3 SEPTEMBER 2020

# H1 2020 results

BIOCARTIS

# TODAY'S PRESENTERS

Jean-Marc Roelandt

Chief Financial Officer

Herman Verrelst

Chief Executive Officer

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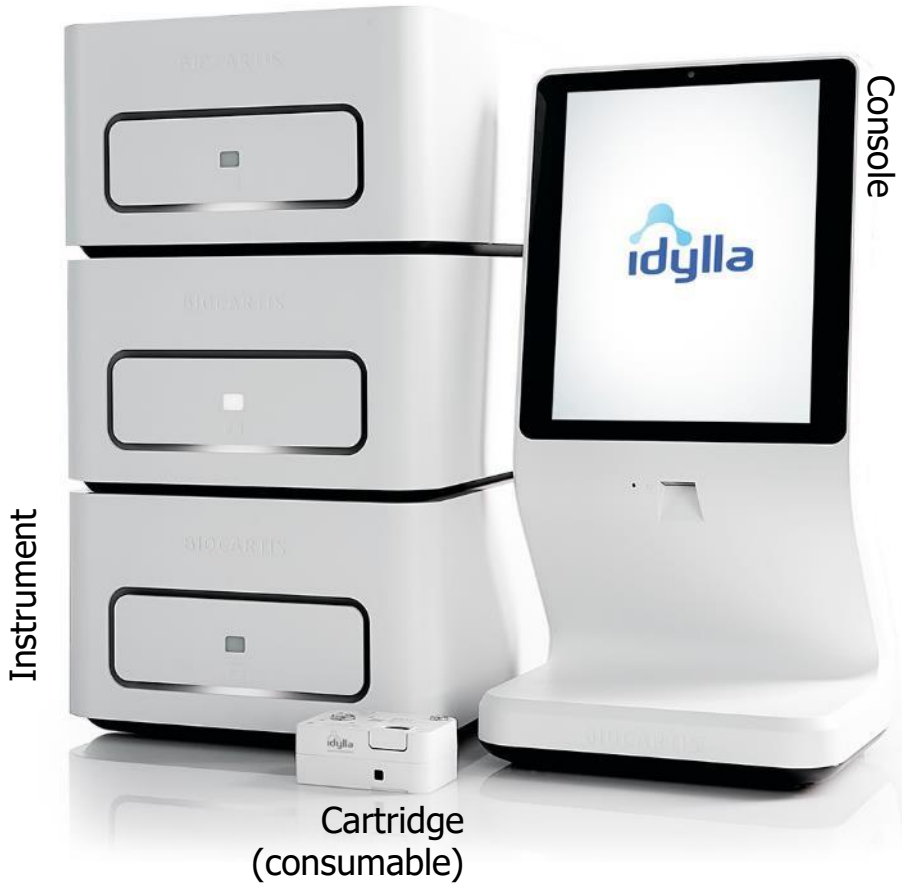
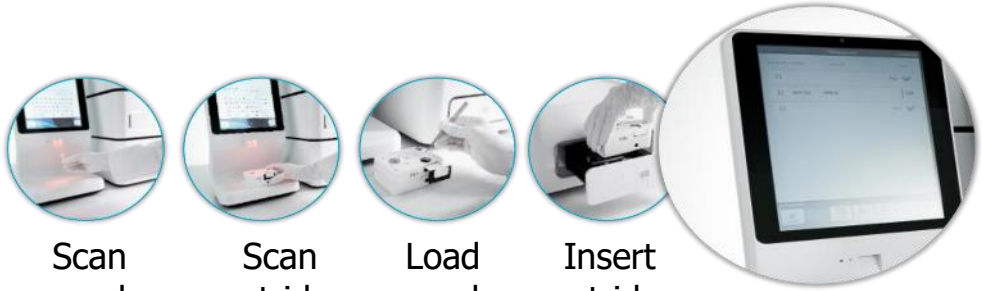
*Since the COVID-19 outbreak in December 2019, it has developed into a pandemic, causing significant disruptions to the global economy, including in certain countries in which the Company is operating its business. During H1 2020, the Company has experienced a slow down of its commercial activities and delays of certain partner projects as a result of various measures taken to contain the spreading of the virus.The extent to which the pandemic will continue to affect the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including but not limited to the duration of the pandemic, the severity and resistance of the virus and the actions taken to contain the virus or treat its impact. In particular, and although the Company currently expects that significant demand for its pandemic response products could mitigate the impact of COVID-19 on its oncology business, the continued spread of the virus could adversely impact its operations, including among others, the manufacturing and supply chain, sales and marketing and collaboration activities with partners, and could have an adverse impact on the Company's business and financial results.*

# AGENDA

1. Strategy recap
2. Commercial & business review H1 2020
3. Financial results H1 2020
4. Outlook 2020
5. Q&A

# FULLY AUTOMATED MOLECULAR TESTING WITH IDYLLA™




Superior sensitivity and ease-of-use, combined with sample-to-result turnaround time of 85 to 160* minutes

* Based on turnaround times of current on-market oncology tests



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# MARKET TRENDS DRIVE ONCOLOGY MENU STRATEGY

## Targeted therapies

- Therapy selection driven by specific cancer mutations
- Significant pipeline of new targeted therapies across cancer types
- Examples
  - Zelboraf®[1] (BRAF)
  - Tagrisso®[2] (EGFR)
  - Erbitux®[3] (RAS)
  - Vectibix®[4] (RAS)

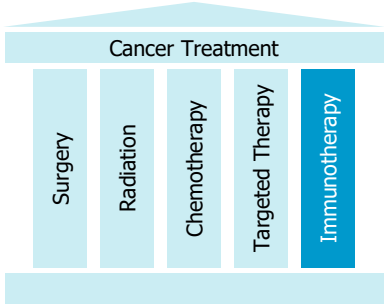
## Pan-tumor therapies

- Therapy selection driven by genetics rather than location of the tumor
- Allows therapy use across multiple cancer types
- Positive impact on underlying test volumes
- Examples
  - Vitrakvi®[5]
  - Keytruda®[6]
  - Rozlytrek®[7]

## Gene signatures

- MDx tests that target applications beyond therapy selection, e.g.:
  - Cancer risk
  - Prognosis
- Often high value once validated and clinical value demonstrated
  - Critical information for medical decision-making

## Immuno-oncology




- 'Fifth pillar' of cancer treatment
- Consists of several therapeutic classes, e.g.:
  - Immune checkpoint inhibitors
  - Cell and viral therapies
  - Vaccines
- High unmet need for underlying clinical testing

## Liquid biopsy

- Assess tumor information via liquid samples
- Clinical value increasingly demonstrated
- Front-runner applications:
  - Therapy selection
  - On-therapy monitoring
  - Post-treatment Minimal Residual Disease ('MRD')

1. Marketed by Roche. 2 Marketed by AstraZeneca. 3. Marketed by Merck KGaA and Eli Lilly. 4. Marketed by Amgen. 5. Marketed by Bayer (licensed from Eli Lilly's Loxo). 6. Marketed by Merck. 7. Marketed by Roche.



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# RESILIENT H1 PERFORMANCE AND AGILE RESPONSE TO COVID-19

Undebated need for **high quality**, **rapid** and **easy diagnostic testing** for every patient

**1.**
Continued oncology growth, despite COVID-19

**2.**
Robust performance, slow-down temporary with regional differences

**3.**
Continued focus on oncology, but new strategic opportunity

**Staying on course**
through **resilient performance** and **agile response** to the pandemic



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# Commercial & business review H1 2020

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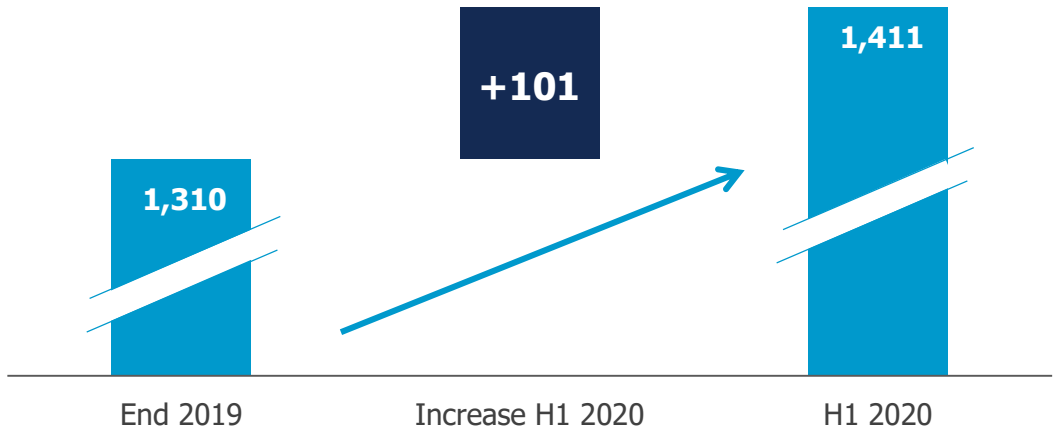
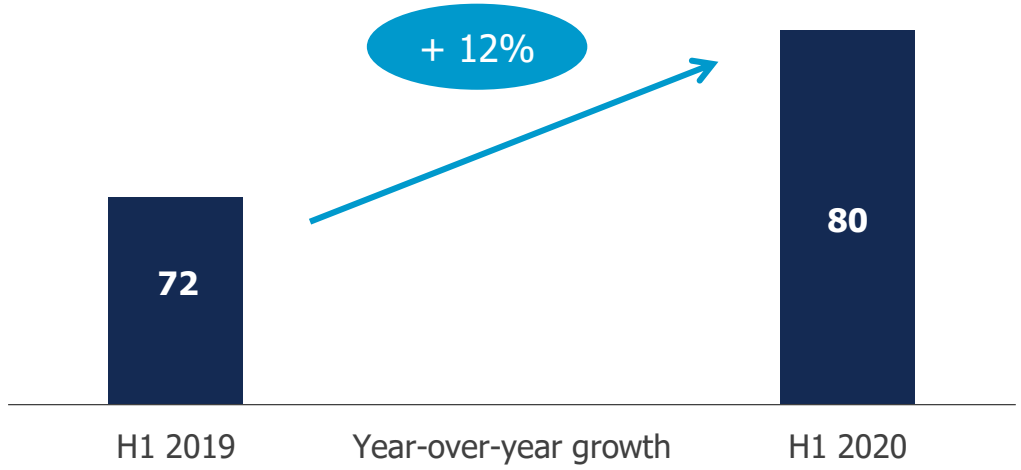
# CONTINUED INSTALLED BASE & CARTRIDGE VOLUME GROWTH

## Installed base (in # instruments)




## Commercial cartridge volume (x ~1,000)




- 101 new Idylla™ instruments placed versus 156 in H1 2019
- Total installed base of 1,411 end H1 2020
- 50% of the new placements in Europe
- Temporary slow-down in US and RoW[1] due to highly restricted access to customers

- Strong 68% year-over-year growth in Q1 2020
- Q2 2020 20% lower year-over-year
- Commercial cartridge volume increased to +/- 80k in H1 2020
- Swift recovery in some regions leads to +12% year-over-year despite COVID-19 pandemic

1 RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan



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# CARTRIDGE VOLUME GROWTH +12% IN H1 2020, DESPITE COVID-19 IMPACT

## Europe

- Cartridge volumes continued to grow
- Europe accounted for half of new Idylla™ instruments placements
- Negative impact pandemic most notable at start of Q2 2020
- Strength of customer base led to swift recovery, sales tracking to initial pre-pandemic expectations by end Q2 2020

## US

- Cartridge volume growth strong in Q1 2020, balancing the strong impact in Q2 2020
- COVID-19 measures severely limited new customer prospection in Q2 2020: stalled growth of Idylla™ installed base expansion and commercial cartridge volume mainly in Q2
- Pandemic expected to have prolonged effect into H2 2020, but thanks to customer investments in Q4 2019 and Q1 2020, net growth realized in H1 2020 and expected in H2 2020
- Strong demand for Idylla™ SARS-CoV-2 test to act as a catalyst for future oncology growth

## RoW[1]

- Cartridge growth most impacted in RoW, COVID-19 peak still not reached in many regions and Latin America particularly affected
- New market authorizations obtained for Idylla™ MSI Test in Colombia, Canada, Malaysia and Singapore, and for Idylla™ EGFR Mutation Test in Argentina
- Strong Q1 2020 and main impact in Q2 2020
- Limited visibility on recovery but currently no further erosion

## China[3] & Japan

- China:
  - Joint venture with Wondfo[2]: further steps towards local manufacturing
  - First CDx partnership with BMS for registration of Idylla™ MSI Test as CDx test in mCRC in China
  - First Idylla™ test product registrations in China earliest by end 2021
- Japan:
  - Continued progress for Idylla™ IVD registrations[4]
  - Paving the way to commercialization with Nichirei Biosciences[5]
  - First Idylla™ test product registrations in Japan earliest by end 2021



1 RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan; 2 Guangzhou Wondfo Biotech Co. Ltd is a fast growing diagnostics leader in China, listed on Shenzhen Exchange; 3 China is one of fastest growing MDx markets in the world. Source: DataMintelligence, "Global Molecular Diagnostics Market 2018-2025"; 4 PMDA = Pharmaceuticals and Medical Devices Agency in Japan. The Japanse MDx market is one of the largest MDx markets in the world, representing ~ 10% of the global MDx market. Source: DataMintelligence, "Global Molecular Diagnostics Market 2018-2025" 5 Part of Nichirei Corporation (TYO: 2871). The agreement was announced on 7 January 2019

# NEW IDYLLA™ INFECTIOUS DISEASE MENU:
## PANDEMIC RESPONSE IN H2 2020, START OF LONGER TERM STRATEGIC DIVERSIFICATION

### SeptiCyte® RAPID test on Idylla™

Immunexpress

- Agreement with Immunexpress expanded[1] in H1 2020
- A rapid, host-response[2] test that distinguishes sepsis from non-infectious SIRS (systemic inflammatory response syndrome), expected to provide actionable results in about one hour
- Biocartis will lead commercialization in Europe as exclusive distributor of SeptiCyte® RAPID (CE-IVD), Immunexpress will lead commercialization in US

### Idylla™ SARS-CoV-2 Test

- Intended to detect SARS-CoV-2, the virus that causes COVID-19, from nasopharyngeal swabs in viral transport medium
- Submission of Idylla™ SARS-CoV-2 Test for Emergency Use Authorization ('EUA') with the US FDA on 10 August 2020[3]


*Unique combined offering for ICUs[4] as recent data[5] indicate that sepsis is the most frequently observed complication in COVID-19[6]*

1 Announced on 26 March 2020. Developed in collaboration with Immunexpress. More info here
2 Host-response based tests focus on measuring biomarkers that are indicative of the response of a patient's immune system to an infection rather that measuring pathogens that are the cause of the infection. Moreover, SeptiCyte® RAPID not only discriminates sepsis from SIRS but also correlates with viral sepsis infection, versus procalcitonin (PCT) which increases with severity of bacterial but not viral infection and is also a non-specific marker of inflammation
3 Subject to interactions with the US FDA. US FDA 510(k) clearance of SeptiCyte® RAPID Test on Idylla™ expected along the same timelines
4 The Idylla™ SARS-CoV-2 Test and the SeptiCyte® RAPID (CE-IVD) Test on Idylla™ are intended for use in microbiology labs
5 Zhou et al., Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, published online 9 March 2020, https://doi.org/10.1016/S0140-6736(20)30566-3
6 Sepsis developed at a median of 9 days (7–13) after illness onset among all patients, followed by ARDS (12 days [8–15]), acute cardiac injury (15 days [10–17]), acute kidney injury (15 days [13–19.5]), and secondary infection (17 days [13–9]);



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# EXPANDED PARTNERSHIPS IN H1 2020

## LifeArc

- Expansion partnership announced 1 September 2020
- Ongoing co-development of Idylla™ ABC Panel, targeting multi-gene panel of predictive & resistance-inducing mutations based on a FFPE[5] sample (breast cancer)
- Under new agreement: LifeArc obtains non-exclusive licence to use Idylla™ platform for development of Idylla™ assays in infectious & immune related diseases
- Aimed at supporting patient stratification & treatment monitoring of patients with a.o. bacterial, fungal & viral infections

## BMS

- Agreement[1] focused on MSI testing in connection with IO therapies[2]
- Joint developments & registrations of Idylla™ MSI Test for use in variety of indications, commercial settings & geographies
- Two ongoing projects:
  - US: registration of Idylla™ MSI Test as a CDx in mCRC
  - China: registration of Idylla™ MSI Test as CDx in mCRC

## AstraZeneca

- Expansion partnership announced 22 January 2020
- Collaborative development & commercialization of Idylla™ tests to support AstraZeneca's pharma products, such as CDx[3] development projects
- Expansion focused on:
  - Ongoing European prospective study Idylla™ EGFR Mutation Test extended to additional countries in- & outside Europe
  - New: study if liquid biopsy testing using the Idylla™ ctEGFR Mutation Assay (RUO[4]) could provide further benefits to tissue-based EGFR testing



1 The agreement with Bristol-Myers Squibb Company (NYSE: BMY), a global biopharmaceutical company, was announced on 12 March 2019; 2 OPDIVO® (nivolumab) plus low-dose Yervoy (ipilimumab) is the first immuno-oncology combination treatment approved by US FDA for MSI-High or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with certain chemotherapies. Treatment with fluoropyrimidine, oxaliplatin and irinotecan. Note that OPDIVO® is also approved in the US as as a single agent, for the treatment of adult and pediatric patients 12 years and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. OPDIVO® generated USD 7.2m of global revenues in 2019 (Source: https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-reports-fourth-quarter-and-full-year-fi-1, last consulted on 3 March 2020); 3 CDx = companion diagnostics; 4 RUO = Research Use Only, not for use in diagnostic procedures; 5 FFPE = Formalin Fixed, Paraffin Embedded

# CONTINUED IDYLLA™ PUBLICATIONS:
## 20 NEW PUBLICATIONS[1] WITH STRONG IDYLLA™ DATA IN H1 2020

### H1 2020 publication highlights

**New US multicenter study**

Dartmouth-Hitchcock

- Published in the 'American Journal of Clinical Pathology'[2]
- Demonstrated that, compared to current standard-of-care testing methods, Idylla™ can substantially improve turnaround time of the results of mutation testing, independent of the size of the laboratory
- One of the largest studies performed involving Idylla™: incl. 20 labs of different types & sizes throughout US & Puerto Rico and data from ca. 800 colorectal cancer samples

**ASCO**

2020 ASCO ANNUAL MEETING

- Virtual annual ASCO (American Society of Clinical Oncology) 2020 meeting[3]
- Publication of five Idylla™ abstracts & posters by key oncology opinion leaders
- Including first Idylla™ data from China where amongst others the Idylla™ EGFR Mutation Assay (RUO) showed excellent concordance with other methods

1 Including publications, abstracts and posters and e-publications ahead of print. Sources can be found in the H1 2020 results press release on https://investors.biocartis.com/en/press-releases or see www.biocartis.com/publications
2 Led by researchers from Dartmouth's and Dartmouth-Hitchcock's Norris Cotton Cancer Center (Lebanon, New Hampshire, US). Tsongalis et al., "Comparison of Tissue Molecular Biomarker Testing Turnaround Times and Concordance Between Standard of Care and the Biocartis Idylla Platform in Patients With Colorectal Cancer", Am J Clin Pathol. 2020 Jun 11;aqaa044. doi: 10.1093/ajcp/aqaa044. Online ahead of print
3 The virtual annual ASCO 2020 meeting took place between 8-10 August 2020



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# TRANSFER OF TWO ADDITIONAL ASSAYS IN H1 2020 TO SECOND CARTRIDGE MANUFACTURING LINE 'ML2'

## H1 2020 manufacturing milestones

- Successful transfer Idylla™ NRAS-BRAF Mutation Test (CE-IVD) and Idylla™ MSI Test (CE-IVD) to second manufacturing line 'ML2' during H1 2020[1]
- 3 out 4 of highest volume assays now produced on ML2: major step in lowering manufacturing cost
- Transfer Idylla™ EGFR Mutation Test (CE-IVD) ongoing
- Transfer Idylla™ SARS-CoV-2 Test to ML2 expected towards end 2020

**Second cartridge manufacturing line 'ML2': facts & figures**

- Located in Mechelen (BE), additional annual capacity of + 1,000,000 cartridges
- Fully automated assembly workstations (vs semi-automated on 1st line, annual capacity +200k cartridges)
- Plastic parts with new multi-cavity molds (vs single cavity on 1st line)
- To support volume growth & cost effectiveness

1 The Idylla™ KRAS Mutation Test (CE-IVD) was transferred to ML2 in 2019

# Financial results H1 2020

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# TOTAL OPERATING INCOME EUR 17.6M IN H1 2020

## Breakdown total operating income

| In EUR 1,000 | H1 2020 | H1 2019 |
|---|---|---|
| Product sales revenue | 11,421 | 9,980 |
| Collaboration revenue | 4,746 | 6,816 |
| Service revenue | 530 | 351 |
| **Total revenue** | **16,697** | **17,147** |
| Grants and other income | 909 | 151 |
| **Total operating income** | **17,606** | **17,298** |

## Additional details (in EUR 1,000)

| Product sales revenue | H1 2020 | H1 2019 |
|---|---|---|
| Idylla™ system sales | 1,837 | 2,499 |
| Idylla™ cartridge sales | 9,584 | 7,481 |
| **Product sales revenue** | **11,421** | **9,980** |

| Collaboration revenue | H1 2020 | H1 2019 |
|---|---|---|
| R&D services | 4,623 | 4,350 |
| License fees | 123 | 2,467 |
| Milestones | 0 | 0 |
| **Collaboration revenue** | **4,746** | **6,816** |



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# OPERATING RESULT OF EUR -26.4M IN H1 2020

## Condensed income statement

| In EUR 1,000 | H1 2020 | H1 2019 |
|---|---|---|
| Total operating income | 17,606 | 17,298 |
| Cost of goods sold | (9,233) | (8,742) |
| R&D expenses | (20,303) | (20,031) |
| S&M expenses | (7,931) | (8,811) |
| G&A expenses | (6,491) | (6,399) |
| Total operating expenses | (43,958) | (43,983) |
| Operating result | (26,352) | (26,685) |
| Net financial result | (5,129) | (2,822) |
| Share in results of associates | (195) | 181 |
| Income taxes | 118 | 18 |
| Net result | (31,558) | (29,670) |

## Comments

- Total operating income of EUR 17.1m, level with H1 2019:
  - Commercial cartridge sales up EUR 1.4m or +28% vs H1 2019 on the back of 12% higher volumes and increasing ASP
  - System sales decrease by EUR 0.7m
    - COVID-19 restricted customer prospection mainly in US and RoW and slowed down new instrument placements
    - Higher proportion of reagent rental
  - Collaboration revenues affected by project delays
- COGS increase of EUR 0.5m driven by higher commercial product sales
- Gross margin on product sales of 19%, compared to 12% in H1 2019
- Operating expenses of EUR 44m remain stable
- Net financial result increase entirely driven by the convertible bond:
  - EUR 3.3m interest on the convertible bond;
  - EUR 2.2m non-cash debt appreciation of the Company's convertible bond



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# STRONG CASH POSITION EUR 150M AS PER END H1 2020

## Condensed cash flow statement

| In EUR 1,000 | H1 2020 | H1 2019 |
|---|---|---|
| Result for the period | (31,558) | (29,670) |
| Depreciation and amortization | 5,010 | 3,713 |
| Impairment losses | 721 | 202 |
| Working capital changes | (20,938) | (26,515) |
| Taxes & interests paid | (3,582) | (1,486) |
| CF operating activities | (24,526) | (28,357) |
| CF investing activities | (1,028) | (5,267) |
| CF financing activities | (3,456) | (179,465) |
| Total net cash flow[1] | (29,010) | 145,841 |
| Cash and cash equivalents[2] | 149,674 | 209,200 |
| Financial debt | 165,259 | 166,578 |

1. Excludes the effect of exchange rate differences on the cash balances held in foreign currencies
2. Including EUR 1.2m of restricted cash in H1 2020 and H1 2019

## Remarks

- The net cash outflow from operating and investing activities amounted to EUR 25.6m in H1 2020 compared to EUR 33.6m in H1 2019:
  - A lower investment in net working capital resulting from the collection of a tax credit
  - A lower capital expenditure resulting from a lower number of Idylla™ instruments placed under reagent rental agreements.
- Net cash flow of EUR 29.0m, resulting in a cash position of EUR 150m as per end H1 2020, in line with expectations



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# Outlook 2020

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# RESILIENT H1 2020 PERFORMANCE, AGILE RESPONSE TO COVID-19

Undebated need for **high quality**, **rapid** and **easy diagnostic testing** for every patient

## 1. Continued oncology growth, despite COVID-19

**Installed base**

- + 101 added, 1,411 total installed base

**Cartridge volume**

- Nearly 80k cartridges, +12% year-over-year growth despite COVID-19 impact
- Strong demand for Idylla™ SARS-CoV-2 Test expected to offset temporary slowdown in Idylla™ core oncology business

**Some projects unavoidably impacted by COVID-19**

- Exact Sciences (Oncotype Breast)
- Amgen (RAS US FDA submission)
- GeneFusion

## 2. Robust performance, slow-down temporary with regional differences

**Europe**

- 50% of new placements
- Strong customer base, swift recovery from pandemic impact

**US**

- Strong Q1 2020 cartridge growth
- Pandemic expected to have prolonged effect into H2 2020, but thanks to customer investments in Q4 2019 and Q1 2020, net growth realized in H1 2020 and expected in H2 2020

**RoW**

- Strong Q1 2020, main impact in Q2 2020
- Limited visibility on recovery but currently no further erosion

## 3. Continued focus on oncology, but new strategic opportunity

**Short-term hedge against COVID-19 impact: new Idylla™ pandemic response test menu[1]**

- Idylla™ SARS-CoV-2 Test made available following submission to US FDA for EUA[2]
- Commercialization rights from Immunexpress (EU[3]) for SeptiCyte® RAPID on Idylla™

**Oncology partnerships strengthened and opportunity to diversify into infectious diseases**

- Partnerships AstraZeneca, BMS expanded in oncology
- Partnerships with Immunexpress, LifeArc expanded in infectious diseases

1 The Idylla™ SARS-CoV-2 Test and the SeptiCyte® RAPID (CE-IVD) on Idylla™ are intended for use in microbiology labs; 2 Emergency Use Authorization; 3 Available to select countries within the EU and European region. Check availability with your local Biocartis representative



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# GUIDANCE 2020 REINSTATED*

- Targeting a year-over-year commercial cartridge volume growth in the range of 30%, representing a volume of Idylla™ cartridges in the range of 228k;
- Targeting an installed base growth in the range of 300-350 new instrument placements; and
- Targeting a cash position in the range of EUR 110m by year-end 2020

** Assumptions:*

- *Resuming normal business activities in the course of H2 2020;*
- *No new widespread lock-down measures will be imposed; and*
- *Idylla™ SARS-CoV-2 Test is granted US FDA Emergency Use Authorization ('EUA')*

# MENU OUTLOOK

- Mobilizing resources for development of Idylla™ SARS-CoV-2 Test affected planning of certain other projects
- Revised test menu outlook is now as follows:

| Area | Test |
|---|---|
|  | Subject to further feedback from US FDA interaction:<br>• US FDA 510(k) submission of Idylla™ MSI Test expected in Q4 2020<br>• US FDA submission of PMA[1] application for Idylla™ RAS tests now expected in H1 2021 (instead of end 2020 initially) |
|  | Minor delay RUO[2] launch Idylla™ GeneFusion Assay to Q1 2021 (versus end 2020) |
|  | Idylla™ IVD Oncotype DX Breast Recurrence Score® test: project suspended due to COVID-19. Project plan under evaluation, timing under review. No launch to be expected in 2020. |
|  | SeptiCyte® RAPID on Idylla™:<br>• CE-IVD market release expected in Q3 2020<br>• US FDA regulatory process ongoing<br>Idylla™ SARS-CoV-2 Test:<br>• Emergency Use Authorization (US) and CE-marking (Europe) is pending |

1 PMA = Pre-Market Approval
2 RUO = Research Use Only, not for use in diagnostic procedures

# FINANCIAL CALENDAR 2020


- 12 November 2020 Q3 2020 Business Update
- 12 November 2020 Capital Markets Day 2020[1]
- 25 February 2021 2020 full year results
- 1 April 2021 Publication 2020 annual report



1 Virtual or physical event, depending on Belgian COVID-19 guidelines

# Q&A


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MOLECULAR DIAGNOSTICS FOR PERSONALIZED MEDICINE
IDYLLA™
MSI ASSAY
A NEW ERA
IN MSI TESTING
Now available!
JOIN US
OUR MSI EVENT
Tuesday 11 September
(07:15 - 08:15) - ROOM A2
RAS, BRAF, EGFR, MSI(1)
Genefusion(2) & ctEGFR - under development
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