tests: two new solid biopsies for oncology, first liquid biopsy for oncology and first infectious disease test
- Total menu of five tests end of 2015: three CE-IVD tests and two Research Use Only (RUO) tests

Manufacturing

- Idylla Instrument and Console manufacturing outsourced
- Second Idylla™ cartridge manufacturing line ordered

Financials

- Total operating income of EUR 15.0m compared to EUR 10.4m in 2015
- 2015 end of year cash position of EUR 104.1m compared to EUR 11.9m end of 2014

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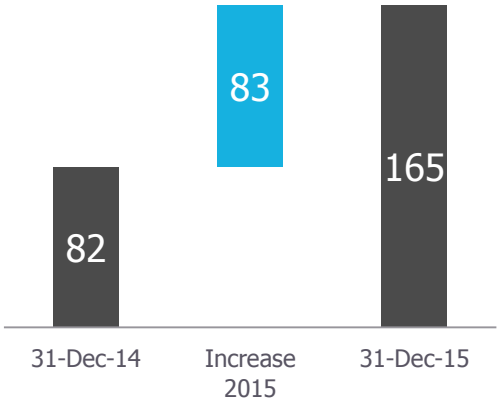
Installed base of 165 Idylla™ instruments end of 2015

Increased installed base



- A total of 83 Idylla™ instruments added to the installed base in 2015
- Instruments placed with clients worldwide
- Clients consisting of reference laboratories and first time users of MDx

"Idylla™ gives you an answer in an absolutely unprecedented time frame."

Filip Janku, MD PhD,
Oncologist,
MD Anderson Cancer Center,
Houston, Texas, USA

"Excellent sensitivity, very quick results and very little hands-on time."

Beatrice Bellosillo, PhD,
Head Molecular lab,
Hospital del Mar, Barcelona, Spain

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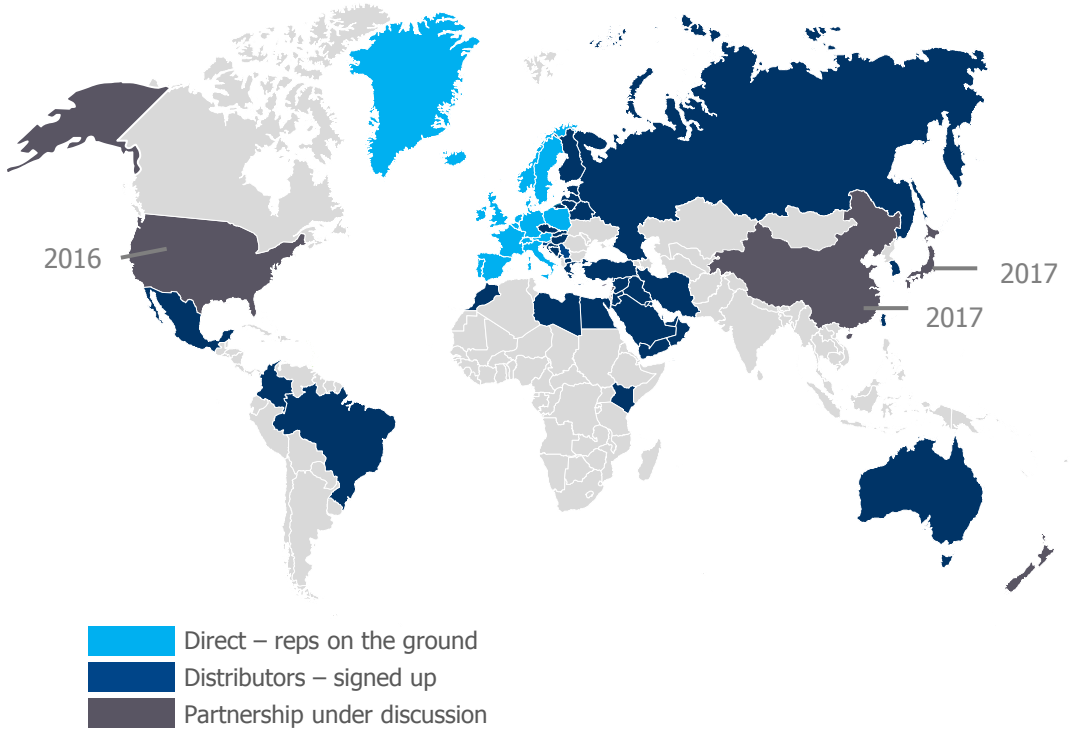
Continued expansion global commercial footprint

- Over 55 countries covered through direct and indirect sales channels
- Direct sales force covering Western European countries
- 23 distributor contracts in place covering approx. 40 countries
- Announcement US commercialisation strategy in 2016
- Announcement commercialisation strategy China and Japan in 2017



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Manufacturing expansion plan ongoing

- Biocartis currently operates one cartridge manufacturing line that is located in Mechelen (Belgium)
- Over 125,000 cartridges manufactured to date
- Capacity current line is being ramped up by adding workstations and implementing additional shifts in 2016
- Equipment and tools of a new higher capacity line ordered end of 2015. This second line should be operational in 2017
- Manufacturing instrument and console successfully outsourced in to a contract manufacturing organisation which enabled:
  - realisation of significant cost efficiencies
  - required scaling of production capacity

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Four new Idylla™ tests launched in 2015

Oncology

KRAS Test

- Colon, lung and pancreas
- Solid biopsy
- 1 FFPE tumour slice
- CE-IVD
- 21 mutations
- Sensitivity of < 5%
- TaT* approx. 2 hours

NRAS/BRAF/EGFR492 Assay

- Colon, melanoma and thyroid
- Solid biopsy
- 1 FFPE tumour slice
- RUO
- 22 mutations
- Sensitivity < 5%
- TaT* approx. 2 hours

ctBRAF Assay

- Melanoma, colon and lung
- Liquid biopsy
- 1ml plasma
- RUO
- 2 mutations (5 amino acids)
- Sensitivity of < 1%
- TaT* around 85 min.

Infectious disease

Respiratory (IFV-RSV) Panel

- Influenza Virus and Respiratory Syncytial Virus
- Developed by Janssen Pharmaceutica
- Nasopharyngeal Swab and VTM**
- CE-IVD
- 8 targets incl. Flu A subtypes, Tamiflu Resistance® mutation
- TaT* around 50 min

Offering complete mCRC[1] mutation analysis within two hours

World's first and only fully automated liquid biopsy

Speed of rapid tests with sensitivity central lab tests

[1] mCRC: metastatic colorectal cancer
* TaT: total turnaround time
** VTM: Viral Transport Medium

Outperforming reference testing

Approx. 5% more patients could have benefited from targeted BRAF therapy

BRAF Mutation Test

STUDY/ TRIAL	LOCATION	# OF SAMPLES	OVERALL CON-CORDANCE*	OVERALL CONCORDANCE AFTER DISCORDANCE TEST**
Validation study	Charité Berlin, UZA Antwerp	236	97.9%	99.6%
Beta trial	6 regional hospitals***	138	94.9%	100%
Research study	MD Anderson	216	97.2%	100%
Trial (off-label)	Medical University of Vienna	191	97.4%	100%
Trial (off-label)	Oxford University Hospitals NHS Trust	98	98.6%	100%

KRAS Mutation Test

STUDY/ TRIAL	LOCATION	# OF SAMPLES	OVERALL CON-CORDANCE+	OVERALL CONCORDANCE AFTER DISCORDANCE TEST++
Mini-performance evaluation (NGS)	In-house	82	100%	100%
Verification study (Ultra Deep Seq)	In-house	116	99.1%	99.1%
Verification study (alpha trial)	Commercial reference lab	108	91.7%	99.1%
Validation study	University Hospital Antwerp	182	96.7%	Na+++

Outperforms reference testing in studies with 879 clinical samples (of which ~590 melanoma samples)

Outperforms reference testing in studies with 488 clinical samples: analysis of beta trials ongoing

* Reference methods: Roche cobas, CLIA laboratory PCR-based sequencing, Sequenom MassARRAY and Pyrosequencing
** Ultra deep sequencing and digital droplet PCR
*** Rigshospital Copenhagen, Imelda Bonheiden, Jan Yperman Ieper, Hospital del Mar Barcelona, Karlsruhe, LabPON Hengelo
Note: number samples tested with discordance test varies between study/trial

\+ Reference methods: Roche Cobas and NGS
++ Ultra deep sequencing and digital droplet PCR
+++ Out of a subset of the discordant samples, insufficient sample was available to perform a discordance test

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Collaboration with MERCK

Description

- Collaboration on new liquid biopsy technology for RAS biomarker testing
- Aim of collaboration is to improve patient access to ctRAS testing by leveraging the advantages of Idylla™
- Reinforces Biocartis' development of highly innovative liquid biopsy versions of its expanding oncology test menu

Commercial aspects

- Development of Idylla™ ctKRAS and ctNRAS/BRAF tests as CE-IVD
  - RUO launch planned for H2-2016
  - CE-IVD launch expected early 2017 after completion of a concordance study
- Implementation of Idylla™ liquid biopsy RAS tests in numerous medical centers across the world[1]

Patient impact

- mCRC[2] patients need RAS biomarker testing to be eligible for anti-EFGR therapy (such as Erbitux®)
- Today's RAS testing requires expert expertise in molecular diagnostics which is not readily available in all hospitals
- RAS testing from ctDNA is less invasive to the patient and provides a 'real-time' biomarker profile in relapsing patients[3]

1. US, China and Japan are excluded from this collaboration. Commercialisation of assays under the collaboration is on a non-exclusive basis.
2. mCRC: metastatic colorectal cancer
3. FFPE sample are typically obtained at baseline and may not be representative of mutational status in relapsing patients

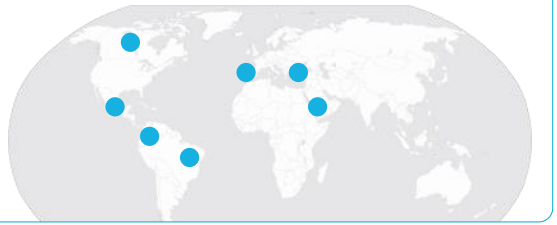
Collaboration with AMGEN

Description

- Collaboration to evaluate Idylla™ RAS testing as tool for rapid decentralised testing
- Aim of the collaboration is to accelerate access to RAS biomarker information in the selected countries
- Underlines Amgen's and Biocartis' commitment to patients in oncology in offering high precision medicine and high precision diagnostics

Commercial aspects

- Amgen will make Idylla™ RAS testing available to several reference hospitals:
  - Brasil
  - Canada
  - Colombia
  - Mexico
  - Saudi Arabia
  - Spain
  - Turkey



Patient impact

- For mCRC[1] patients, timely information on presence of mutations in RAS genes is critical in treatment selection
- Technologies currently used by hospitals across the globe are complex and on average require several weeks (e.g. 9.8 days in Spain[2])
- In some geographies in-country testing not even possible
- With Idylla™ RAS testing can be done locally and in shorter timeframe

1. mCRC: metastatic colorectal cancer
2. Amgen data

Total operating income in 2015 of EUR 15.0m

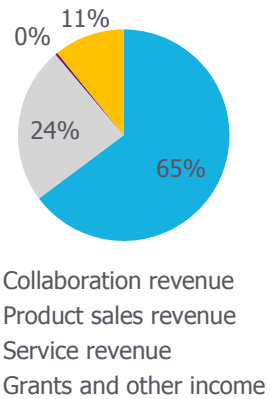
Condensed income statement

In EUR 1,000	2015	2014
Total operating income	**14,951**	**10,367**
COGS	(2,642)	(4,251)
R&D expenses	(36,554)	(25,014)
S&M expenses	(8,747)	(3,095)
G&A expenses	(6,662)	(7,180)
Total operating expenses	**(54,606)**	**(39,540)**
Operating result	**(39,655)**	**(29,173)**
Net financial result	(790)	(961)
Income taxes	648	947
Gain discontinued operations	0	19,472
Net result	**(39,797)**	**(9,715)**

Breakdown total operating income 2015

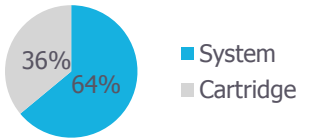
Total operating income

100% is EUR 15.0m

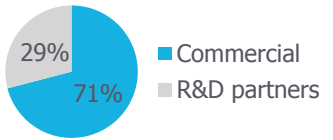


Product sales revenue

By product (100% is EUR 3.6m)



By type (100% is EUR 3.6m)



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End of year cash position of EUR 104m

Condensed cash flow statement

In EUR 1,000	2015	2014
Result for the period	(39,797)	(9,715)
Depreciation & amortisation	5,021	4,437
Working capital changes	11,518	(4,301)
Gain on discon. Operations	0	(26,624)
CF operating activities	**(23,357)**	**(35,884)**
CF investing activities	**(9,414)**	**5,052**
CF financing activities	**125,943**	**12,727**
Exchange rate changes	(4)	(23)
Total net cash flow	**93,169**	**18,128**
Cash position BoY	10,919	29,047
Total net cash flow	93,169	18,128
Cash position EoY	**104,088**	**10,919**

Remarks

- Total operating and investing cash flow of EUR 32.8m (EUR 44.3m excluding working capital impact)
- Cash flow from operating activities
  - Positively impacted by movements in working capital due to decrease in trade receivables and increase in trade payables
  - 2014 exceptionally impacted by gain on disposal MyCartis
- Cash flow from investing activities
  - Includes by EUR 9.2m of capex of which EUR 6.1m capex for manufacturing expansion (current line and second line)
- Cash flow from financing activities
  - Driven by proceeds from second tranche F-round and IPO
  - Includes EUR 5.1m on repayments of borrowing (mainly for the Senter Novem loan)
  - Includes a new financing facility on which EUR 1.8m was drawn end of 2015 (total facility amounts to EUR 5.0m)

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Menu update

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Presenting the menu update

Geert Maertens

Chief Scientific Officer

Nicolas Vergauwe

Head of Innovation

Rudi Pauwels

Chief Executive Officer & Founder

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Market needs and trends drive Idylla™ menu

- Continuous monitoring of market developments, KOL*, Scientific Advisory Board and customer feedback to optimise Idylla™ menu

- Oncology
  - Strong traction with leading pharma companies for Idylla™ based testing
  - Accelerated commercialisation of liquid biopsy market
  - Promising link with novel immunotherapies
  - Opportunity to leverage Idylla™ technology for next-generation sequencing ('NGS')

- Infectious diseases
  - Sepsis: solution directly from blood remains a very high unmet need
  - Global awareness on disease outbreaks drives demand for syndromic panels

* KOL: Key Opinion Leader

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Leveraging new opportunities in oncology

- Larger near term allocation of resources to benefit from oncology momentum in the market
- Increased focus on development fully automated liquid biopsy solutions, including development of CE-IVD tests in collaboration with pharma
- Broadening scope Idylla™ MSI** test, with aim to capture expected value of MSI for predicting response to certain immunotherapies as shown by recent data
- Idylla™ gateway to NGS +: development of Idylla™ NGS Prep Panels that function as gateway to NGS; first NGS Prep Panel expected to be launched in 2017

** MSI: Microsatellite instability
+ NGS: Next-generation sequencing

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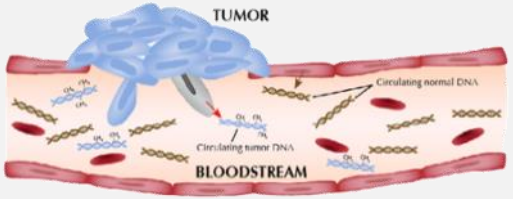
Accelerated commercialisation of liquid biopsy testing

Background

- Cancerous tumours release cell-free circulating tumour ('ct') DNA fragments into the bloodstream



- Circulating blood biomarkers are a promising surrogate for solid tumour tissue-based biomarkers as this approach:
  - Allows for non-invasive sample taking
  - Does not require prior information of the tumour location
  - Is suitable for repeat sampling
- Promising potential*:
  - Market size of estimated at $20 billion in 2020
  - Growth rate for liquid testing in patients expected to be 62% per annum till 2020

Liquid biopsy focus Biocartis

- Build a critical menu of fully automated liquid biopsy tests that complement our solid biopsy test menu
- Combined offering of solid and liquid testing expected to deepen market adoption of Idylla™
- ctBRAF assay launched, to be followed in 2016 by:
  - ctKRAS RUO
  - ctNRAS / BRAF / EGFR492 RUO

  (both products expected to be launched as CE-IVD in 2017 as part of the Merck collaboration)
- Focus for 2017 and beyond on liquid biopsies on:
  - Lung, colon and breast cancers: easy diagnostic inclusion and monitoring of resistance to therapy
  - Liver cancer: early detection in cirrhotic livers

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* Sources: J.P. Morgan Research and liquid biopsy report Insight Pharma

Unique position in MSI testing

What is Microsatellite Instability?

- MSI evolves as a result of the so-called 'inactivation of the body's DNA mismatch repair (MMR) system'
- Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, resulting potentially in tumor growth
- Tumors can be labeled as MSI-High (MSI-H), MSI-Low (MSI-L) or Microsatellite Stable (MSS)
- MSI is a proven prognostic oncology biomarker included in CRC guidelines and found in different cancer types:

Cancer type	% MSI-H	Cancer type	% MSI-H
Colorectal	10-20%[1]	Lung	± 5%[6]
Endometrium	± 30%[2]	Gastric	± 20%[7]
Ovarium	5-10%[3]	Pancreas	± 15%[8]
Melanoma	± 10%[4,5]		

Biocartis' unique position in MSI

- Exclusive license agreement with the Flemish Institute for Biotechnology for rt-PCR compatible MSI markers
- Strong competitive position of Idylla™ based MSI testing versus current manual and complex procedure using capillary electrophoresis (Bethesda method), requiring multiple days to perform
- Idylla™ MSI test does not require sample control; 1 sample per patient required

Idylla™ MSI test initially positioned as prognostic biomarker for colorectal cancer

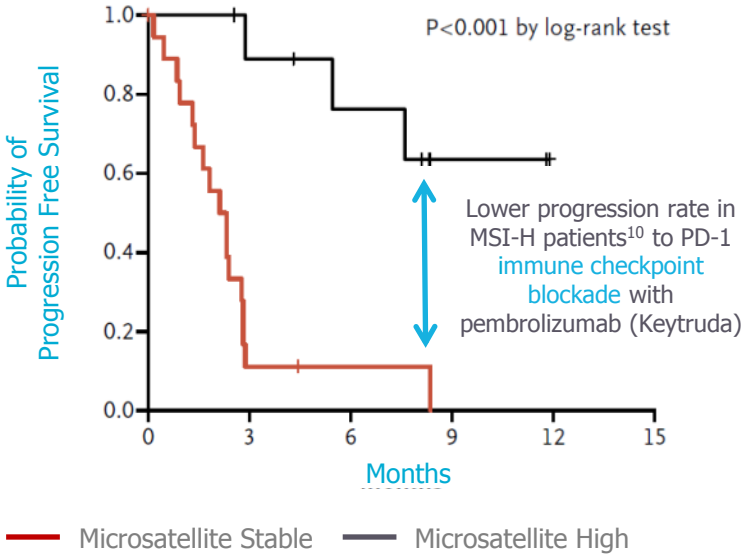
[1] Boland et al, Gastroenterology 2010; [2] Cancer Genome Atlas Research Network, Nature 2013; [3] Singer et al, Int J Cancer 2004 ; [4] Uribe et al, Am J Dermatopathol 2005; [5] Ninomiya et al, British Journal of Cancer 2006; [6] Kroiss et al, Acta Derm Venereol 2001; [7] Cancer Genome Atlas Research Network, Nature 2014; [8] Nakata et al, Clin Cancer Res 2002

Extending scope of Idylla™ MSI test to immunotherapy

Potential to predict immunotherapy response

- Immunotherapies for oncology are shown to have a positive impact on long term survival, especially in combination with targeted oncology therapies
- Immunotherapies focus on fighting cancer cells via the body's immune system and consist of 3 major approaches:
  - Cancer vaccination
  - CAR-T-cells (manipulation of immune system to recognize and attack cancer)
  - Immune checkpoint blockade (blocking ability cancer cells to downregulate activity immune system)
- Recent data show that a tumour's MSI status may predict a patient's response to certain immunotherapies
- Scope of the Idylla™ MSI test will be broadened to capture expected value of MSI for predicting response to certain immunotherapies

Study example (Le et al, NEJM 2015)



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Idylla™: first line testing and gateway to NGS in oncology

Gene alterations*

Melanoma

Colon

Idylla™ positioning

- Idylla™ solid and liquid oncology menu guides treatment decisions for majority of cancer patients:
  - Focus on comprehensive panels for actionable biomarkers (linked to gene alterations)
  - Fully automated and fast turnaround times
  - Enables rapid triaging and same-day treatment
- Comprehensive genome profiling techniques like next-generation sequencing (NGS) to be used for detection of less common alterations that can guide alternative treatments or off-label use
- Challenges NGS to be overcome before widespread clinical use:
  - Complex batch-based workflows and high costs
  - Lack of standardisation can lead to wrong treatment decisions, similar to classical qPCR-based testing**

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* Source: Dienstmann, Salazar, and Tabernero ASCO EdBook 2015 and www.mycancergenome.org.
** Normanno et al. J Transl Med (2015); Patton et al. BJC (2014); Zhang et al. Clin Chem Lab Med (2014)

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 TaT* 5h	3.5h 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:

- Standardisation 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

Sample to result for every patient

- Idylla™'s comprehensive panels for most commonly mutated genes guide treatment decisions for the majority of cancer patients
- For those cancer patients with more complex genomic alterations, Idylla™ NGS Prep Panels function as a gateway to comprehensive MDx testing
- Like for qPCR-based testing, Idylla™ offers the opportunity to revolutionise NGS workflows by:
  - Standardisation
  - Automation
  - Shorter time-to-results

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Update on infectious disease menu

- Idylla™ sepsis test and the workflow automation have been further improved in 2015, initial launch of the Idylla™ sepsis test is now scheduled for 2018
- Increased focus on development of highly multiplexed syndromic panels (e.g. Respiratory Mixed panel, Meningitis, Tropical Fever and Immunocompromised panels)
- Higher volume/lower priced tests to be launched at a later point in time to complete Idylla™ test offering

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Every 3rd heartbeat someone dies of sepsis[1]

Background

- A severe inflammatory response to a bloodstream infection
- Associated with high mortality rates (nearly 50% in the event of severe sepsis)[2]
- Mortality increases by 7.6%[3] for each hour of delay of effective antibiotic therapy (in the first six hours)
- Requires immediate therapeutic intervention
- Average cost per episode of sepsis per patient in U.S. $18,500 to $33,9007[4]

Rapid and accurate diagnostic results are needed

Clinical routine still based on empirical broad spectrum antibiotic therapy before identification of optimal therapy

1. Source: http://www.cscc.uniklinikum-jena.de/en/CSCC.html
2. Source: According to the US Center for Disease Control
3. Source: Kumar et al. Crit Care Med. 2006 Jun;34(6):1589-96
4. Source: Elixhauser, et al., Agency for Healthcare Research and Quality: "Septicemia in U.S. Hospitals, 2009"

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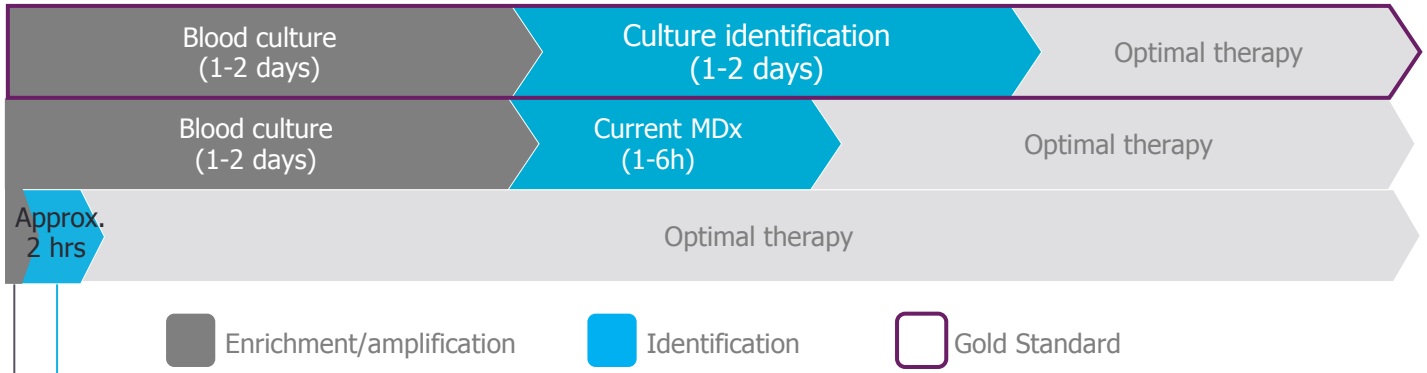
Solution for bloodstream infections (including sepsis)

Towards an integrated system delivering timely and actionable results



Idylla™ Enrich: selective enrichment of pathogen DNA directly from 10 ml of blood

Idylla™ Sespis Test: detection of >15 most common pathogens + several key antibiotic resistance genes

Total time to result around 2 hours

Target LOD* 1-10 CFU/ml

Hands-on time <5 min

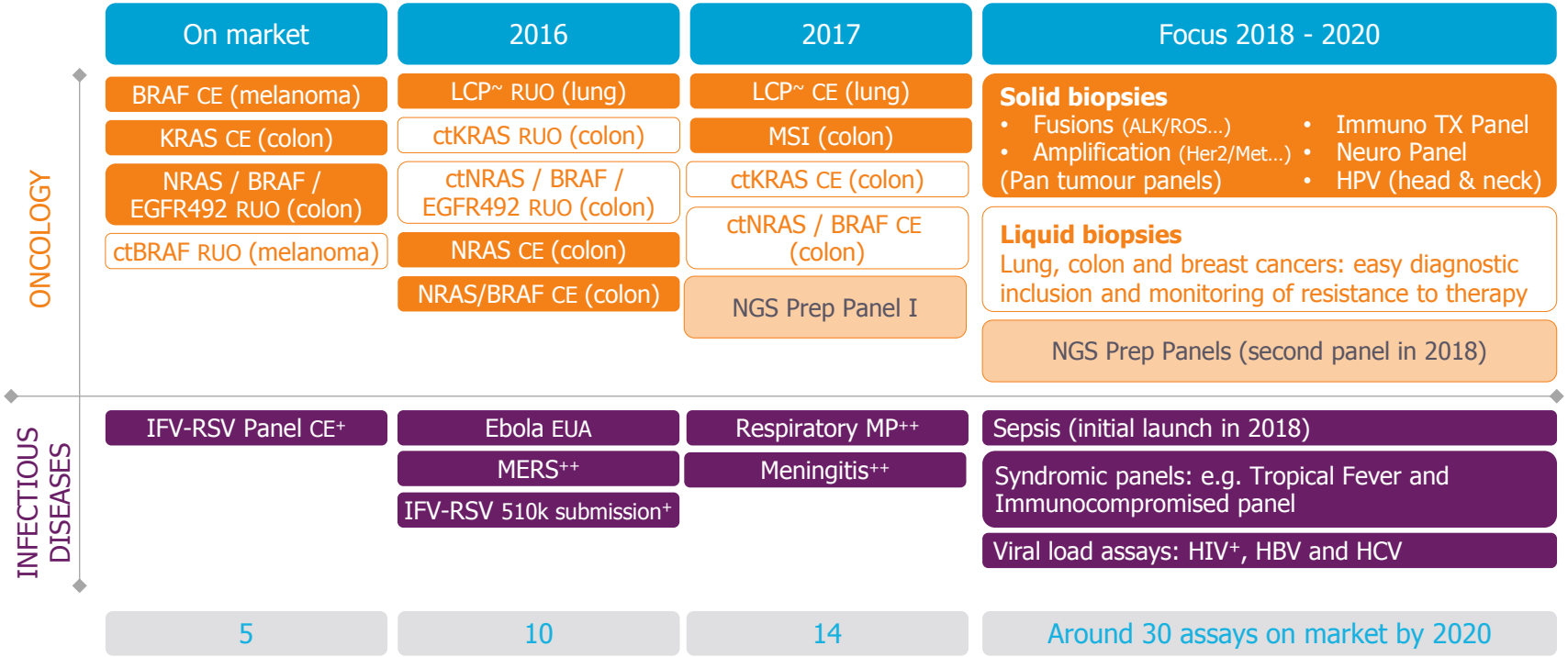
A further integrated solution reduces contamination risk

BIOCARTIS *LOD = Limit of Detection

Our diagnostic app store

Intention to launch at least 4 tests per year

Onco Solid Biopsy | Idylla™ Retrieve
Onco Liquid Biopsy | Infectious
unique tests on market



CE = CE-marked tests. RUO = Research Use Only. EUA = Emergency Use Authorisation label + JnJ test ++ Fast-track Diagnostics development ~ LCP = lung cancer panel
Note: overview is subject to changes in prioritisation of test development driven by several factors such as commercial and operational considerations. Overview excludes regional expansion (as of 2017), life cycle management and potential partner tests.

BIOCARTIS

2016 outlook and news flow

BIOCARTIS

2016 outlook

Installed base of Idylla™ instruments end of 2016 of over 300 by adding 150-175 instrument placements

Launch of at least four new tests in 2016 to further expand its test menu for Idylla™

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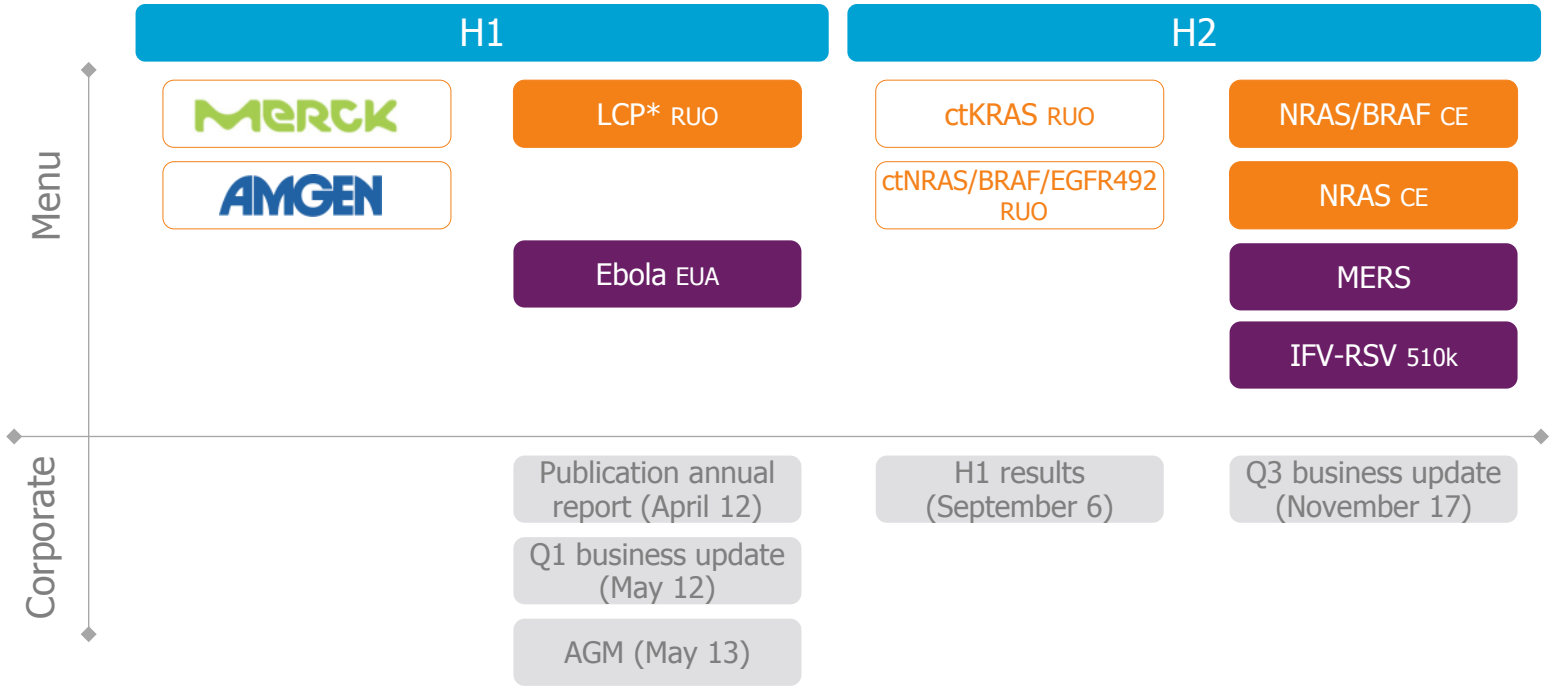
Biocartis targets a cash position by the end of 2016 in the range of EUR 45m to 55m

BIOCARTIS

Expected news flow for 2016



* LCP = Lung Cancer Panel

BIOCARTIS

Biocartis company highlights

NEXT GENERATION diagnostic solutions improving clinical practice for the benefit of patients, clinicians, payers and industry

COMMERCIAL STAGE Idylla™ platform enabling high precision diagnostics for high precision medicine

RAPIDLY EXPANDING test menu addressing key unmet clinical needs in oncology and infectious diseases

STRONG ENDORSEMENT of key opinion leaders and leading pharmaceutical companies

OPERATIONAL FOOTPRINT in place to support commercial expansion

BIOCARTIS


Q&A

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