H1 2021 results

2 SEPTEMBER 2021

BIOCARTIS GROUP NV

TODAY'S PRESENTERS

Jean-Marc Roelandt

Chief Financial Officer

Herman Verrelst

Chief Executive Officer

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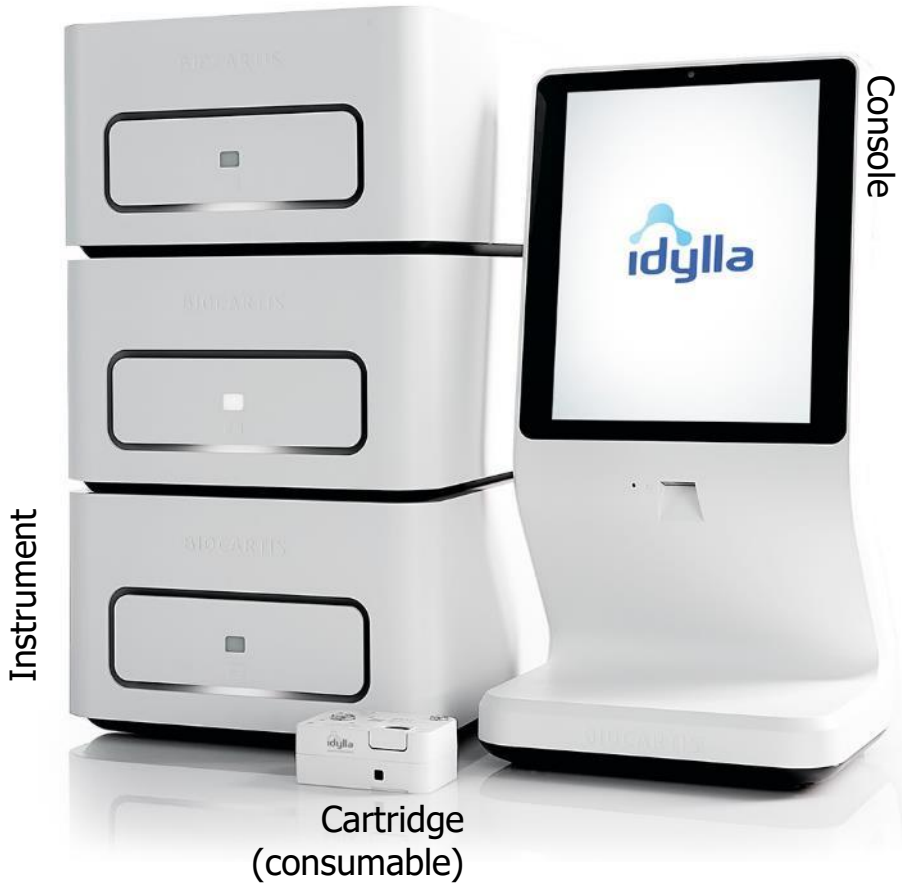
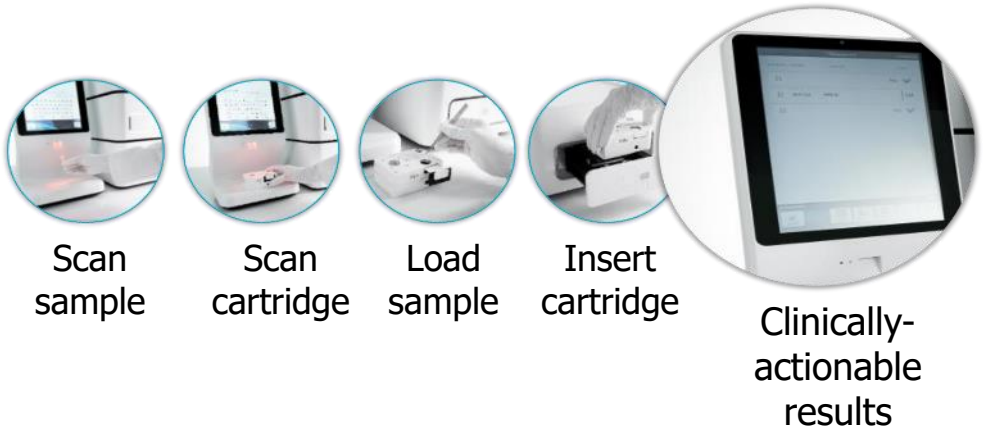
AGENDA

1. Strategy recap
2. Results H1 2021
3. New simplified, cost-efficient cartridge manufacturing concept
4. Outlook 2021
5. Q&A

RAPID MOLECULAR TESTING ON THE FULLY AUTOMATED IDYLLA™





Superior sensitivity and ease-of-use, combined with sample-to-result turnaround time of 65 to 160 minutes*

Unique, versatile platform for dual use in oncology and infectious disease

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

ONE SINGLE PLATFORM, TWO MENU DEVELOPMENT TRACKS

Oncology focus

- On market Idylla™ oncology test menu in colorectal, lung, melanoma, with ongoing developments in breast and thyroid cancer
- Selected opportunities to broaden and deepen in oncology through five strategic areas where Idylla™ can make a difference in the cancer treatment continuum:

1. Gene signatures
2. Targeted therapy
3. Pan-tumor
4. Immuno-oncology
5. Liquid biopsy

Expansion into infectious diseases

Diversifying the Idylla™ test menu to accelerate further installed base growth, focus on rapid response testing for critical illness

First expansions in infectious diseases:

- Pandemic menu: Idylla™ SARS-CoV-2 Test, SeptiCyte® RAPID and recent CE-IVD launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel
- Idylla™ Endpoint Test (in development)

- Growing partner business model to accelerate core strategy

The SeptiCyte® RAPID on Idylla™ is in collaboration with Immunepress. The Idylla™ Endpoint Test is in collaboration with Endpoint Health.

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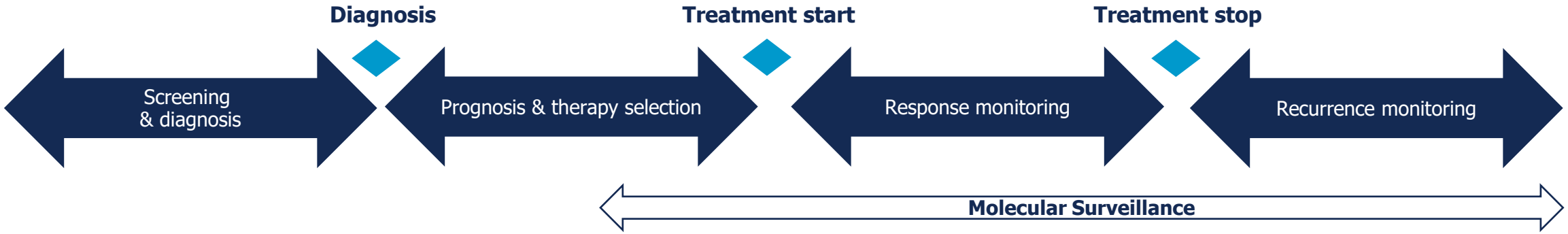
ONCOLOGY STRATEGY

IDYLLA™ IN THE CANCER TREATMENT CONTINUUM



Gene signatures

- MDx tests based on RNA Gene Signatures are used for e.g.:
  - Diagnosis
  - Prognosis
- Often high value once validated & clinical value demonstrated
- Examples
  - SeptiCyte® RAPID
  - ThyroidPrint®

Targeted therapy

- MDx tests detecting specific tumor mutations used for therapy selection in a specific cancer type
- Significant pharma pipeline of new targeted therapies
- Examples
  - Zelboraf®[1] (BRAF)
  - Tagrisso®[2] (EGFR)
  - Erbitux®[3] (RAS)
  - Vectibix®[4] (RAS)

Pan-tumor

- Pan-tumor application of tumor mutation tests for therapies selected based on 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]

Immuno-oncology

- MDx tests supporting immuno-oncology cancer treatments
- Consists of many different therapies, e.g.:
  - Immune checkpoint inhibitors
  - Cell and viral therapies
  - Vaccines
- High unmet need for underlying MDx testing

Liquid biopsy

- MDx tests via liquid samples
- Use in diagnosis, prognosis and Molecular Surveillance (i.e. therapy selection, response and recurrence monitoring)
- Can be done through off-the-shelf catalogue panels as well as tumor-informed, personalized panels

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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INFECTIOUS DISEASE MENU STRATEGY

TOWARDS A PRECISION MEDICINE ICU WORKFLOW FOR PATIENTS WITH CRITICAL ILLNESS

1. COVID-19

- Pandemic: more decentralized MDx testing, faster installed base building in acute settings
- Support Intensive Care Unit (ICU)[1] positioning, together with SeptiCyte® RAPID[5] on Idylla™
- Idylla™ tests:
  - Idylla™ SARS-CoV-2 Test (CE-IVD, EUA pending)
  - Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD)

2. SEPSIS

- Responsible for est. 11m deaths/year globally[2], annual healthcare costs est. at > USD 60bn in the US alone[3]
- High unmet need: current markers are not rapid (blood cultures) or non-specific (PCT, CRP)[4]; increased risk in pandemic times
- Fast clinical decisions impact patient outcome
- Idylla™ tests:
  - SeptiCyte® RAPID[5] (with Immunexpress)
  - Idylla™ EndPoint Test (with EndPoint Health): aims at enabling biomarker-based therapeutic decisions in patients with critical illnesses[6], such as sepsis

3. FUTURE POTENTIAL

- Syndromic panel testing:
  - One of fastest growing MDx segments
  - Idylla™'s unique multiplexing platform capabilities allow entry into this market

Towards easy & rapid Idylla™ infectious disease testing to support the patient journey in the intensive care unit (ICU), including rapid triage and therapy selection of critically ill patients

1 The Idylla™ SARS-CoV-2 Test and the SeptiCyte® RAPID (CE-IVD) test on Idylla™ are intended for use in microbiology labs; 2 The Lancet, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32989-7/fulltext, last consulted on 29 October 2020; 3 Paoli et al. Crit Care Med (2018): 46: 1889-1897 and https://journals.lww.com/ccmjournal/Fulltext/2020/03000/Sepsis_Among_Medicare_Beneficiaries__3__The.4.aspx, last consulted on 29 October 2020; 4 PCT = Procalcitonin (PCT) assay is a biomarker for systemic inflammation; CRP = C-reactive protein, a biomarker for systemic inflammation. Positive bacteriological cultures, including blood cultures, may not be available before 24 to 48 hours; interpretation of local colonization may be ambiguous; and traditional markers of infection, such as body temperature and white blood cell (WBC) count, may not be specific; 5 SeptiCyte® RAPID is a host-response test that distinguishes sepsis from non-infectious systemic inflammation in patients suspected of sepsis; 6 The Idylla™ Endpoint test is intended to be a PCR based mRNA-expression classifier test that aims at enabling biomarker-based therapeutic decisions in patients with critical illnesses. More specifically, the test will be intended to help identify patients with critical illnesses that are likely to benefit from corticosteroid therapy versus patients in which such therapy should be avoided

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H1 2021 results

KEY MESSAGES H1 2021 RESULTS

Commercial cartridge volume

- 156k commercial Idylla™ cartridges sold, almost twice as high as in H1 2020 (+96%)
- Q1 2021 marked by 70% growth, followed by an even stronger +136% in Q2 2021
- Robust growth in oncology across all regions
- Solid contribution from infectious diseases

Installed base

- + 189 new Idylla™ placements in H1 2021 (versus 101 in H1 2020)
- Installed base of 1,770 Idylla™ instruments end of H1 2021
- Increasing average annualized cartridge consumption per Idylla™ instrument (for period H1 2021): 209

Total operating & product income

- Total operating income of EUR 23.1m, versus EUR 17.6m in H1 2020
- Product income +62% to EUR 18.5m, versus EUR 11.4m in H1 2020

Cartridge ASP & gross margin

- Cartridge oncology ASP[1] stable: EUR 104; ASP of the Idylla™ SARS-CoV-2 Test lower than last year, in line with expectations and resulting in an overall ASP of EUR 95.
- Gross margin on products: 8% (vs 18% in H1 2020):
  - Lower ASP of Idylla™ SARS-CoV-2 Test
  - Temporarily higher COGS[2] due to lower production volumes on ML2 caused by global shortage of reagent supplies
  - Ramp-up of staff in anticipation of increasing volumes in H2 2021

Partnerships

- New partnership SkylineDx: development of Merlin Assay[3] on Idylla™
- Expanded partnership AstraZeneca: improve access to Idylla™ EGFR testing products in EU and global distributor[4] markets

Idylla™ test menu

- Encouraging first market demand for the Idylla™ GeneFusion Assay (RUO[5]), launched end Q1 2021
- First oncology assay US FDA submission: 510(k)[6] notification for the Idylla™ MSI Test[7]
- Post the reporting period: successful CE-IVD launch of the Idylla™ SARS-CoV-2/Flu/RSV Panel[8]

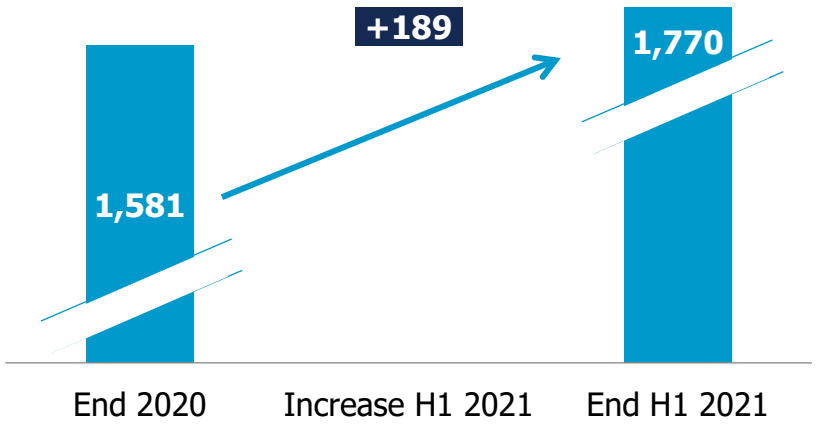
Cash position

- Cash and cash equivalents of EUR 85.0m end of H1 2021

1 ASP = Average Sales Price; 2 COGS = Costs of Goods Sold; 3 This assay is aimed at predicting a patient's risk of nodal metastasis in melanoma. Under the terms of the partnership agreement, SkylineDx will lead the development of the Merlin Assay on Idylla™, while Biocartis will lead the commercialization in Europe through its growing Idylla™ network; 4 Defined as the world excluding European direct markets, US, China and Japan; 5 RUO = Research Use Only, not for use in diagnostic procedures; 6 A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). A 510(k) or Premarket Notification (PMN) with the US FDA is required when introducing a device into commercial distribution for the first time. Source: https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances, last consulted on 17 August 2021; 7 For the detection of MSI (Microsatellite Instability) and to aid in the differentiation between sporadic colorectal cancer and potential Lynch Syndrome; 8 The Panel detects SARS-CoV-2, Flu A/B and RSV (respiratory syncytial virus) nucleic acids in one single cartridge within approx. 90 minutes and was launched as CE-IVD

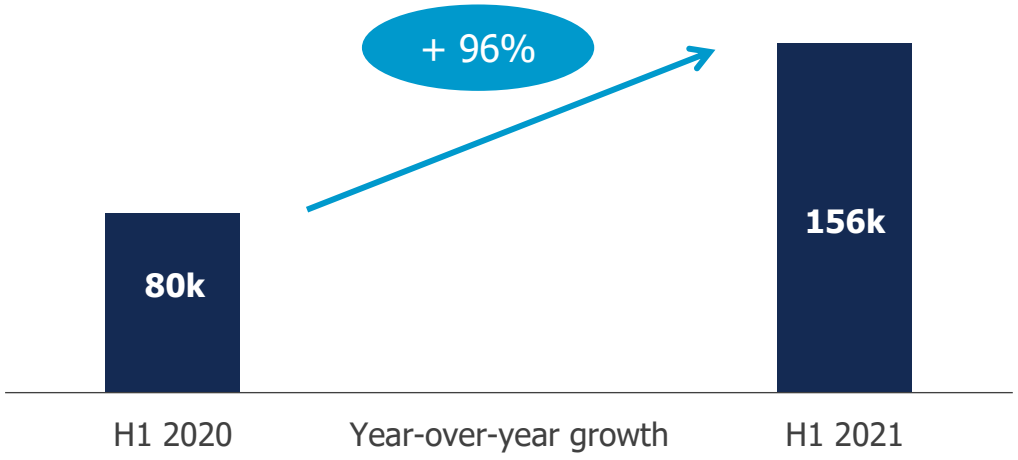
CONTINUED INSTALLED BASE & CARTRIDGE VOLUME GROWTH

Installed base (in # instruments)



- Increasing annualized average cartridge consumption per Idylla™ instrument: 209
- In part reflecting high utilization for infectious disease testing

Commercial cartridge volume (x ~1,000)



- Q1 2021 marked by 70% growth
- Followed by an even stronger +136% in Q2 2021
- Robust growth in oncology across all regions
- Solid contribution from infectious diseases, comparable to H2 2020 volumes against backdrop of declining global COVID-19 testing volumes

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CARTRIDGE VOLUME GROWTH H1 2021 NEARLY TWICE AS HIGH AS H1 2020

Europe

- Strong increase new Idylla™ placements
- Drives continued growth of EU cartridge volumes
- Strongest growth in oncology
- Combined with acquisition of new European customers in need for rapid SARS-CoV-2 testing for safe access to hospitals, events, travel

US

- Commercial cartridge volumes +150%
- Slowdown Idylla™ placements: constrained hospital budgets following the pandemic
- Growth driven by increased demand for oncology biomarker testing, return to pre-pandemic oncology biomarker testing volumes more disparate across the US
- Infectious diseases: demand for SARS-CoV-2 testing in H1 2021 significantly down from 2020 levels

Distributor markets[1]

- Strong performance in terms of Idylla™ placements
- Cartridge volume regained traction in oncology in all regions
- Registration completed in Russia for the Idylla™ platform, Idylla™ BRAF Mutation Test (CE-IVD) and Idylla™ EGFR Mutation Test (CE-IVD)
- Registration completed in Taiwan for the Idylla™ MSI Test (CE-IVD)

China & Japan[2]

- Registration Idylla™ instrument in China expected by end 2021
- Idylla™ assay registrations expected to follow earliest end 2022 in both countries
- Good progress in local manufacturing set-up in China during H1 2021, with local manufacturing of first cartridge volumes needed for local registration of the assays expected in H1 2022

1 Distributor markets = World excluding European direct markets, US, China and Japan;2 In China, Biocartis established a joint venture ('China JV') with Guangzhou Wondfo Biotech Co., Ltd (SHE: 300482), a fast-growing diagnostics leader in China. In Japan, Biocartis is collaborating with Nichirei Biosciences

LAUNCH OF THE IDYLLA™ GENEFUSION ASSAY (RUO*)

The Idylla™ GeneFusion Assay (RUO) highly multiplexed panel of biomarkers, the first FFPE[3] RNA[4]-based assay on Idylla™

- Gene fusions have become important biomarkers for cancer diagnosis, prognosis and selection of targeted therapies[1]
- The discovery & research for further understanding of fusion genes across multiple cancer types may provide more effective therapies in the future
- Current gene fusion testing techniques are complex:
  - Require combination of different technologies[2], often only available in different laboratories, to test all biomarkers
  - Implies need for sufficient sample quality & quantity: difficult to obtain, esp. for certain cancers including lung cancer

Detection of ALK, ROS1, RET & MET Exon 14 skipping plus NTRK1/2/3 fusion screening in one cartridge

Fully automated molecular testing platform
On-demand testing

<2 minutes hands-on time (HOT)
Assay turnaround time (TAT) of approx. 180 min.

Directly from 1-3 FFPE[3] slices

Preliminary data[4] comparing the Idylla™ GeneFusion Assay (RUO) with today's frequently used technologies such as Immunohistochemistry, FISH or NGS[2], show excellent results of the Assay, with concordance up to 100%

* RUO = Research Use Only, not for use in diagnostic procedures; 1 Stransky et al. The landscape of kinase fusions in cancer. Nat Commun. 5, 4846, 2014; Mertens et al. The emerging complexity of gene fusions in cancer. Nat Rev Cancer 15, 371-381, 2015; 2 Techniques used to detect NTRK gene fusions include DNA-based next-generation sequencing (NGS), RNA-based NGS, reverse-transcriptase PCR (RT-PCR), fluorescence in situ hybridisation (FISH), and immunohistochemistry (IHC). Source: OncologyPro, ESMO, see here, last consulted on 15 March 2021; 3 FFPE = formalin fixed, paraffin embedded; 4 The concordance study was performed on NSCLC (non-small cell lung cancer) and thyroid cancer samples with prototype cartridges but re-analyzed with final Idylla™ GeneFusion Assay (RUO) decision tree. Moreover, the Idylla™ GeneFusion Assay was able to generate accurate results in 29/32 inconclusive IHC and FISH results. Preliminary data can be found on https://www.biocartis.com/en/meetidylla/idylla-oncology-assays

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FIRST US FDA SUBMISSION OF ONCOLOGY ASSAY
WITH IDYLLA™ MSI TEST 510(K) NOTIFICATION

- Announced 20 April 2021: US FDA 510(k) submission[1] of Idylla™ MSI Test[2] for use as an IVD diagnostic device intended for the identification of microsatellite instability (MSI) status in colorectal cancer (CRC) to aid in the differentiation between sporadic CRC and potential Lynch syndrome
- Today, MSI testing is recommended in the guidelines for CRC patients for screening for Lynch syndrome[3]
- MSI testing today still underused due to complexity of current methods
- Idylla™ MSI Test allows fully automated MSI testing, providing info on the MSI status[4] of CRC tumors within approx. 150 minutes, without the need of a reference sample
- Once the 510(k) clearance is obtained, both large and small US labs are expected to benefit from this fast and easy to use Idylla™ MSI testing thanks to the fully automated sample-to-result nature of the Idylla™ platform

1 A 510(k) or Premarket Notification (PMN) with the US FDA is required when introducing a device into commercial distribution for the first time. Source: US FDA; 2 The Idylla™ MSI Test, for use on the Idylla™ system, is intended for the qualitative identification of microsatellite instability (MSI) in colorectal cancer (CRC) tumors and to aid in the differentiation between sporadic CRC and potential Lynch Syndrome. The clinical performance of this device to guide treatment of MSI-H patients has not been established; 3 Van Cutsem et al. (2016) ESMO Consensus Guidelines for the management of patients with mCRC. Annals of Oncology 27, 1386; NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Colon Cancer V.2.2018. Accessed 25 July 2018. See www.NCCN.org; 4 The Idylla™ MSI Test reports results as either microsatellite stable (MSS), or microsatellite instability high (MSI-H) or invalid

NEW PARTNERSHIP SkylineDx: FIRST PROJECT IN MELANOMA, LONGER TERM HIGHLY VALUABLE TEST PORTFOLIO AT EXPECTED ATTRACTIVE PRICING

About melanoma & Merlin Assay on Idylla™

- Melanoma is deadliest form of skin cancer: prognosis & treatment decisions depend on disease staging
- Current staging methods include an invasive SLN biopsy[1]:
  - Carrying a >10% risk of complications[2] whereas
  - 80-85% are unnecessary as no nodal metastases are found[2]
- Principal agreement announced 22 April 2021:
  - Development by SkylineDx of its novel Merlin Assay, on Idylla™
  - Predicting a patient's risk of nodal metastasis in melanoma, identifying patients who may safely forgo an SLN biopsy[1]
  - Biocartis will lead commercialization in Europe through its growing Idylla™ network
- Complements Biocartis' current BRAF assay offering[3]

About SkylineDx & the agreement

- SkylineDx: Dutch & US based private biotech company active in oncology & inflammatory diseases MDx
- Immediate market development ahead of IVD strategy:
  - LDT[4] version of Merlin Assay through CAP/CLIA certified laboratory in San Diego (CA, US)
  - Molecular subtyping test kit for IVD use under development for Europe
  - Commercialization by Biocartis in Europe through its growing Idylla™ network
- Access to SkylineDx's highly valuable biomarker content:
  - Additional novel tests in varying stages of development
  - Biocartis to invest up to EUR 10m in secured convertible notes issued in different project-based instalments throughout the collaboration
  - Expected attractive value-based pricing

1 A sentinel lymph node biopsy (SLNB) is a surgical procedure used to determine whether cancer has spread beyond a primary tumor into the lymphatic system. Source: Mayo Clinic, https://www.mayoclinic.org/tests-procedures/sentinel-node-biopsy/about/pac-20385264, last consulted on 21 April 2021; 2 Ascha M, et al. Ann Plast Surg 79:509-515, 2017, https://journals.lww.com/annalsplasticsurgery/Abstract/2017/11000/Identification_of_Risk_Factors_in_Lymphatic.22.aspx; Bellomo et al. JCO Precision Oncology, https://ascopubs.org/doi/10.1200/PO.19.00206; 3 The Idylla™ BRAF Mutation Test (CE-IVD) is validated for use in metastatic melanoma; 4 A laboratory developed test (LDT) is a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory. Source: US FDA, last consulted on 19 August 2021

POST THE REPORTING PERIOD:
SUCCESSFUL CE-IVD LAUNCH IDYLLA™ SARS-COV-2/FLU/RSV PANEL

About the Panel

- Fully automated rRT-PCR[1] test intended for qualitative detection of SARS-CoV-2, Flu A/B and RSV nucleic acids in nasopharyngeal swab specimens from individuals suspected of respiratory infections by their healthcare provider
- Collected in viral transport medium[2], can be pipetted directly into the cartridge
- Panel includes fully automated nucleic acid testing with the extraction, amplification and detection in a single-use cartridge
- Less than 1 minute hands-on time, results in approx. 90 minutes

Clinical performance

- Panel showed excellent performance in the clinical performance study with 98% overall agreement compared with other currently used methods
- Timing of Emergency Use Authorization ('EUA') submission with the US FDA to be decided

1 Real-Time Reverse Transcription-Polymerase Chain Reaction; 2 Of which 400 µl VTM is used in Idylla™; 2 Performance was evaluated across two arms of a clinical evaluation, all samples were residual nasopharyngeal swab in viral transport media. In the first arm 322 specimens were collected to evaluate the performance of the Idylla™ COVID-19/Flu/RSV Panel compared to the DiaSorin Molecular Simplexa™ Flu A/B & RSV Direct. In the second arm 341 specimens were collected to evaluate the performance of the Idylla™ COVID-19/Flu/RSV Panel compared to the Luminex Aries® SARS-COV-2 Assay. More information here

Only selected studies shown on slide

19 NEW IDYLLA™ PUBLICATIONS, ABSTRACTS & POSTERS WITH STRONG IDYLLA™ DATA IN H1 2021

H1 2021 publication highlights

Two studies on rapid EGFR Idylla™ testing

Memorial Sloan Kettering Cancer Center

- Studies included the publication of two studies[1] by Memorial Sloan Kettering Cancer Center ('MSKCC', New York, US)
- Concluding that Idylla™ EGFR testing (RUO[2])
  - Enables rapid assessment of the most common EGFR mutations with low sample input, even on different sample types, without compromising subsequent more comprehensive NGS[3] testing
  - Can be useful in cases where EGFR mutation results were negative and further testing is needed

ASCO and ECCMID

2021 ASCO ANNUAL MEETING

31st ECCMID EUROPEAN CONGRESS OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES

- One abstract[4] presented at the ASCO (American Society of Clinical Oncology) Annual Meeting (4-8 June 2021)
- One abstract on the SeptiCyte© RAPID on Idylla™ presented at the 31st ECCMID (European Congress of Clinical Microbiology & Infectious Diseases) congress (9-12 July 2021)

1 Arcila ME, Yang S-R, Momeni A, Mata DA, Salazar P, Chan R, Elezovic D, Benayed R, Zehir A, Buonocore DJ, Rekhtman N, Lin O, Ladanyi M, Nafa K, Ultra-Rapid EGFR Mutation Screening Followed by Comprehensive Next-Generation Sequencing: A Feasible, Informative Approach for Lung Carcinoma Cytology Specimens with a High Success Rate., JTO Clinical and Research Reports (2020), doi: https://doi.org/10.1016/j.jtocrr.2020.100077., available online 18 July 2020; Arcila ME et al., Rapid EGFR Mutation Detection Using the Single-Institution Experience of 1200 Cases Analyzed by an In-House Developed Pipeline and Comparison with Concurrent Next-Generation Sequencing Results Idylla Platform, J Mol Diagn 2020, Published on 23 December 2020, 1-12; https://doi.org/10.1016/j.jmoldx.2020.11.009; 2 RUO = Research Use Only, not for use in diagnostic procedures; 3 Next Generation Sequencing; 4 Behera et al. Circulating tumor DNA mutation as a prognostic marker in melanoma with brain metastasis. J Clin Oncol 39, 2021 (suppl 15; abstr e21560); 4 Only the abstracts at the virtual AMP Europe congress (Association for Molecular Pathology, virtual congress taking place 14-18 June 2021) and ASCO (American Society of Clinical Oncology) in the US were screened

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HIGH-THROUGHPUT MANUFACTURING ML2 LINE AS KEY DRIVER OF COST OPTIMIZATION

H1 2021: Key oncology assays on ML2 line

- Successful transfer Idylla™ EGFR Mutation Test (CE-IVD) to second manufacturing line 'ML2' during H1 2021
- Key oncology assays now all on ML2 line
- Product gross margin improvement temporarily held up, global pandemic shortage of certain reagents limited planned production volumes

ML2 cartridge manufacturing line facts

- 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)
- Key to support volume growth & cost effectiveness

DESPITE IMPACT OF THE FIRE, CONFIRMING 40% GROWTH TARGET OF COMMERCIAL CARTRIDGE VOLUMES

Fire incident on 30 July 2021

- Immediate actions taken to mitigate loss of finished products & raw materials, and temporary unavailability of high-throughput ML2 line

- Actions to safeguard continued supply to customers:
  - Redirection of additional personnel & resources to the unaffected ML1 line to temporarily increase production
  - Orders placed to replenish critical reagents lost in fire to minimize production delay
  - Prioritization of oncology & partner project tests, which also reduces the number of available Idylla™ SARS-CoV-2 Test cartridges

Despite impact of the fire…

- Biocartis to confirm a 40% cartridge volume growth for 2021:
  - Subject to timely and sufficient availability of reagents
  - Subject to full restart of the ML2 line, now expected by 2nd half of September

- Delays in supply of assay-specific reagents may cause certain Idylla™ products to be temporarily unavailable to meet the entire customer demand

TOTAL OPERATING INCOME EUR 23.1M IN H1 2021

Breakdown total operating income

In EUR 1,000	H1 2021	H1 2020
Product sales revenue	18,463	11,421
Collaboration revenue	2,640	4,746
Service revenue	748	530
Total revenue	**21,851**	**16,697**
Grants and other income	1,206	909
Total operating income	**23,057**	**17,606**

Additional details (in EUR 1,000)

Product sales revenue	H1 2021	H1 2020
Idylla™ system sales	3,715	1,837
Idylla™ cartridge sales	14,749	9,584
Product sales revenue	**18,463**	**11,421**

Collaboration revenue	H1 2021	H1 2020
R&D services	2,590	4,623
License fees	50	123
Milestones	0	0
Collaboration revenue	**2,640**	**4,746**

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OPERATING RESULT OF EUR -33.1M IN H1 2021

Condensed income statement

In EUR 1,000	H1 2021	H1 2020
Total operating income	23,057	17,606
Cost of goods sold	(17,059)	(9,233)
R&D expenses	(23,389)	(20,303)
S&M expenses	(7,740)	(7,931)
G&A expenses	(7,935)	(6,491)
Total operating expenses	(56,132)	(43,958)
Operating result	(33,075)	(26,352)
Net financial result	(4,249)	(5,129)
Share in results of associates	(101)	-195
Income taxes	149	118
Net result	(37,276)	(31,558)

Comments

- Total operating income of EUR 23.1m, versus EUR 17.6m in H1 2020:
  - Product revenues +62% to EUR 18.5m in H1 2021
    - Cartridge sales revenues +54%
    - Instrument sales revenues doubled on the back of 189 new instrument placements, +88 year-over-year
  - Collaboration revenues EUR 2.6m (R&D services to partners): highly sensitive to timing of collaboration projects
- Higher COGS mostly driven by volume growth
- Gross margin on products 8% versus 18% in H1 2020:
  - Lower ASP of the Idylla™ SARS-CoV-2 Test
  - Lower than expected production volumes on ML2
- Operating expenses (excl. cost of sales) EUR 39.1m in H1 2021 (H1 2020: EUR 34.7m): planned acceleration & diversification of the Idylla™ test menu, both in oncology & in infectious diseases
- Net result EUR 37.3m compared to EUR 31.6m in H1 2020

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CASH POSITION EUR 85.0M AS PER END H1 2021

Condensed cash flow statement

In EUR 1,000	H1 2021	H1 2020
Result for the period	(37,276)	(31,558)
Depreciation and amortization	4,799	5,010
Impairment losses	598	721
Net financial result & other adjustments	4,636	5,411
Working capital changes	(3,282)	(525)
Taxes & interests paid	(3,227)	(3,585)
CF operating activities	(33,752)	(24,526)
CF investing activities	(2,087)	(1,028)
CF financing activities	(3,518)	(3,456)
Total net cash flow[1]	(39,357)	(29,010)
Cash and cash equivalents[2]	84,905	149,674
Financial debt	149,412	165,259

1. Excludes the effect of exchange rate differences on the cash balances held in foreign currencies
2. Including EUR 1.2m restricted cash related to KBC Lease financing

Remarks

- The net cash outflow from operating and investing activities amounted to EUR 35.8m in H1 2021 compared to EUR 25.6m in H1 2020
- Increased outflow is attributable to:
  - Increased operating loss
  - Large one-off collection of EUR 5.2m tax credit in 2020
- Cash and cash equivalents at 30 June 2021 amounted to EUR 85.0m

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New simplified, cost-efficient cartridge manufacturing concept

NEW SIMPLIFIED, COST-EFFICIENT CARTRIDGE MANUFACTURING CONCEPT UNDER EVALUATION

What and why

- Evaluation of new concept ongoing for simplified, cost-efficient Idylla™ cartridge
- In the mid-to long term, expected to accelerate reduction of cartridge manufacturing cost alongside ongoing development of new Idylla™ technology[1] for offline customization of Idylla™ cartridge
- Reduced complexity of the cartridge for infectious diseases and likely also for certain oncology assays
- Fully compatible with existing Idylla™ platform

Idylla™ standard:
40+ parts

Status & timelines

- Feasibility already externally confirmed by reputable global contract manufacturing organization
- Investment decision still subject to completion of concept design
- Ongoing and future assay menu investments in infectious diseases and oncology under review

New Idylla™:
~12 parts

1 With the support of VLAIO, Flanders Agency for Innovation and Entrepreneurship. The technology is aimed to tap into new market opportunities with customized and personalized products

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Outlook 2021

2021 OUTLOOK
CONFIRMING 40% GROWTH TARGET COMMERCIAL CARTRIDGE VOLUMES

Despite impact of the fire, Biocartis confirms its 2021 guidance at 40% growth target for commercial cartridge volumes:

- Commercial cartridge volume: Targeting a year-over-year growth of 40%, or commercial cartridge volumes of 320k.
  - *Subject to timely availability of reagent raw materials for Idylla™ cartridges*
  - *Subject to restart of the ML2 line by 2nd half of September*

- Installed base: Targeting 300-350 new Idylla™ instrument placements

- Cash position: Targeting at least EUR 50m cash position at year-end, provided timely collection of insurance claims related to the fire incident

MENU OUTLOOK

- Commercial cartridge volume, Idylla™ installed base and cash position outlook: cfr supra
- Idylla™ test menu outlook:

Oncology test menu	Infectious disease (partner) test menu	New simplified, cost-efficient CART concept
Launch Idylla™ EGFR-BRAF+ Mutation Assay: • Suspended awaiting completion of the new simplified, cost-efficient cartridge concept • Timelines will be communicated at a later stage	510(k) clearance with US FDA of SeptiCyte® RAPID on Idylla™ (Immunexpress) is pending	Concept design still to be completed
		Will impact decision to invest in manufacturing equipment and the actual development of new and existing Idylla™ assays based on this concept
Launch Idylla™ ABC (Advanced Breast Cancer) Assay in collaboration with LifeArc expected in H2 2022	Timing of Emergency Use Authorization ('EUA') submission of Idylla™ SARS-CoV-2/Flu/RSV Panel with the US FDA to be decided	Outcomes of the assessment and associated development timelines will be communicated at a later stage
Idylla™ MSI Test US FDA 510(k) pending		

FINANCIAL CALENDAR

- 10 November 2021 Q3 2021 Business Update
- 24 February 2022 2021 full year results
- 31 March 2022 Publication 2021 annual report

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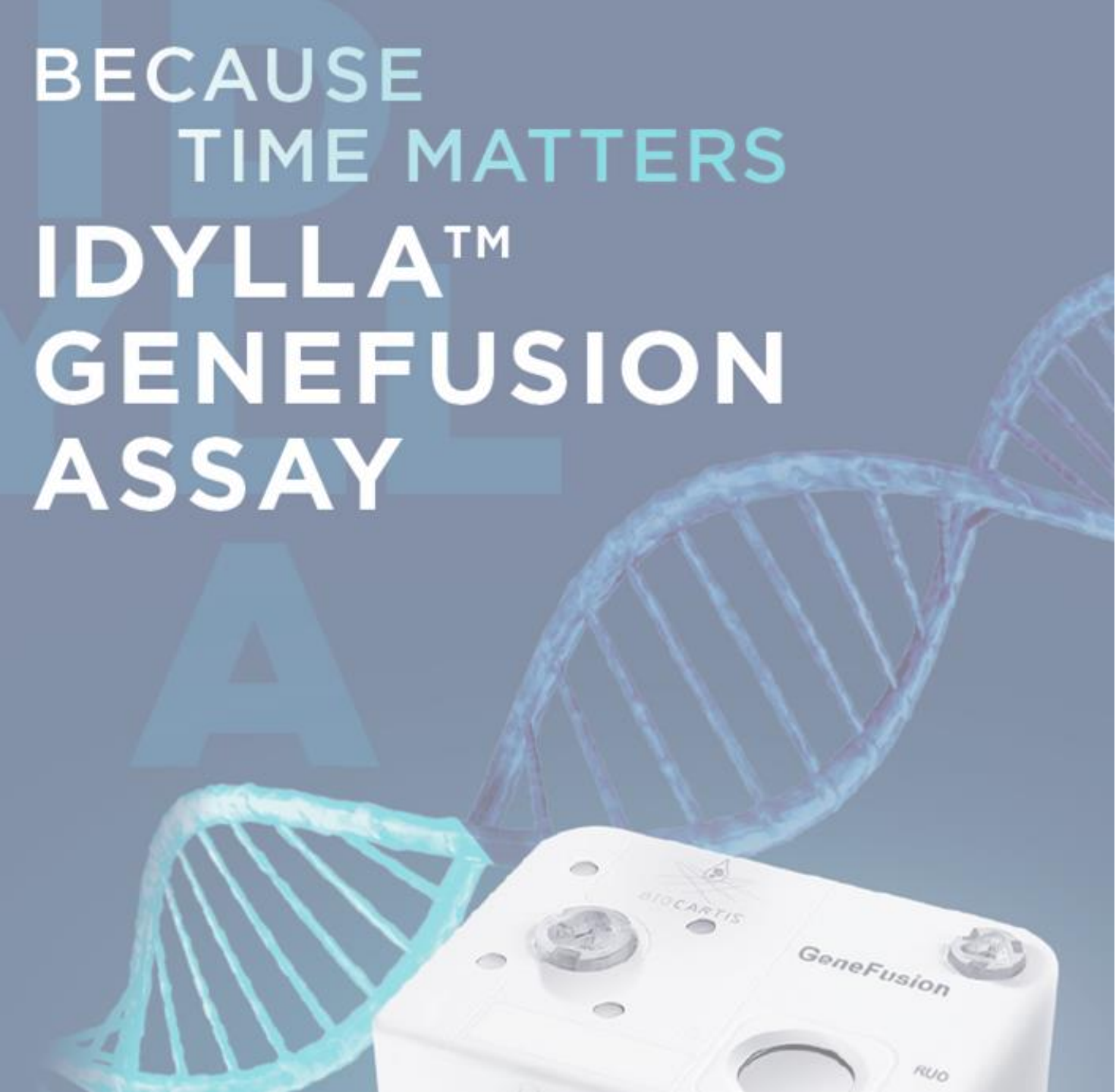
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Q&A

CONTACT

Biocartis Investor Relations
Generaal de Wittelaan 11B
2800 Mechelen
BELGIUM

tel. +32 15 63 17 29
ir@biocartis.com

www.biocartis.com