BIOCARTIS

# CORPORATE PRESENTATION

Q1 2023 | 20 APRIL 2023

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The COVID-19 pandemic impacted Biocartis' business in various respects. Initially, the pandemic deprioritized and disrupted cancer care globally, with patient access to hospitals significantly restricted throughout much of H1 2020, as well as resulting in a severe hampering of seeking new customers. Testing volumes started to recover and gradually normalized to pre-pandemic levels in the second half of 2020. In 2021, patient access to hospitals was more sporadically restricted in specific regions with a high surge of COVID-19 cases, which resulted in overburdened healthcare systems and resulted in delays to cancer diagnosis and treatment. In 2021, Biocartis was also affected by the worldwide reagent supply shortages caused by the growing and worldwide need for COVID-19 PCR testing, one of the most effective components in the fight against the pandemic. The shortfall in critical reagents constrained Biocartis' production capacity during H1 2021. As of today, Biocartis is no longer materially impacted by the aforementioned supply constraints. Biocartis may not be able to run its operations without future disruptions from a potential resurgence of COVID-19, as new variants of the virus may result in increased absence of employees in manufacturing, development and other key positions. Biocartis' suppliers and partners may be exposed to similar risks, which could lead to a disruption in the supply of components in sufficient quantity and quality required to manufacture the Idylla™ platform and Idylla™ tests, result in disruptions in ongoing development and partner activities, or adversely affect Biocartis' ability to manufacture its products and deliver them to its customers. Conversely, with the progression of the response to the pandemic COVID-19 testing using the Idylla™ SARS-COV-2 assay have declined.


# OUR MISSION

**ENABLE UNIVERSAL ACCESS TO PERSONALIZED MEDICINE FOR PATIENTS AROUND THE WORLD**

**BY MAKING MOLECULAR TESTING CONVENIENT, FAST, AND SUITABLE FOR ANY LAB.**

# KEY INVESTMENT HIGHLIGHTS

Empowering decentralized MDx for large addressable markets in oncology and infectious diseases through a broad network of high-value partnerships

Offering the validated Idylla™ platform, a fully automated, decentral qPCR platform enabling superior sensitivity, unmatched ease of use, and rapid turnaround times

Expanding product menu of highly differentiated oncology MDx by leveraging growing partnership network, as well as continued advancements in Idylla™ technology

Commercial-stage, revenue generating business with a wide, global footprint and an existing installed base of 2,000+ in oncology

Financial model with revenues growing across multiple customer channels and applications, as well as continued improvements in margins

Best-in-class management team with successful track record of execution in the global diagnostics industry; Strengthened balance sheet with amendment of existing converts, issuance of new convertible bonds and equity raise

**VALIDATED PLATFORM**

PRODUCT MENU

GROWTH STRATEGY

Q1 2023 RESULTS AND OUTLOOK

LEADERSHIP TEAM

ANNEX: FY 2022 RESULTS

# IDYLLA™ IS A MOLECULAR DIAGNOSTIC SYSTEM THAT COMBINES:

### FAST RESULTS

- ± 2 minutes hands-on time
- Short turnaround time from 85 to 180 minutes

### ACCURACY

- High sensitivity
- Highly standardized technology
- Contamination-controlled design

### ACCESSIBILITY

- Access on demand - no need for pre-processing or batching

### MULTIPLEXING CAPABILITY

- Detection of up to 51 relevant mutations in one cartridge
- Multiple genes and loci detection in one cartridge

### EASE OF USE

- Fully automated sample-to-result process
- Walk-away system (no need for any intervention during the automatic process)
- All reagents integrated in a single cartridge
- Storage and shipment at room temperature

### SAMPLE VERSATILITY

- For solid and liquid biopsy

### CONNECTIVITY

- Remote assistance, monitoring and upgrading

# IDYLLA™ OFFERS A FULLY AUTOMATED WORKFLOW WITH A WIDE VARIETY OF SAMPLE INPUTS

## The Idylla™ workflow


**Wide variety of sample input, incl. liquid biopsy**

Incl. blood/plasma/serum, swab, urine, sputum, stool, FFPE[1], Fine Needle Aspirate

## Fully integrated & multiplexed workflow


Superior sensitivity and ease-of-use, combined with sample-to-result turnaround time **4x faster** than current methods[2]



1) FFPE = Formalin Fixed, Paraffin Embedded; 2) A. Finall et al., J Clin Pathol . 2022 Jan 18;jclinpath-2021-207987. doi: 10.1136/jclinpath-2021-207987. Online ahead of print. Available here

# SCIENTIFIC VALIDATION OF THE IDYLLA™ PLATFORM

## Technology backed by evidence is driving adoption

Memorial Sloan Kettering Cancer Center

Clinical Utility and Performance of an Ultrarapid Multiplex RNA-Based Assay

For Detection of ALK, ROS1, RET, and NTRK1/2/3 Rearrangements and MET Exon 14 Skipping Alterations[1]

THE JOURNAL OF MOLECULAR DIAGNOSTICS

Memorial Sloan Kettering Cancer Center

Rapid EGFR Mutation Detection Using the Idylla™ Platform

Single-Institution Experience of 1,200 Cases Analyzed by an In-House Developed Pipeline and Comparison with Concurrent Next-Generation Sequencing Results Idylla™ Platform[2]

THE JOURNAL OF MOLECULAR DIAGNOSTICS

2022 ASCO ANNUAL MEETING

ADVANCING EQUITABLE CANCER CARE THROUGH INNOVATION

Study (China): Evaluation of the ability of Idylla™ EGFR to differentiate result of ARMS EGFR in gray area & identify rare mutation variants

Study (China): Comparison of 3 PCR-based assays for MSI detection in FFPE tissues of CRC patients

Study (Italy): Phase III study to compare bevacizumab or cetuximab plus FOLFIRI in patients with advanced CRC RAS/BRAF wild type (wt) on tumor tissue & RAS mutated (mut) in liquid biopsy

**End of 2022, 160 publications highlight the Idylla™ platform, with 42 new papers published in 2022 alone**



1) Arcila ME et al., Clinical Utility and Performance of an Ultrarapid Multiplex RNA-Based Assay for Detection of ALK, ROS1, RET, and NTRK1/2/3 Rearrangements and MET Exon 14 Skipping Alterations, published 14 April 2022, DOI: https://doi.org/10.1016/j.jmoldx.2022.03.006; 2) 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; 3) Evaluation of the ability of Idylla™ EGFR to differentiate result of ARMS EGFR in gray area and identify rare mutation variants; 4) Comparison of 3 PCR-based assays for MSI detection in FFPE in colorectal cancer; 5) Phase III study to compare bevacizumab or cetuximab plus FOLFIRI in ctRAS colorectal cancer: LIBImAb Study

# CLINICAL VALUE OF IDYLLA™ TESTS

## Proven technology, backed by evidence

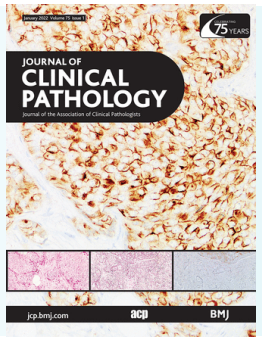
**Idylla™ testing is positioned as complementary to NGS, but can provide faster, actionable results that may result in better health outcomes and lower overall healthcare costs**

Large **UK study**[1] demonstrated value of early EGFR testing with Idylla™

96 patients tested with both Idylla™'s rapid EGFR test and Next-Generation Sequencing (NGS)

Idylla™'s rapid test was **4x faster** than NGS: 3.8 days vs. 17 days

**6% of the 96 patients died before the NGS report was available**




**18%**

of rapidly deteriorating patients were identified as having an actionable variant in EGFR that could have been treated with tyrosine kinase inhibitors (TKIs)



1) A. Finall et al., J Clin Pathol . 2022 Jan 18;jclinpath-2021-207987. doi: 10.1136/jclinpath-2021-207987. Online ahead of print. Available here

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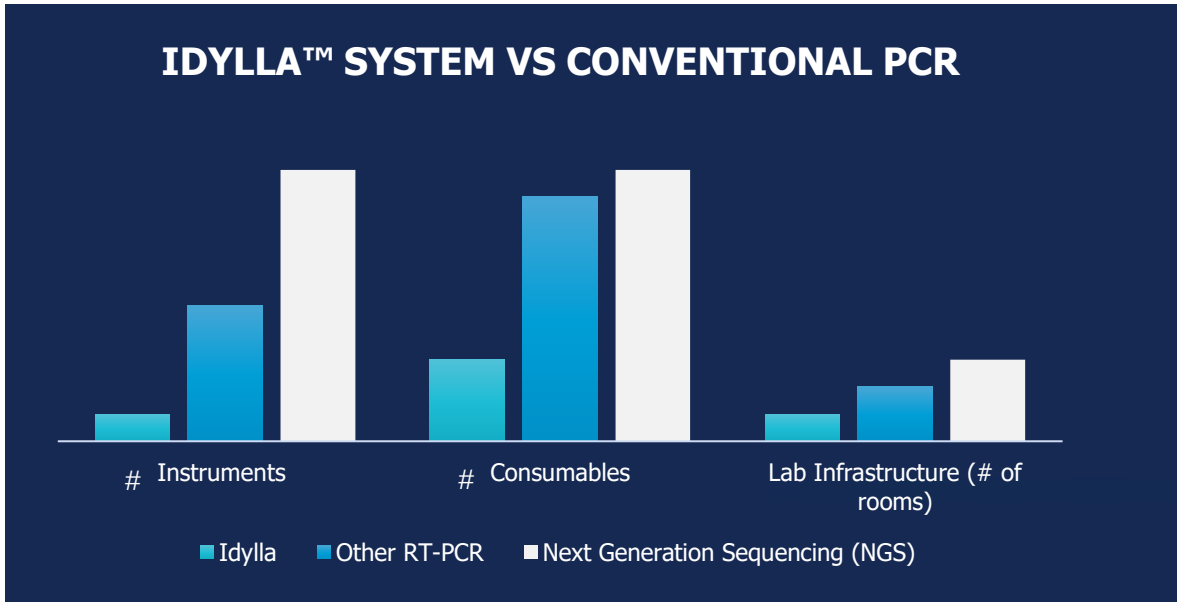
# IDYLLA™ VERSUS NGS AND OTHER PCR TESTING METHODS

## IDYLLA™ VS. OTHER TECHNOLOGIES: IT'S SIMPLY ONE AND DONE

- Lower user expenses as Idylla™ eliminates need for multiple instruments, lab space & large amounts of consumables (~60%[1] of total testing cost)
- Everything needed is in a single disposable cartridge
- Cartridge is loaded onto the Idylla™ system to enable the simultaneous detection of up to 30 molecular targets
- Fast, easy to use and is revolutionizing the way labs and hospitals work

### Idylla™ time to treatment vs other technologies[2]




1) Bryan-Garnier & Co initiating coverage report, Jan 2019; 2) Sources: Schwaederle et al. (2014) Oncologist 19, 631 – 636; Saunders et al. ESMO 2016, Abstract #; INCa 2012 Survey, Etude FLASH RAS 2014; JMD, May 2017; Scott et al. (2014) Asia Pac J Clin Oncol. 10(3):261-5.

# THE NEW IDYLLA™ FLEX TECHNOLOGY: FIRST ASSAY LAUNCHED

The new Idylla™ technology combines the **core strengths of Idylla™** (ease-of-use, speed, performance and sample versatility) with **off-line customization**

**First assay launched** > the Idylla™ IDH1-2 Mutation Assay Kit (RUO)[1]

## Lower cost & shorter time-to-market

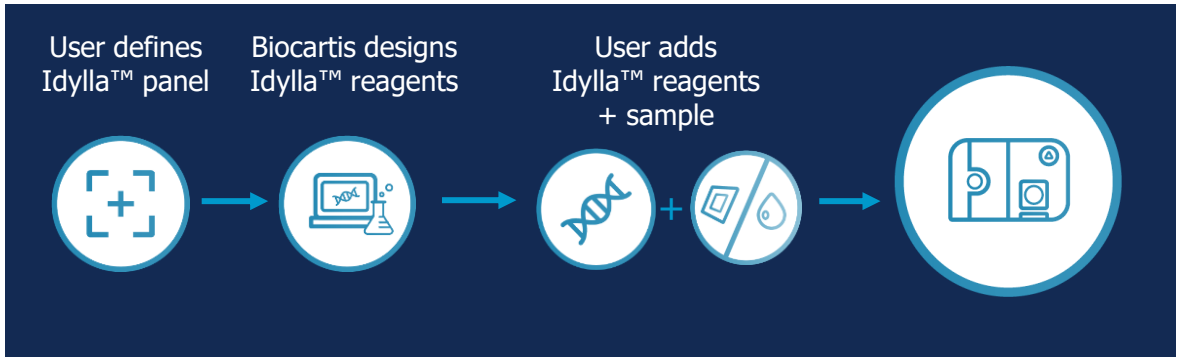
Generic cartridge and shorter development lead times

## Customized

Develop Idylla™ products faster with shorter lead times

## Liquid biopsy in molecular surveillance

Large opportunity in liquid biopsy-based testing across the entire spectrum of molecular surveillance






1) Launch among selected customers. The assay will become globally available to customers during the second half of 2023

VALIDATED PLATFORM

**PRODUCT MENU**

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# ONCOLOGY

## We serve testing needs across the entire cancer spectrum

Screening & diagnosis → Prognosis & therapy selection → Response monitoring → Recurrence monitoring

| Gene signatures | Targeted therapy | Pan-tumor | Immuno-oncology | Liquid biopsy |
|---|---|---|---|---|
| RNA gene signature tests a.o. | Tests detecting specific tumor mutations used for therapy selection in a specific cancer type | Tests for pan-tumor application | Tests supporting immuno-oncology treatments | Tests based on liquid samples |
| Often high value once validated & clinical value demonstrated | Significant pharma pipeline of new targeted therapies | For therapies based on genetics rather than location of tumor, across multiple cancer types | Many different therapies: immune checkpoint inhibitors, cell & viral therapies, vaccines,… | Use in diagnosis, prognosis & molecular surveillance (= therapy selection, response & recurrence monitoring) |
| Examples: ThyroidPrint® (GeneproDx), Merlin Assay (SkylineDx) | Examples: Zelboraf®[1] (BRAF), Tagrisso®[2] (EGFR), Erbitux®[3] (RAS), Vectibix®[4] (RAS) | Examples: Vitrakvi®[5], Keytruda®[6], Rozlytrek®[7] | Examples: partnership with Kite (Gilead), Bristol Myers-Squibb (BMS) | Generic or customized panels for molecular surveillance (incl. treatment response monitoring, MRD[8] testing & recurrence monitoring) |



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; 8) Minimal Residual Disease

# ESTABLISHED TESTING BUSINESS IN RAPIDLY GROWING MARKETS

## Idylla™ enables personalized panel building technology that brings molecular monitoring closer to the patient

### Estimated annual market opportunity in oncology across the cancer spectrum

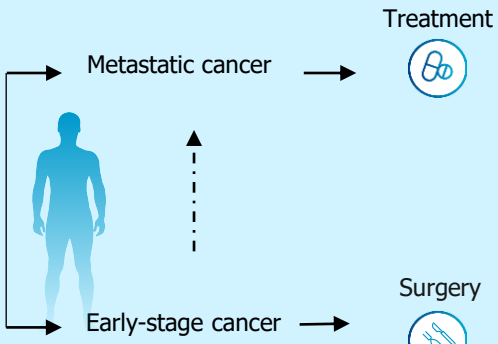
**Early detection / screening**
USD 50bn market potential

Screening & early detection

**$50B**

Canaccord estimates the market potential for early detection/screening at USD 50bn: USD 20bn for average-risk colorectal cancer; USD 30bn for multi-cancer screening

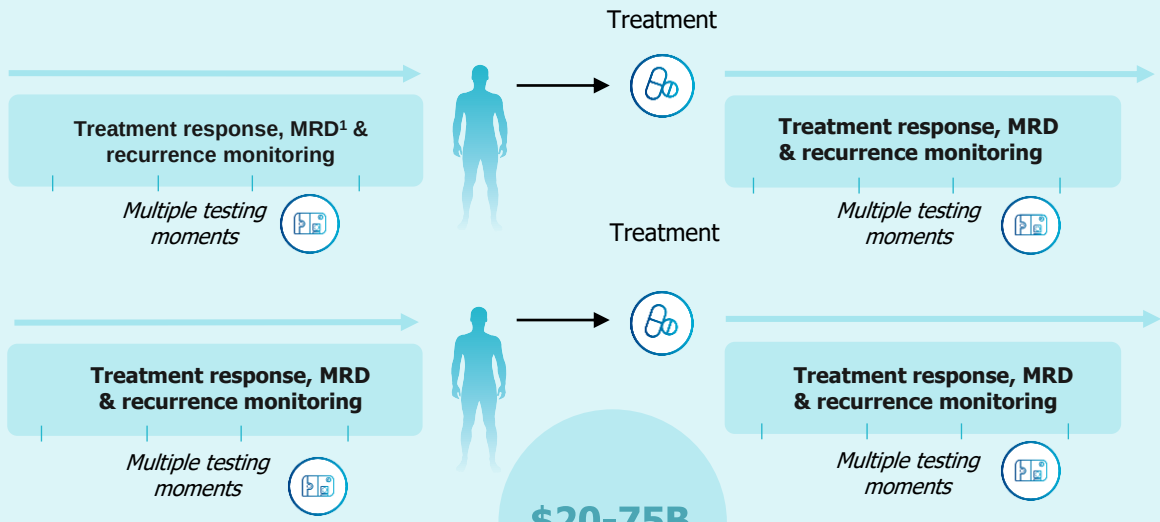
**Prognosis & treatment selection**
USD 6bn market potential




**$6B**

Canaccord and Piper-Sandler estimate the market potential of the therapy selection TAM[3] **at** USD 5-6bn and that only accounts for late-stage cancer patients

**Molecular monitoring**
USD 20-75bn market potential




>80% of all cancer patients are treated by **community oncologists**[2]

**$20-75B**

**Bring molecular monitoring testing in-house:** attractive financial model, fast time-to-report

Cowen estimates cancer recurrence monitoring & MRD market size at USD 20-75bn in the US alone, based on ~ 1.8m new cancer diagnoses every year to be followed up on for no residual cancer (with MRD testing) once treated. Additionally, there are ~17m cancer survivors in the US needing monitoring for recurrence, especially for the first 5 years after treatment success

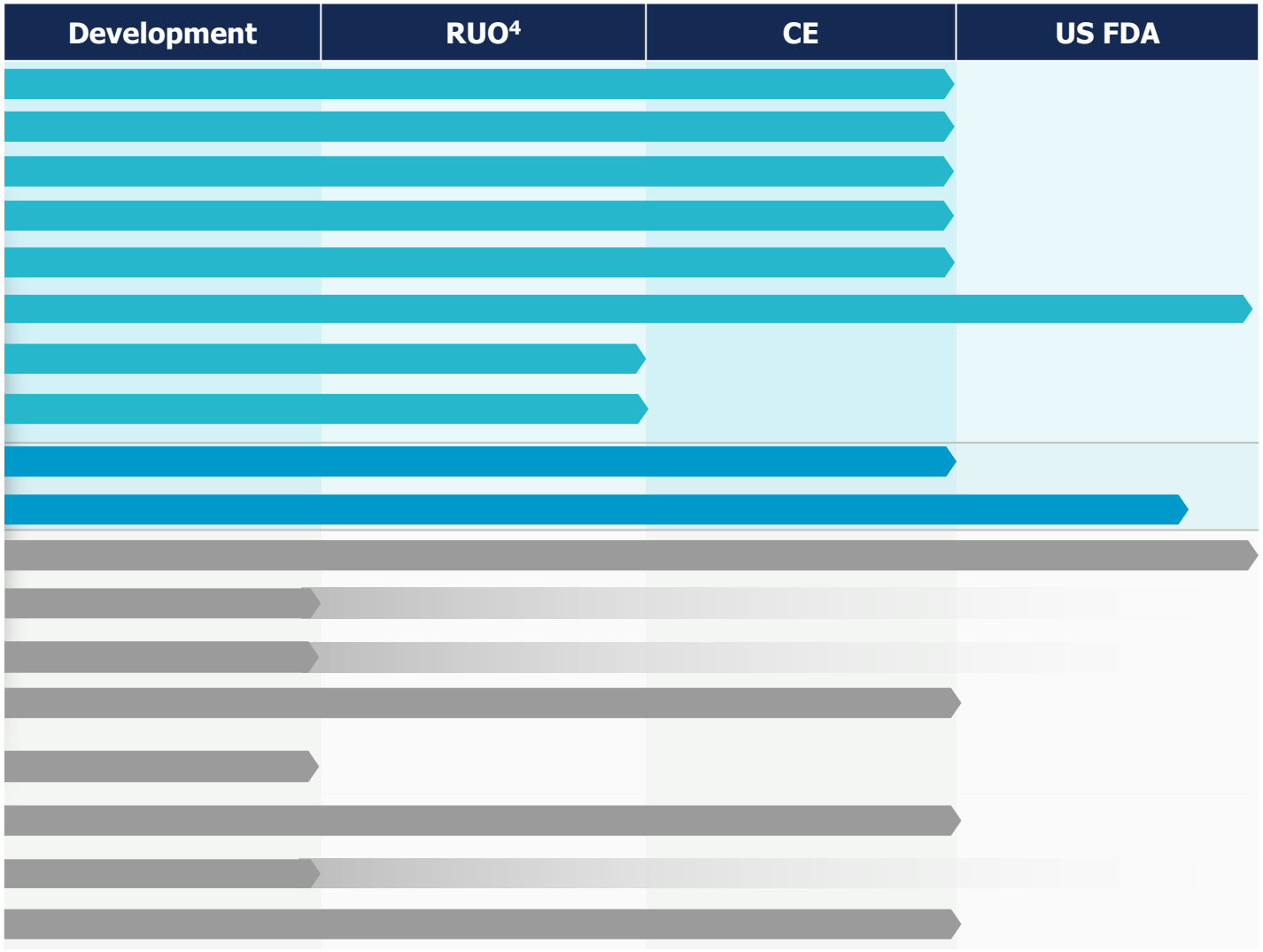


1) MRD = Minimal Residual Disease; 2) Source: Okon 2008, Let oncologists make the medical decisions, Community Oncology; 3) TAM = Total Addressable Market. Numbers on market potential are sourced from Canaccord, 07 JAN 22 — Industry documents on included industries/countries/companies: Welcome to update city: January conference week preview for our Diagnostics and Tools coverage; Piper Sandler: 05 JAN 22 — Industry documents on included industries/countries/companies: Assuming Coverage: AKYA, CTKB, HSKA, ILMN, NTRA, OCX, PACB; Cowen: 'The Liquid Biopsy report: Early Detection of a Huge Opportunity', 18 Sept 2020

# EXTENSIVE PIPELINE OF TESTS ON MARKET

## Focus on oncology, upside from infectious disease in acute settings

| | Indication | Product |
|---|---|---|
| Biocartis tests | Oncology tests | Idylla™ BRAF |
| | | Idylla™ EGFR |
| | | Idylla™ KRAS |
| | | Idylla™ NRAS-BRAF |
| | | Idylla™ GeneFusion Panel |
| | | Idylla™ MSI 510(k) |
| | | Idylla™ ctBRAF/ctKRAS/ctEGFR/ctNRAS3[1] |
| | | Idylla™ IDH1-2 Mutation Assay Kit |
| | Infectious disease tests | Idylla™ SARS-CoV-2/Flu/RSV Panel |
| | | Idylla™ SARS-CoV-2 Test[2] |
| Partner tests | Sepsis | SeptiCyte® RAPID (PLUS) (Immunexpress)[3] |
| | Critical illnesses | Endpoint Health Test (Endpoint Health) |
| | Breast cancer | Idylla™ PIK3CA-AKT1 Mutation Assay (LifeArc[4]) |
| | | APIS Breast Cancer Subtyping (kit version APIS Assay Technologies[5]) |
| | Thyroid cancer | ThyroidPrint® (GeneproDx) |
| | Melanoma | Idylla™ Merlin (kit version SkylineDx[6]) |
| | | Idylla™ Merlin CP-GEP Assay (SkylineDx) |
| | Liver (HCC[7]) | HepatoPredict (kit version Ophiomics) |






1) Idylla™ ctNRAS3 is the Idylla™ ctNRAS-BRAF-EGFR-S492R Mutation Assay 2) In the US, distribution of the Idylla™ SARS-CoV-2 Test was initiated in Q3 2020 per US FDA Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), May 2020, Section IV.C. Commercial Manufacturer Development and Distribution of Diagnostic Tests Prior to EUA Submission; 3) Under the partnership with Immunexpress, Inc, US FDA 510(k) clearance for the SeptiCyte® RAPID was obtained in December 2021 4) RUO (Research Use Only) product development in collaboration with LifeArc 5) APIS will lead the development of the Breast Cancer Subtyping test on Idylla™, while Biocartis will lead the commercialization through its growing Idylla™ network. The kit is currently offered by APIS in the UK and will be broadly commercialized by Biocartis ahead of the Idylla™ version of the assay becoming available. 6) An Idylla™ version of the Merlin test is in development 7) Hepatocellular Carcinoma

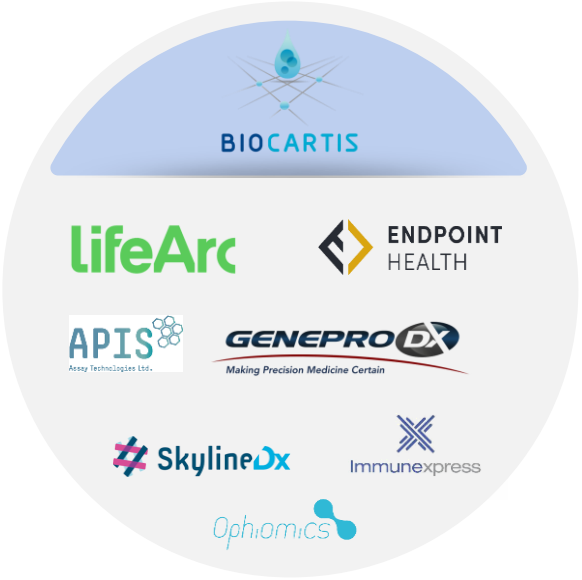
# REVENUE THROUGH COLLABORATIONS WITH A BROAD NETWORK OF PARTNERS TO DEVELOP NOVEL TESTS ON IDYLLA™

## High-value, novel test content & development partners

**For partner**:
Validated 3rd parties' access to Idylla™ platform

Accelerated global roll-out of content

Focus on test content and improved cost structures




**For Biocartis**: add proprietary 3rd party content on Idylla™ platform, expand menu appealing to larger audience, attractive margin profile

## Leading pharma partners incl. for CDx[1] test development

**For partner**:
Fast pinpointing of therapy selection for eligible patients

Fast turnaround time further differentiates therapy and reduces competition

High sensitivity identifies more patients


**For Biocartis**: dedicated partner, faster commercial adoption & global registrations, access to attractive pipelines, higher market shares



1) A companion diagnostic (CDx) is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product

# LEVERAGING ESTABLISHED BIOMARKERS WITH NOVEL PARTNER CONTENT IN BROAD ONCOLOGY PROGRAM

| | On-market tests | | | Tests under development | | |
|---|---|---|---|---|---|---|
| | Melanoma | Colorectal cancer (CRC) | Lung cancer | Thyroid cancer | Breast | Brain |
| Indication | Deadliest form of skin cancer<br>Prognosis: depends on disease stage<br>BRAF: BRAF testing has become a common practice in the diagnostic process of advanced melanoma patients<br>Treatment: multiple effective 1st-line treatment options for patients with advanced BRAF-mutated melanoma | 3rd most common cancer<br>4th leading cause of cancer-deaths worldwide<br>RAS mutations in ~50% | EGFR mutations: 2nd most common cancer driver mutation in NSCLC[2]<br>~50% of NSCLC patients have tumor mutations that could inform targeted treatment, but many are not tested<br>Key issue: insufficient/low quality samples<br>Sample failure results in high rejection rate for NGS testing | ~1.2 million thyroid cytology evaluations are reported as indeterminate[4] each year<br>Surgical intervention or removal of thyroid is often unnecessary | Breast: most common cancer in women worldwide.<br>The presence or absence of hormone receptors and markers in breast cancer cells can guide the selection of appropriate treatment options | Brain: biggest cancer killer of children & adults under 40[6] |
| Partner | SkylineDx | Bristol-Myers Squibb | AstraZeneca | GENEPRODX | LifeArc[7]<br>APIS[8] | |
| Testing / need | Idylla™ Merlin:<br>• Reduce unnecessary lymph node surgeries<br>• Identify patients at low risk of nodal metastasis[1] | Companion Diagnostic: CDx of Idylla™ MSI Test for immuno-oncology therapies (under development) | Collaboration for rapid & easy access to EGFR testing products[3]<br>Extended collaboration to a companion diagnostic test for Tagrisso® (June 2022) | Prognosis: ThyroidPrint® on Idylla™<br>• qRT-PCR based mRNA-expression classifier test<br>• Helps determine indeterminate cytology result as benign or malignant[5] | • RUO product development of Idylla™ PIK3CA-AKT1 Mutation Assay with LifeArc<br>• Development of APIS' Breast Cancer Subtyping Assay with APIS | |



1) Bellomo et al. JCO Precision Oncology, https://ascopubs.org/doi/10.1200/PO.19.00206; 2) Non-Small Cell Lung Cancer; 3) More info here; 4) S. Vargas-Salas et al., Genetic testing for indeterminate thyroid cytology: review and meta-analysis, 2018, Endocrine-Related Cancer, https://erc.bioscientifica.com/: 5) More info here; 6 Source: Brain Tumor Charity, see here; 7) RUO product development of the Idylla™ PIK3CA-AKT1 Mutation Assay with LifeArc; 8) The APIS Breast Cancer Subtyping Kit is available as a manual kit for in vitro diagnostic use, mainly addressing centralized expert laboratories. The kit is currently offered by APIS in the UK and will be broadly commercialized by Biocartis ahead of the Idylla™ version of the assay becoming available

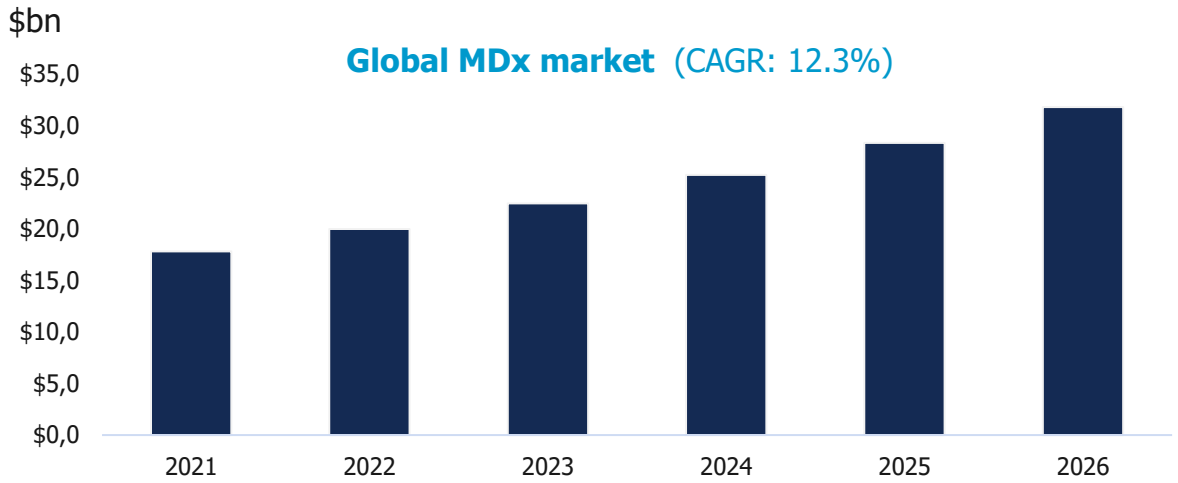
# ESTABLISHED TESTING BUSINESS IN RAPIDLY GROWING MARKETS

## Molecular diagnostics (MDx) & oncology markets

### GLOBAL $MD_X$ MARKET

Expected to reach USD 31.8bn by 2026 from USD17.8bn in 2021, 12.3% CAGR[1]

Oncology fastest growing sub-segment with a 5-year CAGR of 12.6%[2]




### ONCOLOGY

Large, global customer base (in pathology labs) with opportunity to unlock new customer segments. Current on-market test menu serves a market of 5 million tests per annum[3], doubling to 10 million with assays in the pipeline. Market potential:

- Treatment selection USD 6bn[4]
- Recurrence monitoring USD 20-75bn+[5]
- Early detection (screening) USD 50bn[4]

Ongoing expansion of oncology test menu through novel gene signature tests and liquid biopsy based personalized patient monitoring




1) MarketsandMarkets, Molecular Diagnostics Market worth $31.8 billion by 2026; 2) IMARC Group, Oncology Molecular Diagnostics Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2021-2026;
3) Company sources on Total Addressable Market (TAM) calculations 4) Immuno Oncology Assay Market Size and Growth Analysis (alliedmarketresearch.com); 5) Cowen: 'The Liquid Biopsy report: Early Detection of a Huge Opportunity', 18 Sept 2020

# ESTABLISHED TESTING BUSINESS IN RAPIDLY GROWING MARKETS

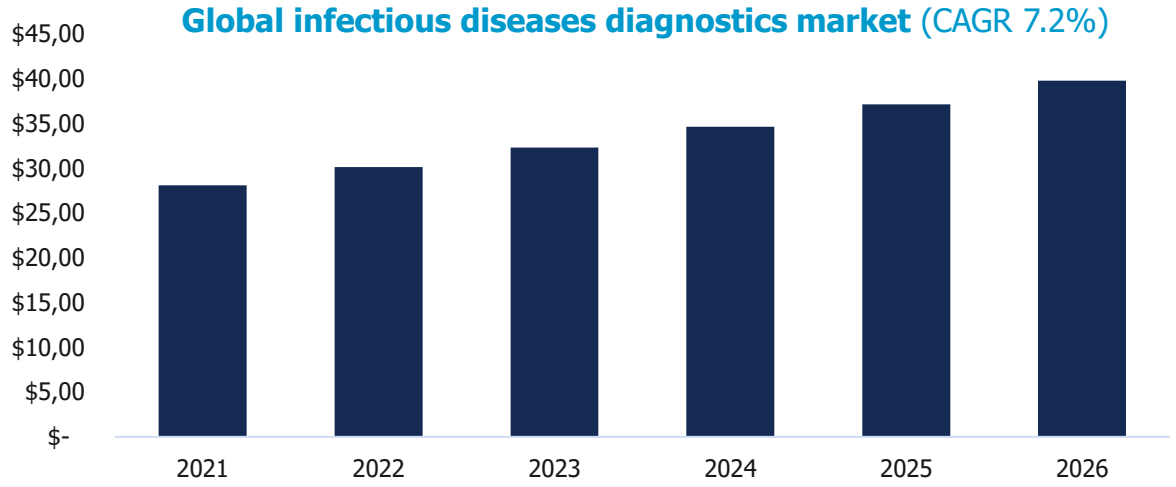
## Infectious diseases & sepsis

### INFECTIOUS DISEASES

The global infectious diseases diagnostics market is projected to grow from USD 28.1bn in 2021 to USD 39.8bn in 2026 at a CAGR of 7.2%[1]

Proven market access & expanding into infectious diseases

Broadening test menu based on COVID-19 and sepsis testing to support patient journey in hospital ICU. Longer term opportunity based on unique multiplexing-related capabilities of Idylla™ (syndromic panels)




### SEPSIS

According to global data, sepsis affects 49 million people and was linked to approximately 11 million deaths

According to estimates from the CDC, in the US:

- At least 1.7 million adults develop sepsis
- Nearly 270,000 Americans die as a result of sepsis
- 1 in 3 patients who dies in a hospital has sepsis

Annual healthcare costs estimated at ~ USD 60bn in the US alone[2]


Annual healthcare cost due to sepsis in the US



1 Markets and Markets 2 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

# BUILDING ON A CORE INFECTIOUS DISEASE TEST MENU

## Other ID tests to develop with the appropriate partners

**Idylla™ currently offers tests supporting sepsis, SARS-CoV-2 as well as respiratory panel testing for SARS-CoV-2 Influenza A/B and RSV nucleic acids in one single cartridge focused on the acute settings, when rapid diagnostic information is needed most**

| | |
|---|---|
| SeptiCyte® RAPID[1] on Idylla™ (CE-IVD, 510(k)) | A fully automated, rapid host-response test that distinguishes sepsis from infection negative systemic inflammation in patients suspected of sepsis, providing actionable results in approx. 1 hour, enabling physicians to optimize patient management decisions. US FDA 510(k) clearance (led by Immunexpress) |
| Idylla™ SARS-CoV-2 Test (CE-IVD) | A fully automated test intended for qualitative detection of SARS-CoV-2 RNA in nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider. Results within 90 minutes, < 2 minutes hands on time |
| SARS-CoV-2/Flu/RSV Panel (CE-IVD) | A fully automated test that detects, in 1 single cartridge, SARS-CoV-2, Flu A/B and RSV nucleic acids. Results in approx. 90 minutes, < 2 minutes hands on time. 98% overall concordance compared with other currently used methods |
| Idylla™ Endpoint Health Test | A fully automated test that aims to enable biomarker-based therapeutic decisions in patients with critical illnesses, such as sepsis (under development, collaboration with Endpoint Health) |



1) Launch of new SeptiCyte RAPID® EDTA (CE-IVD) blood compatible cartridges by Biocartis' partner Immunexpress on 23 August 2022. In addition to blood samples collected in PAXgene blood RNA tubes (per the manufacturer's instructions), this test is now also able to process undiluted EDTA blood samples which are commonly used for most hematology procedures, with results available in about one hour

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# IDYLLA™: MULTI-PRONGED APPROACH TO ADOPTION

## Faster local testing drives quicker treatment and may lower healthcare costs

| | |
|---|---|
| **Large hospitals<br>Reference labs<br>Cancer centers** | Fast turnaround-time<br>Complementary to Next Generation Seq.<br>Directly actionable |
| **Regional hospital labs & specialized group practices** | Decentralized<br>Ease-of-use<br>No technical lab skills required |
| **Community setting hospitals<br>& medical offices** | Fully automated<br>Allows local MDx testing<br>Sample retention |


**Idylla™ provides strong economic incentive for customers to retain MDx testing in-house**

# GLOBAL COMMERCIAL PRESENCE

## Growing global market with a geographical footprint in +70 countries

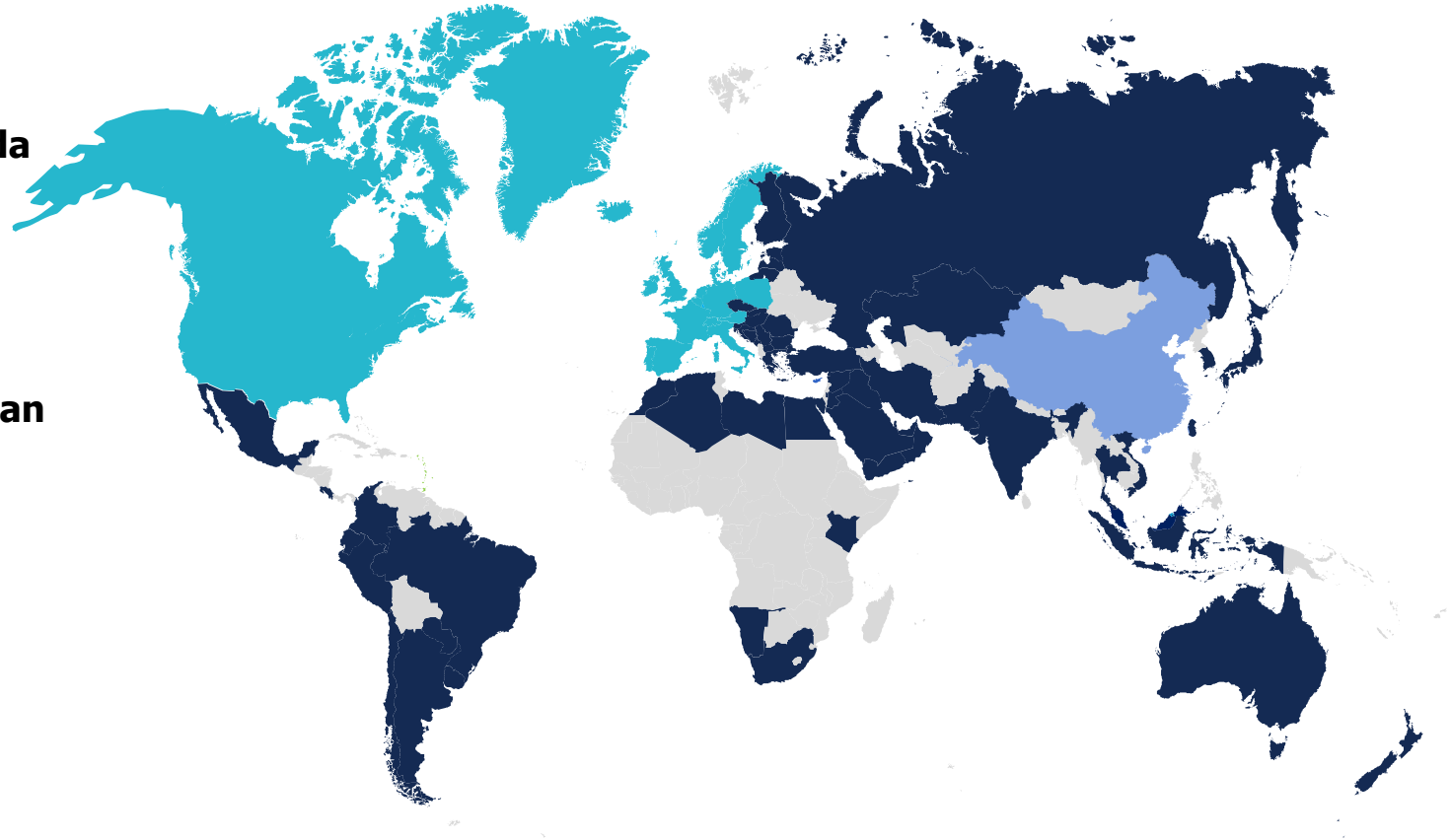
Direct sales force covering **Europe** (30), **US** and **Canada** (25)

Joint venture in **China** with Wondfo

Distribution agreement with Nichirei Biosciences for **Japan**

**Pharma collaborations:** Merck KGaA (Darmstadt, Germany), Amgen, AstraZeneca, BMS and Kite/Gilead

**Content partnerships:** Immunexpress, GeneproDx, Endpoint Health, SkylineDx, Ophiomics, APIS Assay Technologies



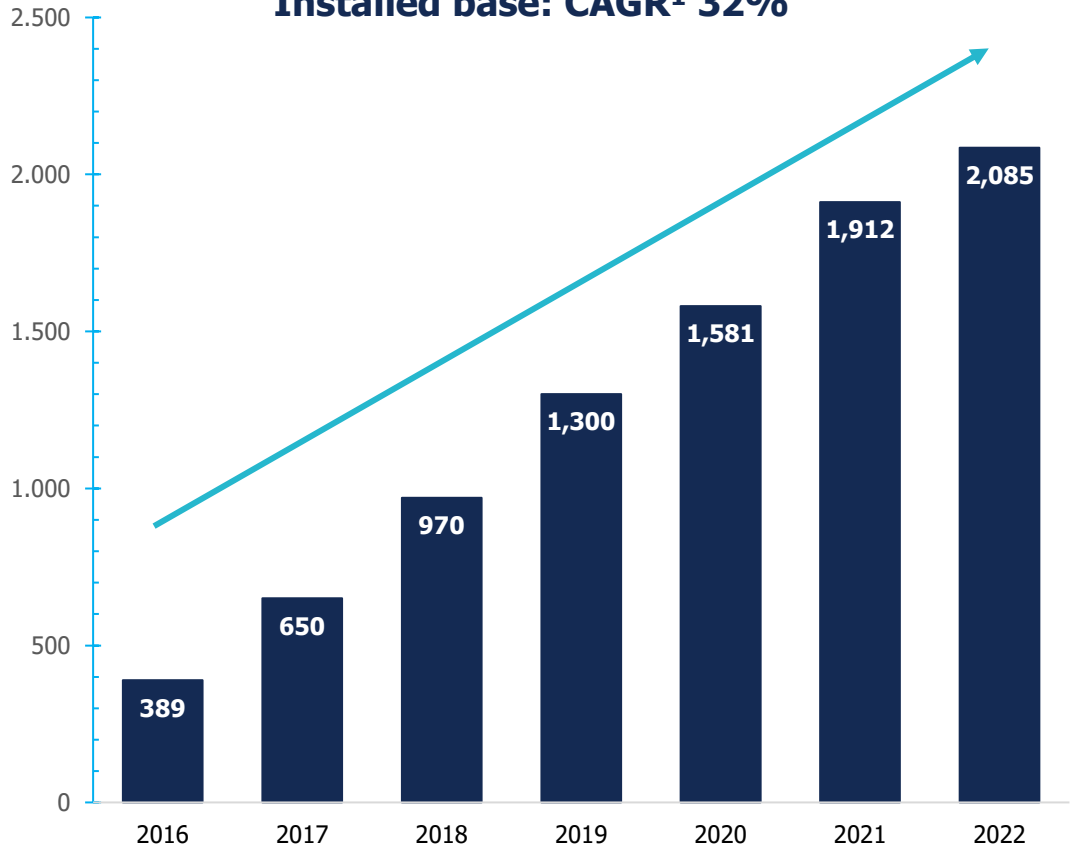
Commercialization through direct sales force

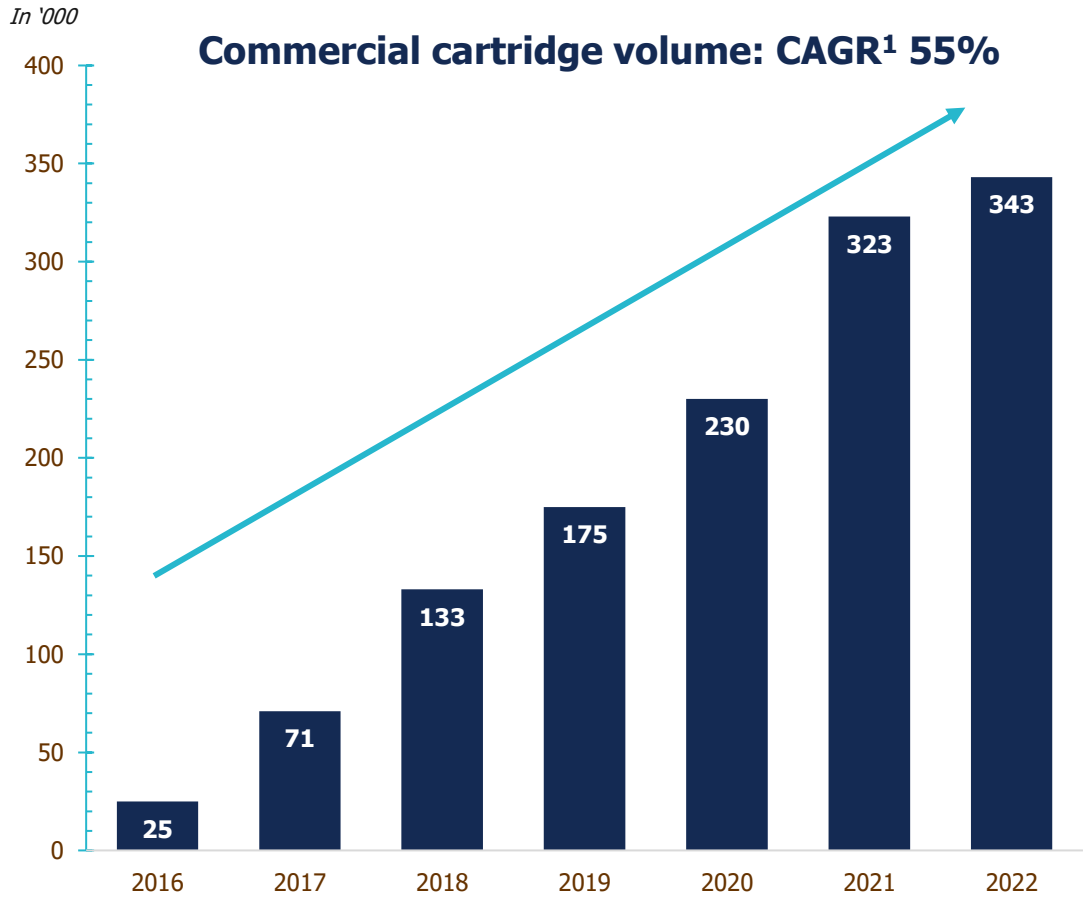
Commercialization through distribution partners

Commercialization through joint venture

# CONSISTENT BUILD-OUT OF INSTALLED BASE AND CARTRIDGE VOLUME

## Towards critical mass



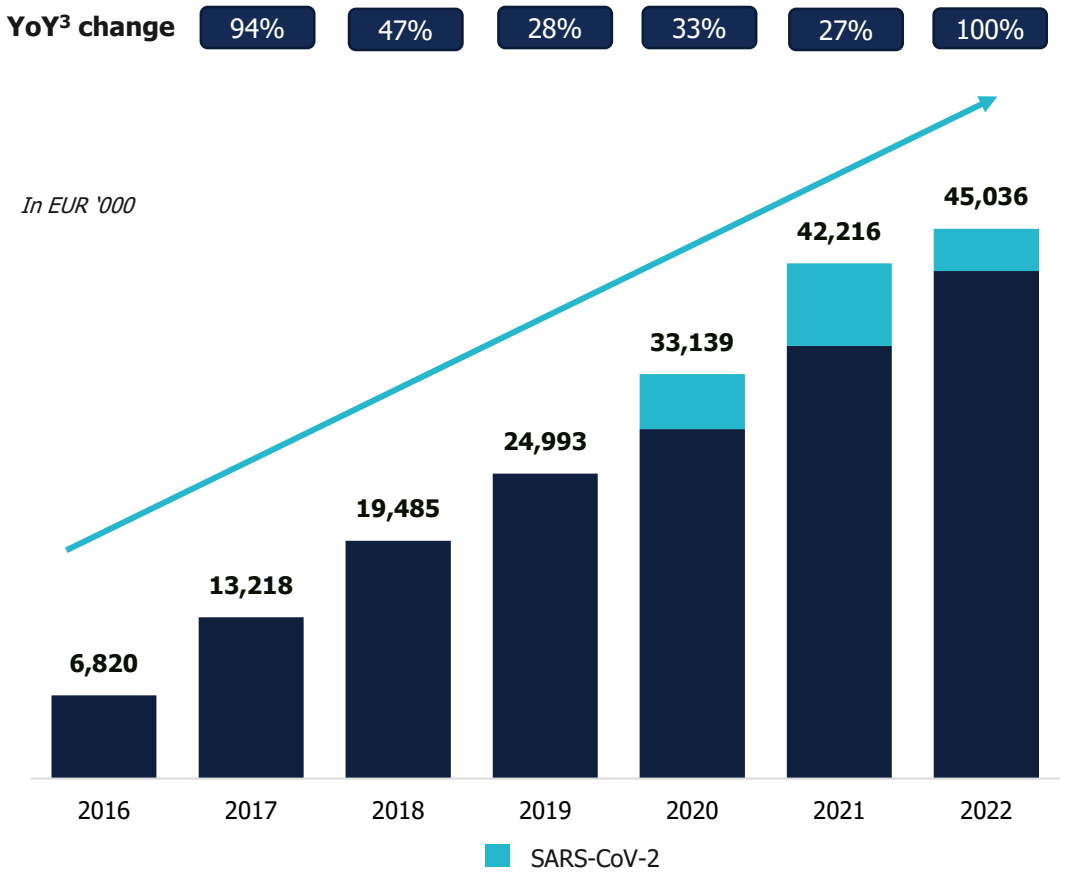

**More than 1 million cartridges sold and global installed base of 2,142 instruments placed end Q1 2023**


1) CAGR = Compound Annual Growth Rate

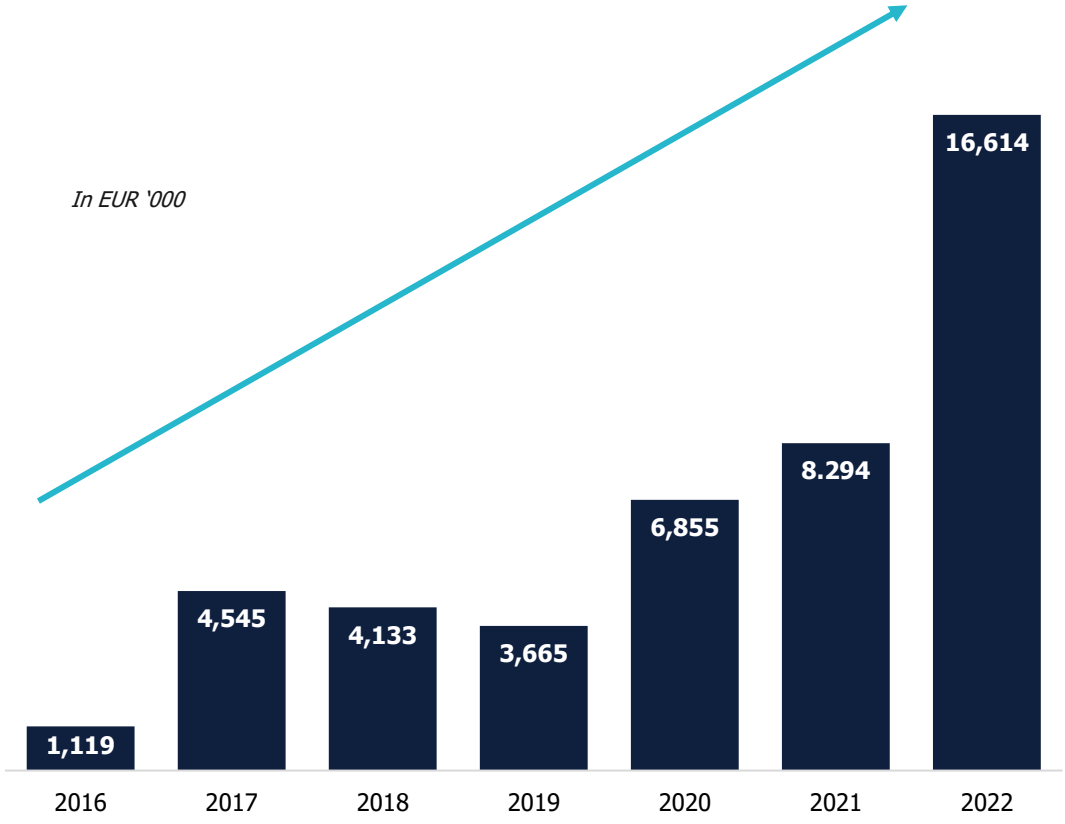
# SCALABLE STRONG PRODUCT REVENUE GROWTH

## Gross profit on product sales doubled in 2022

### Product revenues[1]: CAGR[2] 37% (35% excl. SARS-CoV-2)




### Gross profit on product revenues[4] : CAGR 57%






Note: 2021E figures are unaudited.
1) Includes total revenues from product sales, system servicing and collaborations; 2) CAGR = Compound Annual Growth Rate; 3) Year-over-Year; 4) Gross profit on revenues from product and system service

# SCALABLE BUSINESS MODEL DRIVING STRONG GROWTH AND HIGHER MARGINS

## Key revenue and margin drivers

### Revenue growth drivers

- Favorable shift in geographic mix through regulatory approvals and registrations
- Favorable shift in product mix and volume growth through menu expansion
    - Higher ASP[4] from novel tests with high clinical value

### Margin growth drivers

- Continued scaling of ML2 lowers manufacturing costs
- Continued improvements in operational efficiency to lower fixed costs

## Key forward-looking guidance

**2023 Product Revenue[1]**
EUR 55m – EUR 60m

**2023 Product Gross Margin[2]**
40% – 45%

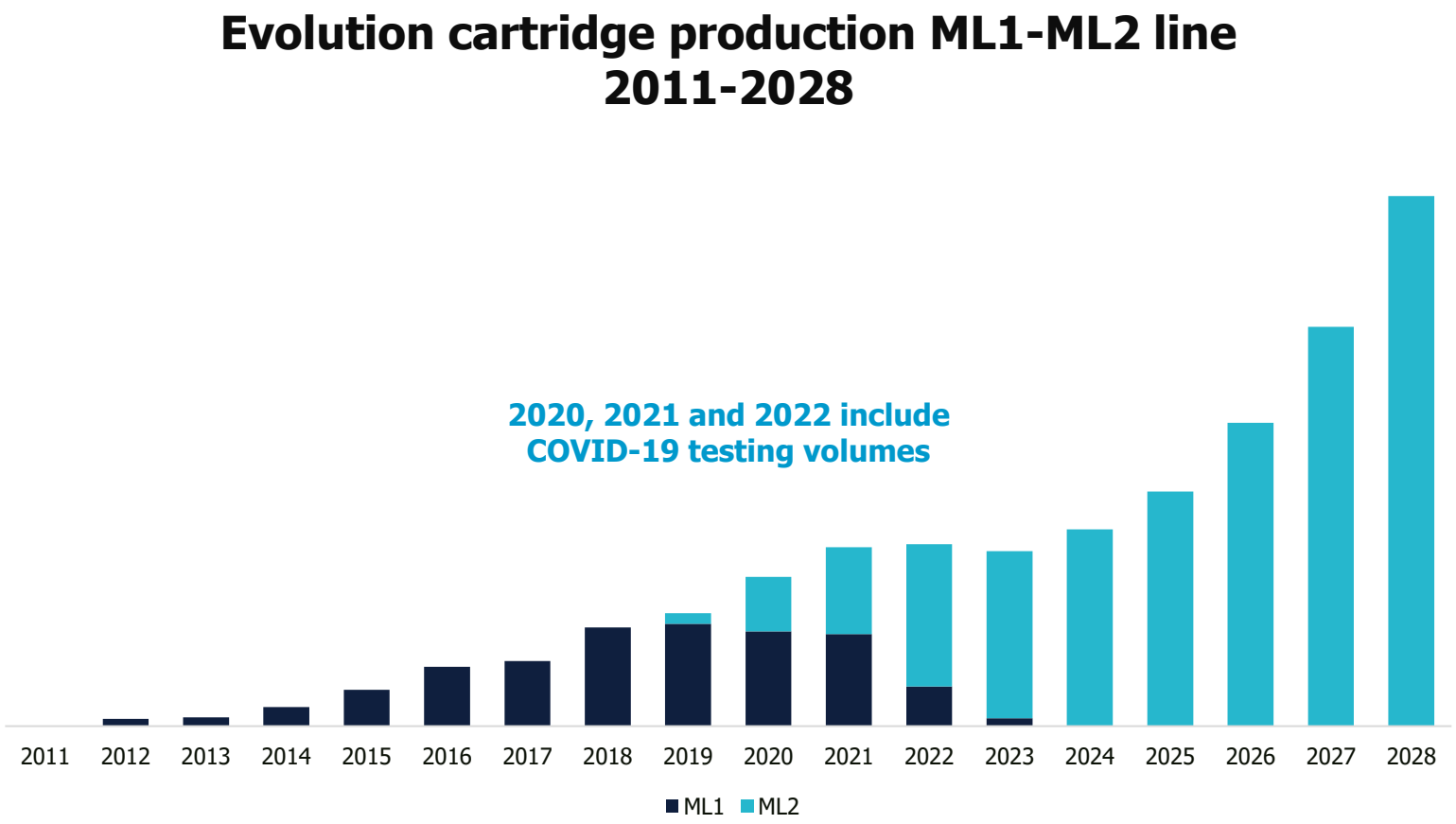
**2023 EBITDA[3]**
(EUR 25m) – (EUR 28m)

**Long-term revenue growth**
30% – 40%

**Long-term product gross margin**
50% – 60%

1) Including revenues from instrument servicing; 2) Excluding revenues from instrument servicing; 3) Earnings before interest, taxes, depreciation and amortization; 4) ASP = Average Sales Price

# INCREASING VOLUMES ON ML2 MANUFACTURING LINE DRIVE COST REDUCTION




- Two manufacturing lines located in Mechelen (ML1 and ML2)
- ML1 line has been essential to **support growth** during ML2 build-out and learning curve but is end-of-life and was **decommissioned** in January of 2023
- ML2: **automated** high-throughput cartridge manufacturing with **capacity of > 1.2 million** cartridges p.a.
- Fully automated assembly workstations and multi-cavity molds for plastic parts supplied by CMO
- Starting 2023, **more than 90% of commercial cartridge production** will have been **transferred to ML2 line**, allowing to further grow the gross margin

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# STRENGHTENED US ORIENTATION ON ORGANIZATIONAL LEVEL

**ORGANIZATIONAL CHANGES:**

- Announcement 22 February 2023:
  - Appointment of **Bryan Dechairo** as a **new independent Board member** & member of the Audit Committee of the Company
  - + 25 years of experience developing and commercializing revenue generating clinical innovations that improve patient lives, proven track record of scaling businesses into profitable fortune 50 public companies

- Announcement 11 April 2023:
  - Appointment of **Roger Moody** as **Chief Executive Officer**[1] effective 24 April 2023
  - + 30 years of experience in the technology & healthcare industry, brings a unique combination of deep knowledge of molecular diagnostics in the US and a proven track record of scaling up public companies



1) Roger Moody will also become a member of the Board of Directors, subject to the approval by the Company's general shareholders' meeting

# KEY MESSAGES Q1 2023 RESULTS

**Product revenue**

- **Product related revenue EUR 10.8m** (+2% year-on-year) incl. EUR 8.5m cartridge revenue from 75k cartridges sold and EUR 2.2m from instrument sales, rentals and servicing:
  - Oncology cartridge revenue EUR 8m (+16% year-on-year)
  - Contribution from Idylla™ SARS-CoV-2 sales -53%, EUR 0.5m in Q1 2023 (vs EUR 1.1m in Q1 '22)
  - ASP[1] EUR 120 in oncology and EUR 113 overall, vs EUR 114 and EUR 101 in Q1 2022, resp.
  - EUR 2.2m revenue from instruments, 57 net new instruments year-to-date
  - Total installed base 2,142 instruments end Q1 2023

**Gross profit product sales[2]**

- **Gross profit on product sales[2] EUR 3.8m** (Q3 2022: EUR 3.5m)
- Gross margin **37%** (full year 2022: 34%)
- Last quarter including production on ML1, now discontinued

**EBITDA[3]**

- EBITDA[3] of **EUR -8.4m**, an improvement of EUR 1.1m or **12%** year-on-year
- Cash position end Q1 2023 amounted **EUR 43.9m**

**Partnerships**

- **APIS:** development of APIS' Breast Cancer Subtyping assay on Idylla™ and commercialization by Biocartis of the kit version (CE-IVD) ahead of the Idylla™ version

**Product menu**

- **Idylla™ IDH1-2 Mutation Assay Kit (RUO[4])** launched among selected customers; first test developed with the new Idylla™ FLEX technology
- **Idylla™ MSI Test 510(k) clearance** by the US FDA



1) ASP = Average Sales Price; 2) Excluding instrument servicing; 3) Earnings before interest and taxes; 4) Research Use Only, not for use in diagnostic procedures

# COMPANY OUTLOOK 2023 REITERATED

- **Product related revenues[1] of between EUR 55m and EUR 60m,** reflecting growth of 25%-35% when excluding sales of SARS-CoV-2 tests that are expected to further decrease
- A **gross margin on product sales[2]** of **between 40% and 45%**
- **EBITDA[3] of between EUR -25m and EUR -28m,** an improvement of between EUR 8.5m to EUR 11.5m

*Note: These projections are based on foreign currency exchange rates applicable on 23 February 2022, the date on which the 2022 results and 2023 outlook were published*



1) Including revenue from instrument servicing; 2) Excluding revenue from instrument servicing; 3) Earnings before interest, taxes, depreciation and amortization

# MENU OUTLOOK 2023

- **Idylla™ MSI Test:** 510(k) clearance by the US FDA[1]
  - **Septicyte® RAPID on Idylla™ EDTA**: submission of 510(k) to the US FDA by Immunexpress
  - **Idylla™ IDH1-2 Mutation Assay Kit (RUO**): Global availability to all customers
  - **Idylla™ PIK3CA-AKT1 Mutation Assay**: RUO product development in collaboration with LifeArc
  - **Idylla™ Merlin CP-GEP Assay**: RUO launch in collaboration with SkylineDx
  - **Idylla™ ThyroidPrint Assay**: RUO launch in collaboration with GeneproDx

*Note: The timing of the planned launch of partner tests remains subject to changes imposed by the relevant partners*

1) 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). 510(k) (premarket notification) to FDA is required at least 90 days before marketing unless the device is exempt from 510(k) requirements. Source: https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances, last consulted on 28 Feb 2022

# FINANCIAL CALENDAR 2023

- 12 May 2023 — Annual General Shareholders' Meeting Biocartis Group NV
- 31 August 2023 — H1 2023 results
- 9 November 2023 — Q3 2023 Business Update

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# LEADERSHIP TEAM

## Management team

### HERMAN VERRELST[1]

Chief Executive Officer, Director until 24 April 2023

Seasoned executive and serial entrepreneur with proven international commercial track record in molecular diagnostics

### ROGER MOODY[2]

Chief Executive Officer, Director as from 24 April 2023

+ 30 years of experience in the technology & healthcare industry, brings a unique combination of deep knowledge of molecular diagnostics in the US and a proven track record of scaling up public companies

### JEAN-MARC ROELANDT

Chief Financial Officer

Senior executive with an established track record of + 25 years as Chief Financial Officer in globally active publicly listed companies, including in the field of diagnostics

### PIET HOUWEN

Chief Operating Officer

Strong track record in manufacturing, process engineering, project & people management with more than 25 years in various operational and general management roles including in the life sciences industry

### DAVID DEJANS

Global Head of Sales

Accomplished leader with more than 15 years experience in managing commercial organizations in the field of molecular biology and immuno-assays

### MADHU GHOSH

Head of Strategic Partnering & Business Development

Experienced leader in alliance management and product development for more than 20 years in molecular diagnostics and clinical assay development

### BENOIT DEVOGELAERE, PHD

Chief Technology Officer

Experienced molecular diagnostics professional with proven track record in diagnostic assay development and product innovation, started his career in the pharmaceutical sector in the area of virology



1) Herman Verrelst will move into the new position of Executive Chairman of the Board of Directors as from 24 April 2023
2) Roger Moody will also become a member of the Board of Directors, subject to the approval by the Company's general shareholders' meeting

# LEADERSHIP TEAM

## Board of directors

### HERMAN VERRELST[1]

Executive Chairman

Seasoned executive and serial entrepreneur with proven international commercial track record in molecular diagnostics

### ROGER MOODY[2]

Chief Executive Officer

+ 30 years of experience in the technology & healthcare industry, brings a unique combination of deep knowledge of molecular diagnostics in the US and a proven track record of scaling up public companies

### CHRISTIAN REINAUDO[3]

Lead Independent Director

Joined the Company's board of directors in May 2018
International executive with strong track-record in different industries incl. leading ehealth & digital imaging

### ANN-CHRISTINE SUNDELL

Independent Director

Has more than 30 years of experience in the diagnostics and life science sector, where she held various global senior positions

### LUC GIJSENS

Independent Director

International executive with deep knowledge in a wide range of areas in finance and capital markets, asset management, corporate and investment banking in Belgium and abroad

### BRYAN DECHAIRO

Independent Director

Seasoned US executive with more than 25 years of experience developing and commercializing revenue generating clinical innovations that improve patient lives and a proven track record of scaling businesses into profitable fortune 50 public companies

### CHRISTINE KUSLICH

Independent Director

In vitro diagnostic senior executive and strategic leader with a particular focus on advancing clinical diagnostics, novel assay and device development as well as quality executive leadership



1) Herman Verrelst will move into the new position of Executive Chairman of the Board of Directors as from 24 April 2023
2) Roger Moody will also become a member of the Board of Directors, subject to the approval by the Company's general shareholders' meeting
3) Christian Reinaudo will move into the new position of Lead Independent Director of the Board of Directors as from 24 April 2023

# KEY INVESTMENT HIGHLIGHTS

Empowering decentralized MDx for large addressable markets in oncology and infectious diseases through a broad network of high-value partnerships

Offering the validated Idylla™ platform, a fully automated, decentral qPCR platform enabling superior sensitivity, unmatched ease of use, and rapid turnaround times

Expanding product menu of highly differentiated oncology MDx by leveraging growing partnership network, as well as continued advancements in Idylla™ technology

Commercial-stage, revenue generating business with a wide, global footprint and an existing installed base of 2,000+ in oncology

Financial model with revenues growing across multiple customer channels and applications, as well as continued improvements in margins

Best-in-class management team with successful track record of execution in the global diagnostics industry; Strengthened balance sheet with amendment of existing converts, issuance of new convertible bonds and equity raise

## CONTACT INVESTOR RELATIONS

ir@biocartis.com

+32 15 631 729

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# KEY ACHIEVEMENTS 2022, A SUCCESSFUL YEAR

## Continued strong growth of product revenues in the core oncology business

- ✓ EUR 45m total product revenues
- ✓ **30%** year-on-year **growth in oncology** cartridge revenue
- ✓ ASP in oncology: EUR 116 (+11% vs 2021)

## Unlocking economies of scale on ML2

- ✓ **Gross margin more than doubled** to 34%, target of 50%-60% in sight
- ✓ Transfer of all assays to ML2 completed for more than 90%
- ✓ ML1 to be decommissioned in the course of 2023

## Extended cash runway

- ✓ Significant reduction of operating cash burn
- ✓ **Recapitalization** brought new cash and extended the maturity of the convertible debt by more than 2 years

## New tests, partnerships and regulatory approvals lay solid foundation for continued growth

- ✓ Extended collaboration with AstraZeneca: **new CDx**[1,2] test
- ✓ Start of commercialization of two new CE-marked IVD kits from SkylineDx and Ophiomics[3]
- ✓ Launch of the CE-marked IVD Idylla™ GeneFusion Panel
- ✓ Regulatory approval of the Idylla™ Instrument in China and the Idylla™ MSI Test as a CDx in Japan
- ✓ **New Idylla™ FLEX technology**: first assay launched (Idylla™ IDH1-2 Mutation Assay Kit (RUO)



1) A companion diagnostic (CDx) is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product; 2) For development & applicable pre-market notification with the US FDA of a novel test on Idylla™, for use with Tagrisso® (Osimertinib, AstraZeneca's third-generation EGFR-TKI (tyrosine kinase inhibitor) treatment); 3) A Lisbon (Portugal) based biotech company developing a precision medicine portfolio focused on liver cancer; 4) Detects in one single cartridge ALK, ROS1, RET and METex14 skipping, a wide range of actionable targets for fast treatment decisions in non-small cell lung cancer (NSCLC);

# TOTAL OPERATING INCOME OF EUR 58M IN 2022

## Breakdown total operating income

| In EUR 1,000 | 2022 | 2021 |
|---|---|---|
| Product sales revenue | 45,036 | 40,486 |
| Collaboration revenue | 11,068 | 6,053 |
| Service revenue | 1,377 | 1,730 |
| **Total revenue** | **57,481** | **48,269** |
| Grants and other income | 495 | 6,629 |
| **Total operating income** | **57,976** | **54,898** |

## Additional details (in EUR 1,000)

| Product sales revenue | 2022 | 2021 |
|---|---|---|
| Idylla™ system sales & rentals | 9,172 | 8,869 |
| Idylla™ cartridge sales | 35,864 | 31,618 |
| **Product sales revenue** | **45,036** | **40,486** |

| Collaboration revenue | 2022 | 2021 |
|---|---|---|
| R&D services | 10,505 | 5,868 |
| License fees | 100 | 185 |
| Milestones | 463 | 0 |
| **Collaboration revenue** | **11,068** | **6,053** |

# OPERATING RESULT OF EUR -47M

## Condensed income statement

| In EUR 1,000 | 2022 | 2021 |
|---|---|---|
| **Total operating income** | **57,976** | **54,898** |
| Cost of goods sold | (29,799) | (33,922) |
| R&D expenses | (38,393) | (48,054) |
| S&M expenses | (20,595) | (16,763) |
| G&A expenses | (16,236) | (15,560) |
| Other expenses | - | (3,244) |
| **Total operating expenses** | **(105,023)** | **(117,543)** |
| **Operating result** | **(47,047)** | **(62,645)** |
| Net financial result | (17,690) | (8,411) |
| Share in results of associates | (884) | (659) |
| Income taxes | 240 | 243 |
| **Net result** | **(65,381)** | **(71,472)** |

## Comments

- **Total operating income** of EUR 58m (2021: EUR 54.9m)
  - **Product revenues** of EUR 45m (2021: EUR 40.5m)
    - **+30%** growth in oncology cartridge revenue (EUR 31.3m)
    - Fading demand for COVID-19 testing: EUR 3.5m
    - EUR 9.2m of revenue from 2,085 instruments
  - Collaboration revenues of EUR 11.1m, +83% mostly from R&D services to partners
- **Gross margin of 34%** vs 16% in 2021
  - 11% increase in oncology ASP (EUR 116)
  - Scaling on ML2
- **Total operating expenses** (excluding cost of sales) of EUR 105m from EUR 117.5m in 2021
  - EUR 9.7m lower spending in R&D
  - Post-pandemic normalization of commercial activities
  - Global inflation
- **Improved profitability**
  - Operating loss reduced by EUR 15m
- Bond restructuring accounted: EUR 7.3m **loss on the derecognition** of the 4% existing bond and the recognition of the new 4.5% bond

# REDUCED OPERATING CASH BURN AND RECAPITALIZATION

## Condensed cash flow statement

| In EUR 1,000 | 2022 | 2021 |
|---|---|---|
| Result for the period | (65,381) | (71,472) |
| Depreciation and amortization | 10,481 | 9,845 |
| Impairment losses | 1,178 | 1,362 |
| Other adjustments [1] | 1,303 | 1,326 |
| Net financial result | 17,690 | 9,545 |
| Working capital changes | (3,857) | (9,648) |
| Taxes & interests paid | (6,269) | (6,674) |
| CF operating activities | (44,855) | (65,716) |
| CF investing activities | (5,431) | (3,748) |
| CF financing activities | (22,463) | (1,204) |
| Total net cash flow [2] | (27,823) | (70,668) |
| Cash and cash equivalents [3] | 26,125 | 53,522 |
| Financial debt | 122,356 | 154,162 |

## Remarks

- **EUR 18.1m reduction of operating cash burn[4]**
  - **EBITDA** of EUR -36.6m (2021: EUR -52.8m)
  - **CAPEX** of EUR 1.9m (2021: EUR 3.8m)
- Working capital investment reduced by EUR 5.8m
- Additional investment of EUR 1m in WondfoCartis and EUR 2.5m in SkylineDx's convertible note
- **Financial cash flows** included:
  - EUR 19.9m net proceeds from the recapitalization
  - EUR 9m net drawdown on working capital facilities
  - EUR 6.6m schedules lease payments
- **Net cash outflow** of **EUR 27.4m**
- **Cash of EUR 62.1m** at the start of 2023: Net cash position of **EUR 26.1m** at 31 December 2022 + **EUR 36.1m** upon completion of the recapitalization in January 2023
- **Financial debt** of EUR 122.4m includes:
  - EUR 75.9 convertible bonds [5] & EUR 16.8m convertible term loan
  - EUR 14.6m lease obligations
  - EUR 15m bank debt



1) Includes share-based payments, share of net loss of a joint venture, net movement in defined benefit obligations and other adjustments 2) Excludes the effect of exchange rate differences on the cash balances held in foreign currencies 3) Including EUR 1.2m restricted cash related to KBC Lease financing 4 Earnings before interest, taxes, depreciation and amortization ('EBITDA') + impairment losses + capital expenditure 5) accounted for as compound financial instrument with the value attributed to the embedded derivative being recorded as equity

# FINANCIAL DEBT POST RECAPITALIZATION

| | 2021 | | 2022 | | |
|---|---|---|---|---|---|
| | Accounting | Notional | Accounting | Notional | Pro Forma Notional [1] |
| Convertible bond 4% | 128,2 | 135 | 9,3 | 14,8 | 14,8 |
| Convertible bond 4.5% | | | 66,6 | 92,1 | 117,1 |
| Convertible Term loan | | | 16,8 | 17,8 | 29,8 |
| Leasing obligations | 20 | 20 | 14,6 | 14,6 | 14,6 |
| Bank debt | 6 | 6 | 15 | 15 | 15 |
| **TOTAL** | **154,2** | **161** | **122,4** | **154,3** | **191,3** |

[1] Including the recapitalization transactions completed on 16 January 2023