Biocartis
Corporate Presentation
September 2017
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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
Excellent performance in comparative studies

Comparative studies 2016 – 2017YTD*

- 5x KRAS
- 2x BRAF
- 2x EGFR
- 1x NRAS

By test

By channel

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

AstraZeneca study confirms **best-in-class** status Idylla™

**Background**

- Comparative study organized by AstraZeneca
- Comparison of 12 different KRAS mutation detecting technologies:
  - 5x NGS
  - 3x qPCR
  - 2x mass spec.
  - 1x ddPCR
  - 1x Sanger sequencing
- Focused on detection of KRAS mutations in lung cancer based on blinded samples

**Conclusions**

<table>
<thead>
<tr>
<th>Technology</th>
<th>Overall sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idylla™ KRAS</td>
<td>96%</td>
</tr>
<tr>
<td>Other qPCR (cobas/therascreen)</td>
<td>46-52%</td>
</tr>
<tr>
<td>Mass-spectrometry</td>
<td>58-92%</td>
</tr>
<tr>
<td>NGS</td>
<td>48-100%</td>
</tr>
<tr>
<td>ddPCR</td>
<td>56%</td>
</tr>
<tr>
<td>Sanger sequencing</td>
<td>0%</td>
</tr>
</tbody>
</table>

- **Sensitivity**
  - Highest score for Idylla™ KRAS technology:
    - Lowest number of manual handling steps in sample preparation (1 to 2 steps versus 3 to > 20 steps)
    - Requires lowest level of expertise (1 versus 2-4 for others*)

- **Ease-of-use**
  - Highest score for Idylla™ KRAS technology on total turnaround time (2 to 4 hours versus 1 day to 3 weeks)

* One being the lowest level of expertise and four the highest
** TaT = total turnaround time

Source: poster by James L. Sherwood et al., presented at 2016 ESMO conference Copenhagen (Denmark)
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
Menu currently focused on oncology

**Oncology – primary focus**

**Fastest growing** segment of the MDx market\(^1\) - CAGR of 17% between 2016-2021

- FFPE*-based sample to result solutions
- Solid and liquid biopsy testing on same platform
- Reduction of time to result from weeks to hours
- Proprietary assay content within immuno-oncology
- Gateway to Next-Generation Sequencing

**Focus**

- Solid biopsies and liquid biopsies
- Clinically proven and reimbursed biomarkers
- Proprietary content in second wave

**Infectious diseases**

**Largest segment** of the MDx market\(^1\) – 43% of total in 2016

- Ability to offer syndromic panels that include quantitation, RNA and DNA combinations
- Short turn around times combined with ease of use and high sensitivity
- Broad sample type and volume capabilities
- Sample enrichment technology for sepsis and other bloodstream infections

**USPs**

- Syndromic panels
- Bloodstream infections (including sepsis)
- Infectious disease strategy going forward could include more partnership elements

2. FFPE is abbreviation of Formalin-Fixed Paraffin Embedded, see appendix for details
### Rapidly expanding Idylla™ test menu

<table>
<thead>
<tr>
<th>Area</th>
<th>On market end 2016</th>
<th>2017</th>
<th>2018</th>
<th>Focus as from 2019 (indicative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>KRAS CE</td>
<td>ctNRAS/BRAF/EGFR492 RUO</td>
<td>MSI</td>
<td>Expansion of existing assay menus:</td>
</tr>
<tr>
<td></td>
<td>NRAS-BRAF CE</td>
<td>NRAS CE</td>
<td></td>
<td>• CRC</td>
</tr>
<tr>
<td></td>
<td>NRAS/BRAF/EGFR492 RUO</td>
<td>ctKRAS CE</td>
<td></td>
<td>• Lung cancer</td>
</tr>
<tr>
<td></td>
<td>ctKRAS RUO</td>
<td>ctNRAS-BRAF CE</td>
<td></td>
<td>• Melanoma</td>
</tr>
<tr>
<td>Lung</td>
<td>EGFR RUO</td>
<td>EGFR CE</td>
<td>ctEGFR RUO</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>GeneFusion Panel</td>
<td></td>
</tr>
<tr>
<td>Melanoma</td>
<td>BRAF CE</td>
<td>ctBRAF RUO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDx</td>
<td>IFV-RSV Panel CE+</td>
<td>IFV-RSV Panel 510k+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infectious</td>
<td>EBNA EUA</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Therapy selection
- MSI (immunotherapy)
- Resistance monitoring
- Oncotype DX⁶+++ [To be further expanded]
- Additional NGS Prep Panels to be launched

#### Oncology
- Expansion into major oncology areas:
  - Immunotherapy (MSI to be first test)
  - Urology
  - DNA repair

#### Infectious diseases
- Syndromic panels (initial assay Respiratory MP++) and bloodstream infections (including sepsis)

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.

## Strategic collaboration with Genomic Health

### Background collaboration

- Focused on exclusive test development of proprietary Genomic Health tests on the Idylla™ platform
- Aimed at accelerating adoption and market access around the world of Genomic Health’s tests
- First test to be developed on Idylla™ is the Oncotype DX Breast Recurrence Score® test

### Oncotype Breast Recurrence Score® test

- Provides personalized information for tailoring treatment of breast cancer patients based on the biology of their individual disease
- Predicts the likelihood of chemotherapy benefit as well as the chance of cancer recurrence in early-stage breast cancer patients
- Included in all major cancer guidelines worldwide and considered as standard of care for women with early-stage breast cancer

## Background Genomic Health

- Leading provider of genomic-based diagnostic tests in cancer with revenues of USD 328m in 2016
- Based in California (US) and listed on NASDAQ (GHDX) with a market cap of approx. USD 1bn
- On-market tests for breast, prostate and colon cancer, currently offered through own service laboratories

Source: company website and financial reporting Genomic Health
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

- Complete mCRC test offering for clinical use: most recent clinical guidelines recommend extended RAS/BRAF testing

- Ability to enable same-day results could open routes towards faster treatment selection for mCRC patients

Pharma collaborations

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.


Lung cancer testing

• Lung cancer is most common cancer worldwide accounting for 13% of all cancer types, 85% of lung cancers are non-small cell lung cancers (NSCLC)

• Today, EGFR mutation testing is recommended in all patients with advanced NSCLC of a non-squamous subtype

• Current molecular testing of lung cancer samples is a complex process:
  - Can take up to several weeks
  - 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

## Initiated breast cancer menu development with partners

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
<th>Partner</th>
<th>Partnership structure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistance monitoring test</td>
<td>- Liquid biopsy test</td>
<td>LifeArc</td>
<td>- Development multiple Idylla™ tests</td>
</tr>
<tr>
<td></td>
<td>- Monitoring of metastatic breast cancer patients for resistance to hormone therapy</td>
<td></td>
<td>- LifeArc acts as development contractor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Biocartis responsible for commercialization under own label</td>
</tr>
<tr>
<td>Therapy selection test</td>
<td>- Solid biopsy test</td>
<td>A*STAR</td>
<td>- Parties will co-invest in development of selected Idylla™ tests</td>
</tr>
<tr>
<td></td>
<td>- Supporting optimal therapy selection decisions for breast cancer patients</td>
<td>Singapore’s Agency for Science, Technology and Research</td>
<td>- A*STAR acts as development partner</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Biocartis responsible for commercialization under own label</td>
</tr>
<tr>
<td>Oncotype Dx Breast Recurrence Score® test</td>
<td>- Solid biopsy test</td>
<td>Genomic Health</td>
<td>- Genomic Health to develop Idylla™ versions of proprietary Genomic Health tests</td>
</tr>
<tr>
<td></td>
<td>- Tailoring treatment of breast cancer patients based on the biology of their individual disease</td>
<td></td>
<td>- Genomic Health responsible for commercialization under own label</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Biocartis acts as supplier of tests</td>
</tr>
</tbody>
</table>

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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)

- 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

- 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
Continued expansion global commercial footprint*

Over 70 countries covered through three sale channels:

1. **Direct sales force** covering Western European countries

2. **Distributor contracts** in place covering 58 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)

* Situation as per 30 June 2017
## 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

- 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

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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.
## 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 weeks\(^1\)

- 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

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

- Initiated in February 2016 with sites in 7 countries\(^2\)

- Significantly expanded in Europe end of 2016 adding several dozen sites

- 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 world\(^3\)

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1. Amgen data
2. Focused on selected reference hospitals in Brazil, Canada, Colombia, Mexico, Saudi Arabia, Spain and Turkey.
3. US, China and Japan are excluded from this collaboration. Commercialization of assays under the collaboration is on a non-exclusive basis.
H1 2017 results and outlook
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
Idylla™ installed base close to 500 end H1 2017

Installed base development

<table>
<thead>
<tr>
<th></th>
<th>End 2016</th>
<th>Increase H1 2017</th>
<th>End June 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Installed base</td>
<td>389</td>
<td>108</td>
<td>497</td>
</tr>
</tbody>
</table>

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

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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**
Commercial product revenues increased 195% in H1 2017

### Breakdown product revenues (in EUR 1,000)

<table>
<thead>
<tr>
<th>By product</th>
<th>H1 2017</th>
<th>H1 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idylla™ System Sales</td>
<td>1,821</td>
<td>988</td>
</tr>
<tr>
<td>Cartridge Sales</td>
<td>3,270</td>
<td>1,723</td>
</tr>
<tr>
<td><strong>Product sales revenue</strong></td>
<td><strong>5,092</strong></td>
<td><strong>2,711</strong></td>
</tr>
</tbody>
</table>

### Breakdown total operating income

<table>
<thead>
<tr>
<th>In EUR 1,000</th>
<th>H1 2017</th>
<th>H1 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product sales revenue</td>
<td>5,092</td>
<td>2,711</td>
</tr>
<tr>
<td>Collaboration revenue</td>
<td>716</td>
<td>3,377</td>
</tr>
<tr>
<td>Service revenue</td>
<td>104</td>
<td>20</td>
</tr>
<tr>
<td><strong>Total revenue</strong></td>
<td><strong>5,912</strong></td>
<td><strong>6,109</strong></td>
</tr>
<tr>
<td>Grants and other income</td>
<td>1,066</td>
<td>641</td>
</tr>
<tr>
<td><strong>Total operating income</strong></td>
<td><strong>6,978</strong></td>
<td><strong>6,750</strong></td>
</tr>
</tbody>
</table>
### Condensed income statement

<table>
<thead>
<tr>
<th>In EUR 1,000</th>
<th>H1 2017</th>
<th>H1 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total operating income</td>
<td>6,978</td>
<td>6,750</td>
</tr>
<tr>
<td>COGS</td>
<td>(3,278)</td>
<td>(1,921)</td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>(19,320)</td>
<td>(20,699)</td>
</tr>
<tr>
<td>S&amp;M expenses</td>
<td>(5,308)</td>
<td>(5,259)</td>
</tr>
<tr>
<td>G&amp;A expenses</td>
<td>(2,781)</td>
<td>(2,874)</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>(30,687)</td>
<td>(30,754)</td>
</tr>
<tr>
<td>Operating result</td>
<td>(23,709)</td>
<td>(24,003)</td>
</tr>
<tr>
<td>Net financial result</td>
<td>(729)</td>
<td>(282)</td>
</tr>
<tr>
<td>Income taxes</td>
<td>456</td>
<td>501</td>
</tr>
<tr>
<td>Net result</td>
<td>(23,982)</td>
<td>(23,784)</td>
</tr>
</tbody>
</table>

### Breakdown operating expenses

#### H1 2017
- R&D expenses: 17%
- S&M expenses: 11%
- G&A expenses: 9%
- COGS: 63%

#### H1 2016
- R&D expenses: 17%
- S&M expenses: 10%
- G&A expenses: 67%
Cash position of **EUR 59m** end of H1 2017

<table>
<thead>
<tr>
<th>Condensed cash flow statement</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In EUR 1,000</strong></td>
<td><strong>H1 2017</strong></td>
</tr>
<tr>
<td>Result for the period</td>
<td>(23,982)</td>
</tr>
<tr>
<td>Depreciation and amortisation</td>
<td>2,428</td>
</tr>
<tr>
<td>Other adjustments</td>
<td>230</td>
</tr>
<tr>
<td><strong>Operational burn rate</strong></td>
<td>(21,324)</td>
</tr>
<tr>
<td>Working capital changes</td>
<td>(848)</td>
</tr>
<tr>
<td><strong>CF operating activities</strong></td>
<td>(22,172)</td>
</tr>
<tr>
<td><strong>CF investing activities</strong></td>
<td>(1,531)</td>
</tr>
<tr>
<td><strong>CF financing activities</strong></td>
<td>(479)</td>
</tr>
<tr>
<td><strong>Total net cash flow</strong></td>
<td>(24,182)</td>
</tr>
<tr>
<td><strong>Cash and cash equivalents</strong></td>
<td>59,042</td>
</tr>
<tr>
<td>Financial debt</td>
<td>33,279</td>
</tr>
</tbody>
</table>

1. Including EUR 1.2 million restricted cash related to KBC Lease financing  
2. Current portion of EUR 4.0m
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 ✓
- CE-marking Idylla™ NRAS Mutation Test ✓
- US FDA 510(k) approval of the Idylla™ Respiratory (IFV-RSV) Panel¹ ✓
- 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
Shareholders, stock performance and coverage

Shareholder overview (as per 13 June 2017)

<table>
<thead>
<tr>
<th>Shareholder</th>
<th># shares</th>
<th>% shares</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson &amp; Johnson Innovation</td>
<td>6,107,518</td>
<td>13.7%</td>
</tr>
<tr>
<td>Debiopharm Diagnostics</td>
<td>4,749,707</td>
<td>10.6%</td>
</tr>
<tr>
<td>RMM</td>
<td>3,989,058</td>
<td>8.9%</td>
</tr>
<tr>
<td>Sycomore Asset Management</td>
<td>2,301,126</td>
<td>5.2%</td>
</tr>
<tr>
<td>Capfi Bank Delen Asset Management</td>
<td>2,204,119</td>
<td>4.9%</td>
</tr>
<tr>
<td>PMV-TINA</td>
<td>1,840,861</td>
<td>4.1%</td>
</tr>
<tr>
<td>Participatie-Maatschappij Vlaanderen</td>
<td>428,000</td>
<td>1.0%</td>
</tr>
<tr>
<td>Topbio1</td>
<td>1,804,644</td>
<td>4.0%</td>
</tr>
<tr>
<td>Hitachi Chemical</td>
<td>1,417,346</td>
<td>3.2%</td>
</tr>
<tr>
<td>Other institutional and retail investors</td>
<td>19,805,726</td>
<td>44.4%</td>
</tr>
<tr>
<td>Total outstanding shares (non-diluted)</td>
<td>44,648,105</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Note: see website Biocartis for more details

Share performance last 12 months*

Coverage

* Source: Euronext
Appendix
Unsurpassed **ease of use** and fast time-to-result

35 to 150 minutes

Offering potential for CLIA waiver
Limitation of erroneous results due to **standardized 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
Step 1: tissue macroscopy

- A laboratory technician cuts the tissue into smaller pieces

Step 2: formalin-fixing

- This incubate overnight in formalin for optimal conservation while maintaining the fixation of the morphology

Step 3: paraffin-embedding

- The next day, the tissue is embedded in fluid paraffin

Step 4: microtome cutting

- The paraffin block is then cut into thin slices (tissue sections), suitable for (microscopic) analysis

FFPE is the gold standard sample type within oncology
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:

<table>
<thead>
<tr>
<th>Cancer type</th>
<th>% MSI-H</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>10-20%(^1)</td>
</tr>
<tr>
<td>Endometrium</td>
<td>± 30%(^2)</td>
</tr>
<tr>
<td>Ovarian</td>
<td>5-10%(^3)</td>
</tr>
<tr>
<td>Melanoma</td>
<td>± 10%(^4,5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cancer type</th>
<th>% MSI-H</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>± 5%(^6)</td>
</tr>
<tr>
<td>Gastric</td>
<td>± 20%(^7)</td>
</tr>
<tr>
<td>Pancreas</td>
<td>± 15%(^8)</td>
</tr>
</tbody>
</table>

What is Microsatellite Instability?

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

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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)

- Lower progression rate in MSI-H patients to PD-1 immune checkpoint blockade with pembrolizumab (Keytruda)
Idylla™: first line testing and gateway to NGS in oncology

Gene alterations*

- **Melanoma**
  - BRAF
  - NRAS
  - Other

- **Colon**
  - KRAS
  - NRAS
  - BRAF
  - MSI
  - Other

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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NGS sample and library preparation revisited

**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%**

**Typical NGS workflow:**
- **Sample prep**
  - Isolate genomic material from clinical sample
  - Quantify genomic material via qPCR
- **NGS library prep**
  - Target amplification via PCR
  - Indexing and tagging via PCR
  - Purification
  - Pool libraries
  - Sequencing
  - Data analysis
- **Sequencing**

**Full NGS prep summary**
- **4** #labs
- **6** #auxilliary devices
- **6h** hands-on
- **3** #PCR reactions
- **18** #samples/batch
- **12h** Turnaround time

*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 revolutionize NGS workflows by:
  - Standardization
  - Automation
  - Shorter time-to-results
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