



Management Presentation

November 2023



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A unique value proposition



- A diagnostic company founded to **revolutionize laboratories’ workflow through automation and data analysis**
- Automated detection, analysis and interpretation of **rare and extremely rare cells**
- Ikoniscope20 digital fluorescence microscope system - A combination of **proprietary instrument, software applications and reagents** covered by numerous international patents

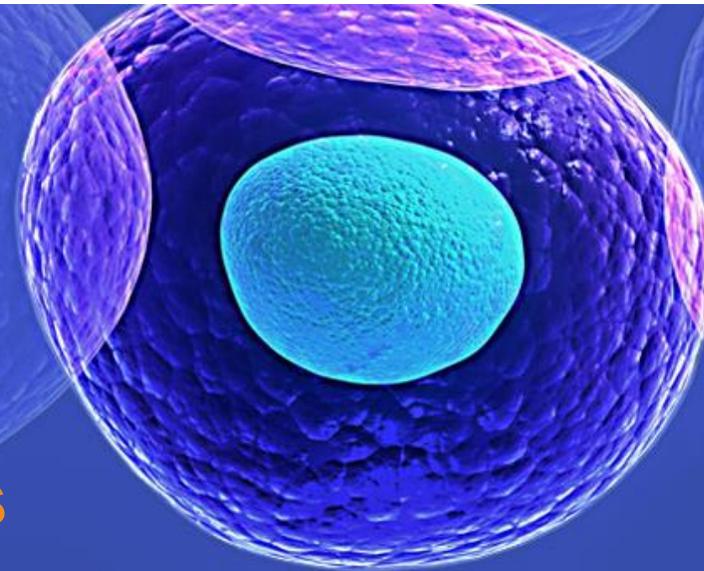
 New Haven, CT, USA
Main R&D, assembly, commercialization
 , **ISO13485** Medical Device Manufacturer

 Paris, France
Commercialization
Listed at **Euronext** Growth Paris

 Milano, Italy
AI, software, commercialization

Ikonisys’ technology enables early, accurate **cancer detection**

We offer a unique fully-automated solution for diagnostics laboratories





An experienced international management team with proven track record



Mario Crovetto
CEO

- CFO of **Eurand NV** (Specialty Pharma), which he brought to NASDAQ in 2007
- Various general management and finance positions notably at **Recordati** (Pharma), **Montedison** (Specialty Chemicals)
- Director of **OpGen**, a molecular diagnostic company listed at NASDAQ
- MSc in Business Economics at **Harvard University**



Alessandro Mauri
CFO

- Portfolio Manager at **Cambria**, a private equity fund regulated by FCA
- Founder and CEO of **B10NIX**, a biotech startup active in biosignal processing
- Master in Corporate finance at **SDA Bocconi**
- MSc in Global Finance at **Fordham University** (NY)
- MSc in Engineering of Computing Systems (major: Robotics and AI) at **Politecnico di Milano**



Michael Kilpatrick, PhD
CSO

- Research at University of Wisconsin-Madison, University of Alabama at Birmingham, the **Imperial Cancer Research Fund laboratories** in London, University of Connecticut Health Center
- **Wellcome Trust Lecturer** in Molecular Genetics at University of Birmingham
- **PhD in Chemistry** at University of Birmingham
- >100 scientific publications in human molecular genetics



Juergen Schipper
CCO

- Experience in General Management, Business and Commercial Development
- Founder and Managing Director of **Microbionix GmbH and Diagnostics & Life Science Consulting**
- Interim Management at companies such as **Luminex Corporation and Omega Diagnostics**
- Master Science (Environmental Sciences): Giessen University of Applied Sciences
- **MBA**: Munich University of Applied Sciences

Years of experience

**1. A UNIQUE VALUE PROPOSITION
IN DIAGNOSTICS**

2. MARKET & COMMERCIALIZATION

3. SUCCESSFUL BUSINESS MODEL AND
GROWTH STRATEGY

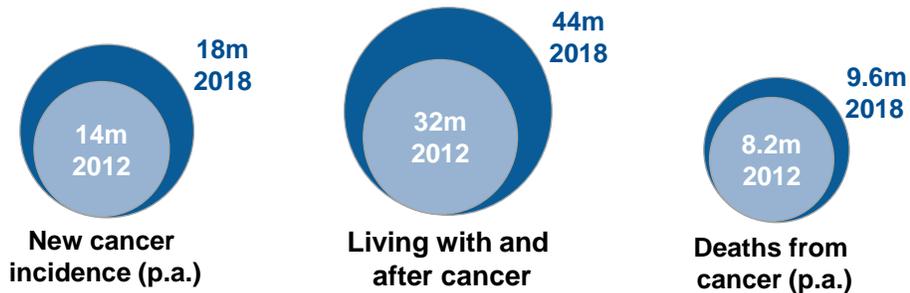
4. COMPANY HIGHLIGHTS





A clear need for fully automated systems in cancer diagnostics

Cancer: a deadly burden for humankind



• **Survival rates** at 5 years, early stage vs late stage:

	Breast	Lung	Colorectal	Ovarian
Stage I-II	>90%	>70%	>90%	>90%
Stage III-IV	~15%	~14%	~20%	~5%

› Results of recent market survey:

- Users of automated systems are aware of system advantages (e.g. efficiency, throughput, less handling risks)
- 60% of automated users plan to purchase a new automated system within the next 2 to 3 years (add on)
- Above 80% of users would want to buy a fully automated and integrated system

Shortage of pathologists is a bottleneck for diagnosis

- **-18%** The decrease between 2007-2017 in the number of active pathologists in the US
- **63%** The percentage of active US pathologists aged 55 years or more
- **44%** The portion of active UK pathologists that already work overtime
- **24%** The percentage of UK pathology labs that have to outsource service on a weekly basis because of shortage of pathologists

Implication: pathologists will need digital, automated systems to deliver more outcomes in less time, with higher specificity / granularity of data



An integrated system for fully automated analysis and interpretation

Ikonisoft broad range of Diagnostic Applications

Test-specific applications in various fields



CTC



Oncology
FISH



Prenatal



Immunology*

Reagents

Consumables

Optimized for Ikoniscope



Ikoniscope20 Robotic Digital Microscope



Ikoniscope20



Ikoniscope20max



- Fully-automated slide scan and analysis in a compact instrument, able to rapidly scan millions of cells
- Single instrument for **multiple applications**, currently including tests for various cancer types and CTC
- **Fast and accurate**, to increase laboratories' throughput
- Automated analysis of **up to 160 slide** with the high-volume variant Ikoniscope20max for high-throughput laboratories

Maintenance

Service agreements
Renewed yearly
Remote fault diagnosis



Data storage, remote connectivity

Data driven

Networking with virtually any laboratory
Internet-based remote access

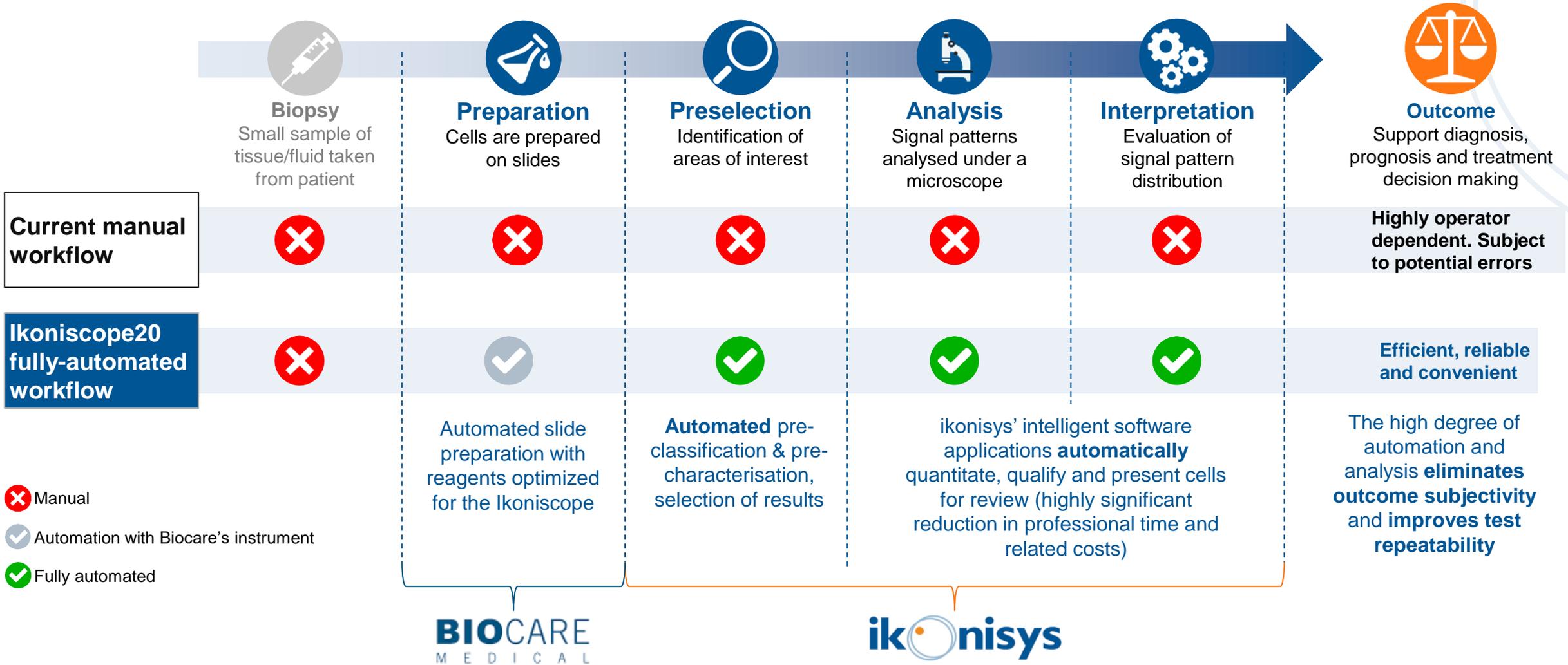


- › Fully integrated technology platform - Instrument, software applications and consumables
- › Fully automated slide handling, cell detection and analysis, data capture, data storage and (remote) review

*In study



Ikoniscope20 greatly improves the laboratory's workflow



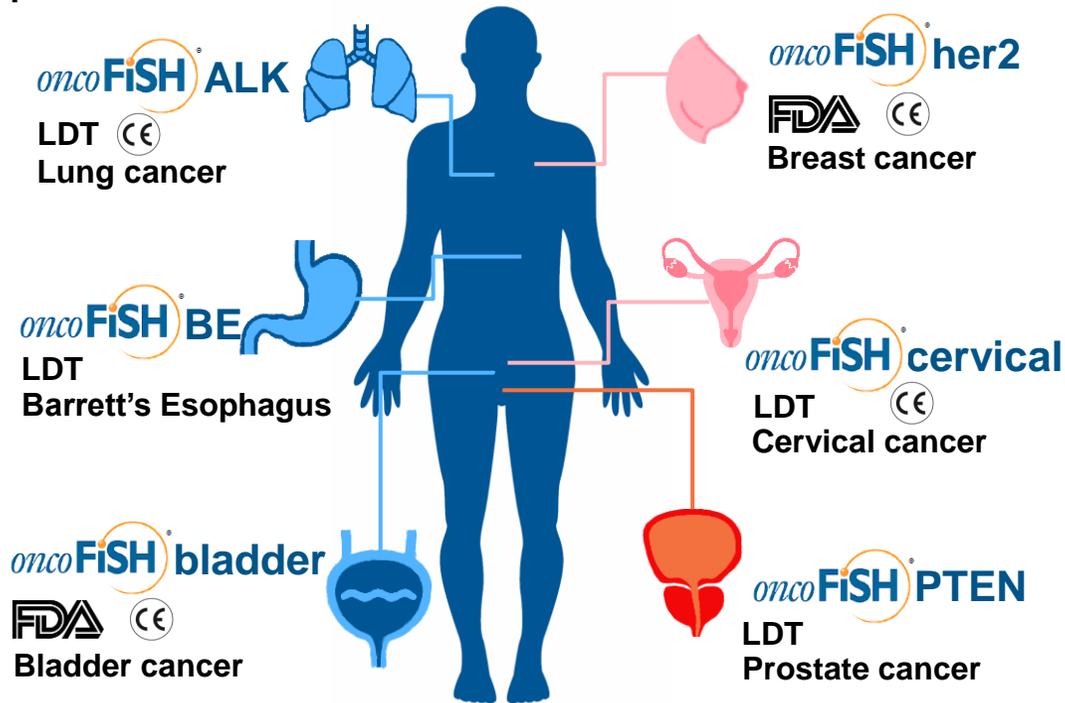
› Ikoniscope20 cuts down up to 65% of the manual workflow through automation, significant cost/time efficiency improvements



A wide current portfolio of diagnostic tests about common diseases

Oncology FISH

Fluorescence In Situ Hybridization - a technique that identifies and quantifies specific genes in cells. Used for **diagnostics** and **personalized medicine**



LDT – Laboratory developed test

Liquid biopsy / CTC (Circulating Tumor Cells)

Aneuploidy-based **CTC detection**, for **early cancer diagnosis, prognosis and treatment monitoring**



- **Flexible approach** - detection and analysis of CTC based on any combination of biomarkers
- **No need for enrichment** - up to 2 million cells per slide
- **Full characterization of cells**
- **Cancer-specific applications** developed with Sheba Medical Center

Prenatal diagnosis



fastFISH amnio FDA

Fully automated detection of fetal cells for **prenatal diagnosis of chromosomal aneuploidies**

> **The current portfolio addresses a wide variety of common diseases that Ikonisys can help detect faster and with more efficacy**



Value proposition: cost and time saving while increasing quality

Multi-purpose: optimized CAPEX

- **Multiple applications:** FISH, CTC, infectious disease, immuno-oncology
- Analyze tissues and biological fluids, hybridized with **any desired combination of probes**
- Fully customizable product, for **flexibility** (area, # scans,...)

Time Saving

- **Selective scanning**, to concentrate analysis only on area of interest, decreasing average scanning time
- Truly walk-away capabilities allow **unattended and overnight scanning** for greater slide volumes.
- **Auto-report** with meaningful info

Cost Saving

- **Increased lab productivity**, saving additional FTEs and allowing a balanced workflow
- **Less consumables used**, thanks to selective scanning (stain only useful areas).
- **Increased lamp life**

Deep Analysis

- **3-D, high-resolution** microscope scanning and digitization
- Proprietary algorithm with **100% accuracy***
- **Quantitative and qualitative** (e.g. morphology) analysis to refine the search for the right cells

Diagnostic confidence

- **Higher confidence** in patient assessment thanks to the higher amount of observations
- Avoid potential errors, **eliminating outcome subjectivity**
- Automatically produce a **readable and reliable report**

Data-driven remote capabilities

- Digitization and storing/sharing easily integrated with the majority of LIS, for **remote diagnosis and second opinion**
- **Remote control** capabilities
- **Remote maintenance** for cost saving

* Zwaenepoel et al, ExpMolPathol 2015 LIS - Laboratory Information System



Solving key challenges of liquid biopsy through oncoCTC

- CTC are cells that detach from a tumor and circulate in blood. They can be present in small numbers long before metastasis.
- These cells can offer clinical utility to guide disease management or early diagnosis
- A major challenge is the rarity of these cells – addressed by the Ikoniscope, thanks to automated microscopy and software-based classification

Large number of cells examined

« If there is only one cell in the analysed sample, ikonisys will be able to identify and qualify it »

Tshering Dorji, Head of Pathology,
TOMA Lab

No enrichment needed

Detects all of the wide variety of CTC cell types, including epithelial and mesenchymal cells

Flexible approach

CTCs by FISH (for nucleic acids) as well as **Antibodies** (for proteins)

Deep Analysis & Interpolation

High resolution imaging provides **detailed morphological information**

Diagnostic confidence

For the development of **cancer specific CTC-based test**

Full characterization

CTC provides characterization of individual tumor cells
ctDNA provides global tumor genotype information

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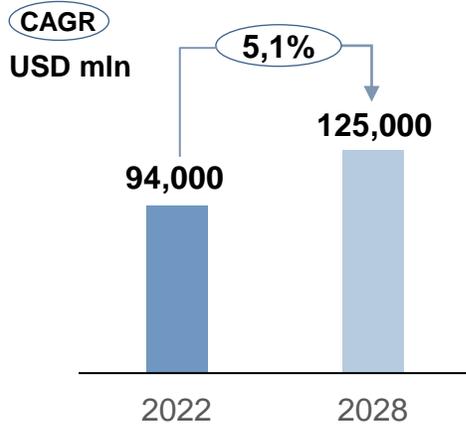
4. COMPANY HIGHLIGHTS





A market with fast growing opportunities

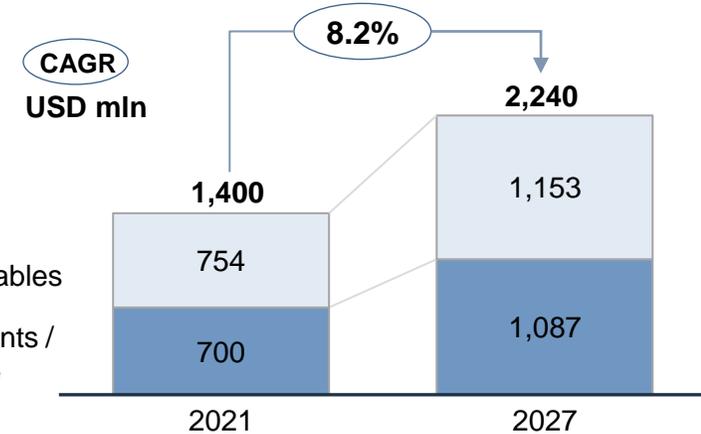
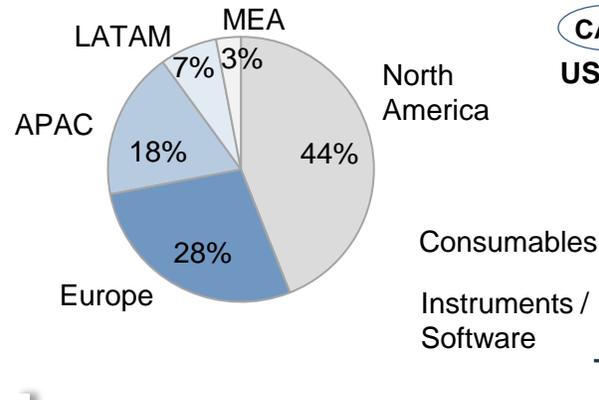
IVD Industry - Market Overview



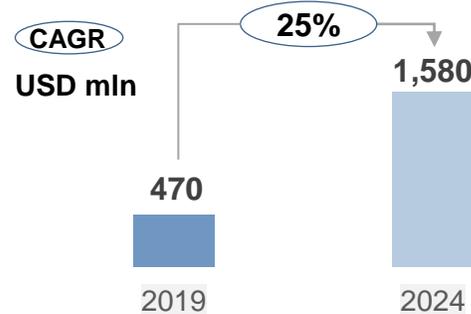
IVD segments - Oncology

- Tissue-based testing for cancer and molecular tests for both cancer and infectious disease will be the main growth engine of the overall In Vitro Diagnostic industry.
- Growth in oncology is based on demographic transition (aging societies) and higher number of tests driven by personalised medicine (e.g. FISH companion diagnostics & others).

FISH – Market Overview



CTC (Liquid Biopsy) – Market Overview



- The market for liquid biopsy testing is **rapidly evolving** as vendors develop and commercialize innovative new technologies to meet the needs of the clinical diagnostic market.

› FISH continues to outgrow the IVD market - CTC is a game changer

Source: DaedalResearch 2022, Kalorama 2020, Siemens Healthineers 2017, Grandview Research 2018, Brandessence 2018, Frost & Sullivan 2018



A new alliance for a worldwide commercialization strategy



Leverage on Biocare's established commercial network in the USA

- **Biocare** will exploit its distribution network, which accounts for more than **4,000 laboratories** all around the world
- 24 month target: **>35 instruments**
- Customers will benefit from a **full solution**, including reagents, automated slide preparation and slide analysis
- **Royalties to Ikonisys on all reagents** used with the Ikoniscope
- **Ikonisys** will continue to support existing customers, notably **high-volume** laboratories

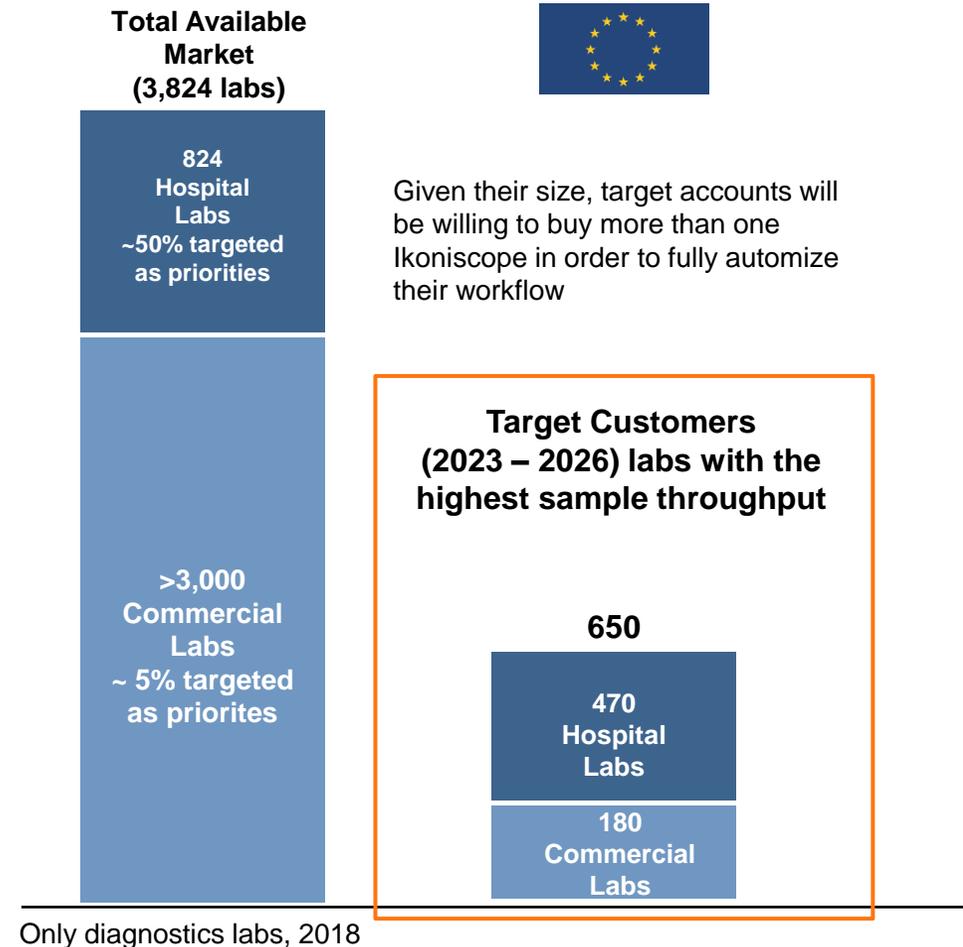
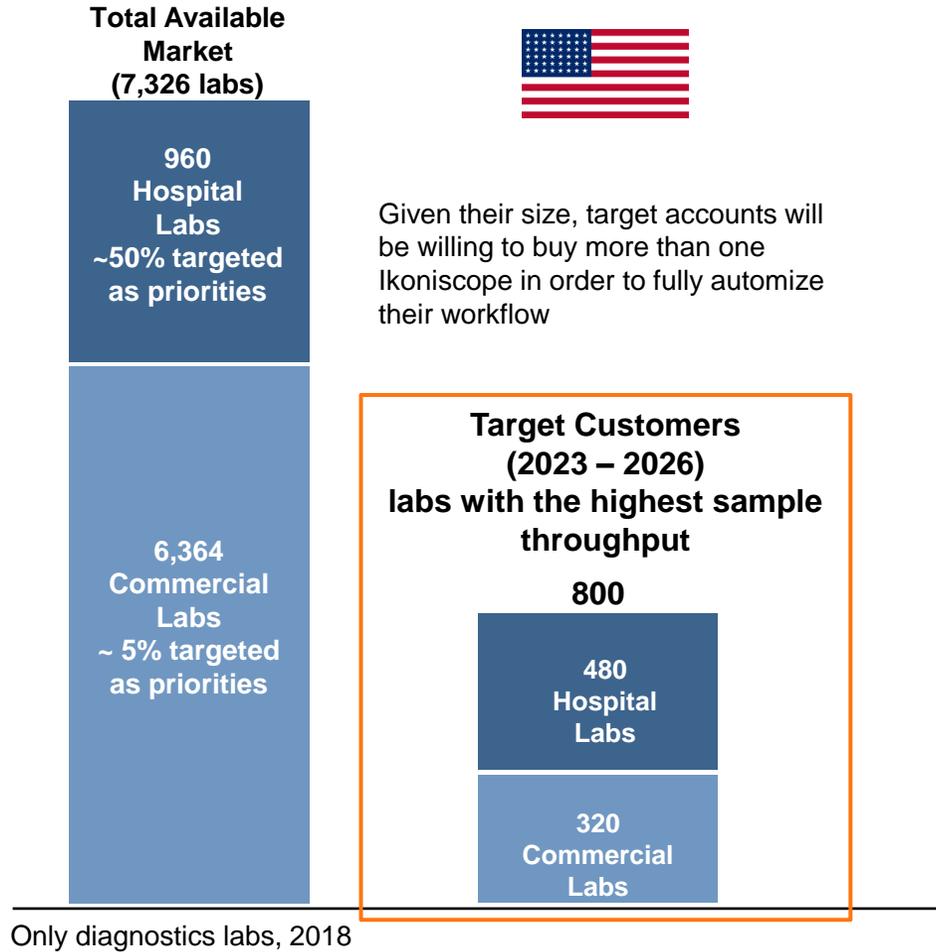
Mixed approach in Europe and the rest of the world

- **Europe:** Ikonisys-Biocare **coexclusivity**, including **sale of reagents**, with focus on "pay-per-test" model
- 24 month target Europe: **>10 instruments**
- **APA:** Biocare distributing the Ikoniscope, with Ikonisys receiving **royalties on all reagents** used with the Ikoniscope
- 24 month target APA: **>5 instruments**
- **Middle East, Northern Africa and India:** Integrated Gulf Biosystems as **distributor**

-  Mixed: Ikonisys / Biocare
-  Distributor: Biocare
-  Distributor: Integrated Gulf Biosystems



The US and European market : >1.4k labs targeted in the short term



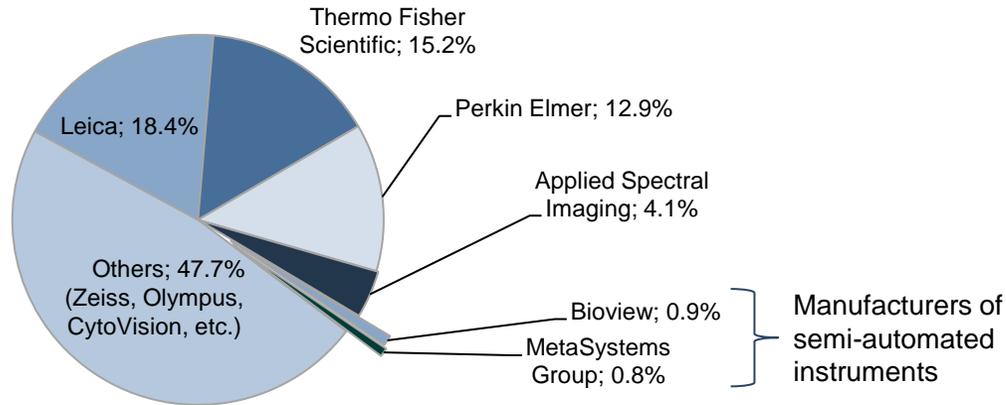
› Due to Ikoniscope’s high-level of automation, target labs will include those that would like to perform FISH testing but currently do not because of lack of staff / resources

Source: DLS Consulting 2018, ikonisys analysis



Ikonisys unique positioning in an attractive market

Global FISH market and (semi-) automation

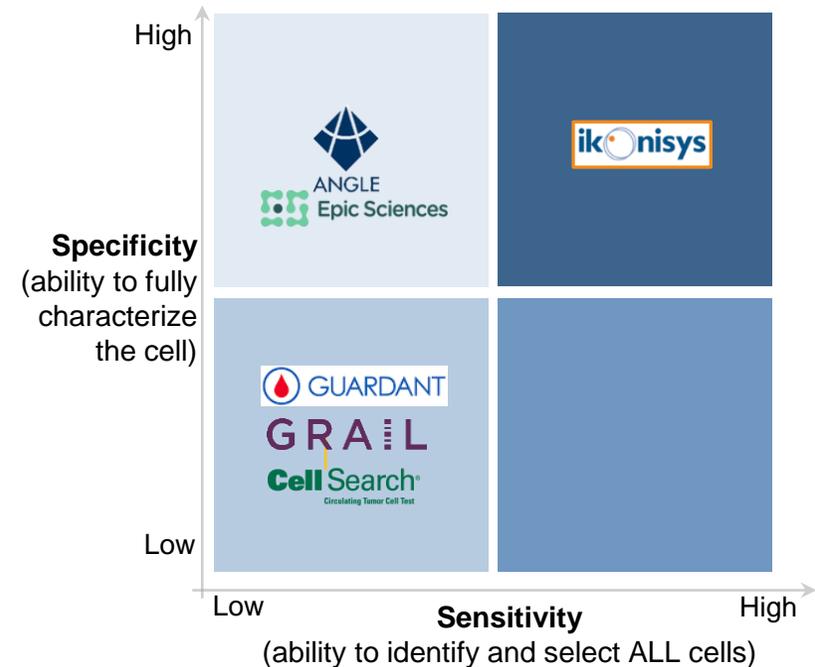


Ikonisys differentiating approach

- **Fully integrated & automated system**, enumerating, classifying and presenting diagnostically relevant cells without user intervention
- **True walk-away system**
- **No requirement for Dark-Room**
- **Comprehensive remote capabilities** (LIS connectivity, remote control, remote maintenance)
- **One-stop solution** for different applications, including Liquid Biopsy

Ikonisys cutting-edge approach in CTC

- **Flexibility:** detection and analysis of CTC based on any combination of biomarkers
- **No need for enrichment:** up to 2 million cells per slide
- **Able to scan for CTC:**
 - based on chromosome signals (aneuploidy detection)
 - **any type**, regardless of cell size or markers expressed



Source: Brandessence 2018, DLS Consulting 2018

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4. COMPANY HIGHLIGHTS





Ikoniscope20 placements driving recurring revenues



Sales driver

- **Ikoniscope20 solutions – Instrument, software applications and optional add-ons**
- Different commercial solutions depending on the client's degree of specialization, volumes and financial preference
- Starting from one single software application to several
- Option to add additional slide loader for high volumes
- Direct sale, rent or lease, to accommodate all needs



Reagent kits

- Offered to clients at competitive conditions
- Ensuring greater performance on our installed base
- In the USA: **royalty** on reagents sold by Biocare Medical
- In Europe: direct sale to customer, with the possibility of a **reagent rental / pay per use** model



Software applications

- **License fees** renewed annually
- Additional applications added regularly, addressing new types of cancers based on market demand
- Allows the implementation of pay-per-use / reagent rental model



Service agreements

- **Renewed annually**
- Low maintenance costs / high margins

› **Recurring revenues are secured by instruments installations**



Next-generation Ikoniscope AI: a quantum leap for personalized medicine

Artificial intelligence: a tool in the hands of the pathologist



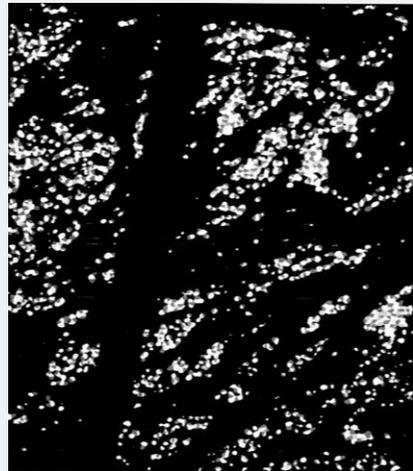
AI will be integrated in the pathologist's workflow, to enhance efficiency and expand possibilities

Example of current usage of deep learning

Input: image of tissue sample



Output: segmentation with location of detected nuclei and their class



A well-defined path to the next-generation instrument

1 AI algorithms

Self-learning **AI algorithms** for increased speed and enhanced decision making

Current step

2 Big data

Analytics on Big Data gathered over the past 12 years, to further expand the capabilities of the platform

3 Cutting-edge direct imaging technology

Novel, miniaturized tech for acquisition and analysis of both **dark field** and **bright field**

4 Data integration

Integration of all patient specific **data**, for truly personalised medicine

› Ikoniscope AI will deliver further innovations, integrating the latest breakthrough in hardware and software



A strong network of development partners

CTC – Circulating Tumor Cells



- **Sheba Medical Center**, one of the 10 best hospitals in the world*
- **Partnership to develop novel cancer-specific CTC tests** with a variety of potential clinical utilities, including treatment monitoring and companion diagnostic
- Sheba's research team, led by Prof. Iris Barshack together with Ikonisys will work to develop new Ikoniscope20 CTC tests
- **Definition of the protocol** for the development of novel CTC tests initially targeting **pancreatic, breast and lung cancer**.
- Specific biomarker panels have been identified for testing



- Acts as reference lab for Europe.
- New tests identified for development

IkoniscopeAI



- Collaboration with prof. Boracchi, professor of Computer Vision and Machine Learning, for the implementation of novel deep learning solutions for image segmentation and cells classification.
- First implementation of a deep learning neural network for segmentation
- Sponsored a PhD student that will continue studies on AI for pathology.

Immuno-oncology



- Evaluate the potential of the Ikoniscope platform in the detection and quantification of specific populations of cells for immuno-oncology
- Results so far demonstrated the capability of the Ikoniscope20 platform to **enumerate specific populations of CD8 T-cells†**.
- These results provide an excellent demonstration of the **ability of the Ikoniscope20 to detect rare cells** in general and CTC in particular
- **Manuscript in preparation**

› **This broad network address future markets and enhances in-house R&D**

†Antigen-specific CD8 T-cells are extremely rare but play a central role in immunity to cancers and infectious agents (such as viruses). This is achieved through their capacity to kill malignant cells upon recognition by T-cell receptor of specific antigenic peptides presented on the surface of target cells.

* Newsweek, 03/03/21

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4. COMPANY HIGHLIGHTS





Key investment highlights

1 Truly digital pathology platform

- Based on a flexible software backbone for identification of rare cells.
- Designed to expand applications in existing and new fields.
- The advantage of microscope-grade images with digital image analysis.

2 Focus on customers needs - Full automation

- Full automation, integration & data interpretation capabilities.
- Allow for top-quality outcome and high-productivity enhancement in laboratories.
- Significant cost/time efficiency improvement
- Fully scalable solution, adaptable to customer's needs

3 Attractive markets - Oncology and immunology

- Enables Personalised Medicine for a broad spectrum of cancer patients.
- Active in FISH and ready to address the high-growth CTC/Liquid Biopsy market
- Additional commercialisation opportunities ex-cancer: infectious disease and veterinary
- Partnership with an established segment leader to expand commercialization

4 Clear growth strategy

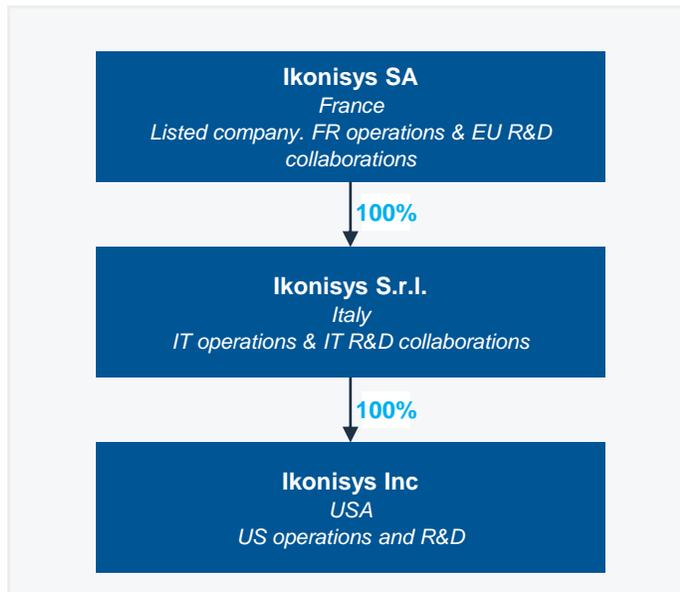
- Ikoniscope20 ready for commercial scale-up
- Integrated product portfolio - Instruments, applications, reagents
- Clear development roadmap
- Significant upside from CTC applications
- AI-based, personalized medicine platform under development



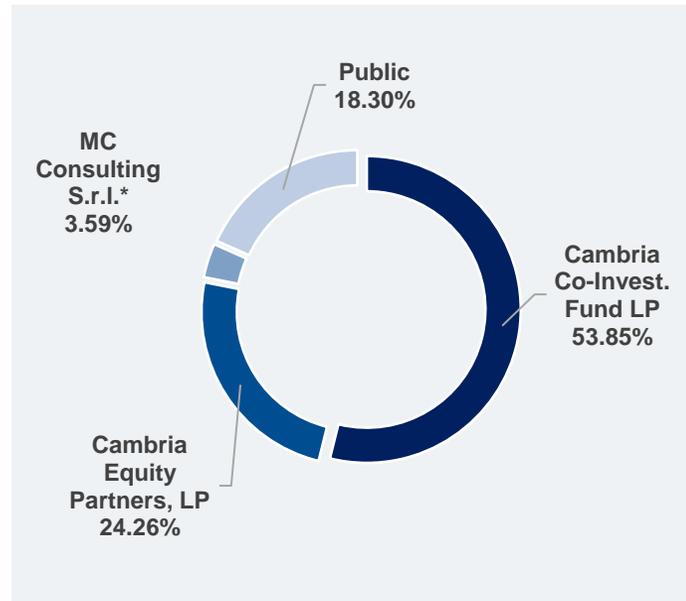
Company information

Euronext Growth Paris: IKONISYS | ISIN : FR00140048X2 | Ticker : ALIKO

Corporate structure



Shareholders



* Holding company of Mr. Mario Crovetto, CEO of Ikonisys

Stock information

- Listing date: July 19, 2021
- # of shares outstanding: 9,784 M
- Market Cap: 14 M€



Analysts' coverage





Contacts

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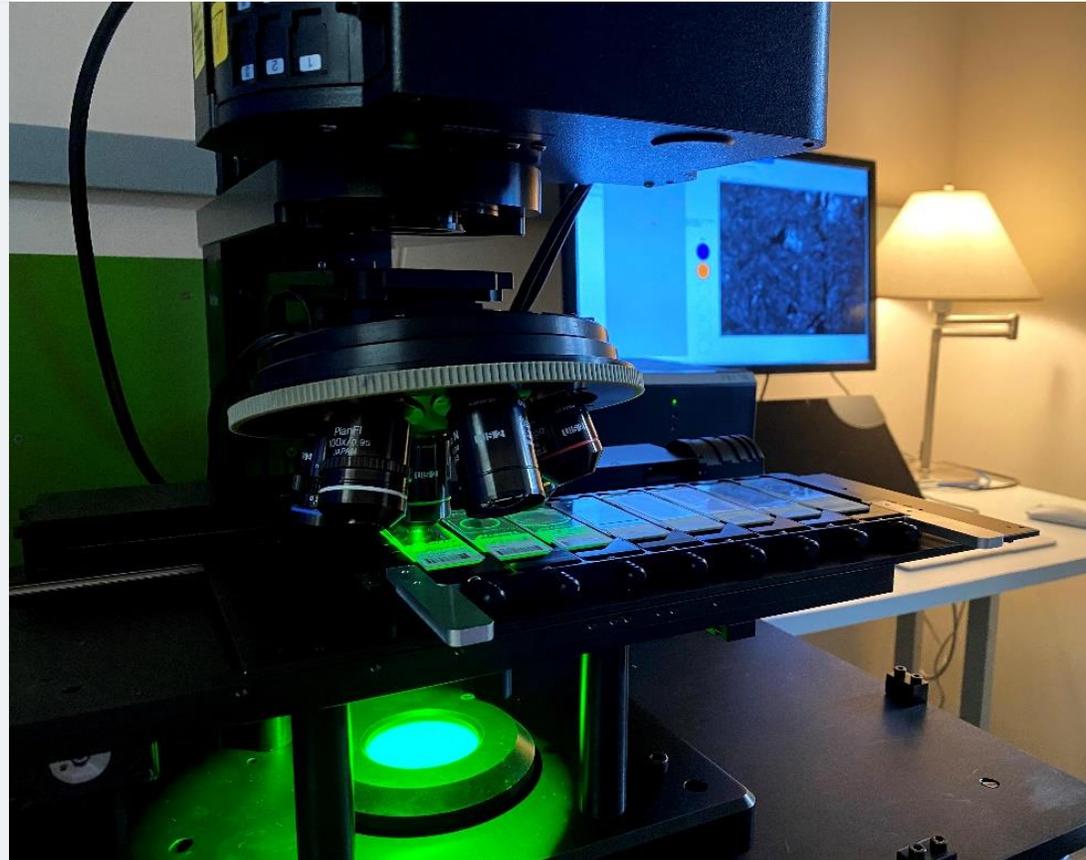
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Alessandro Mauri - CFO

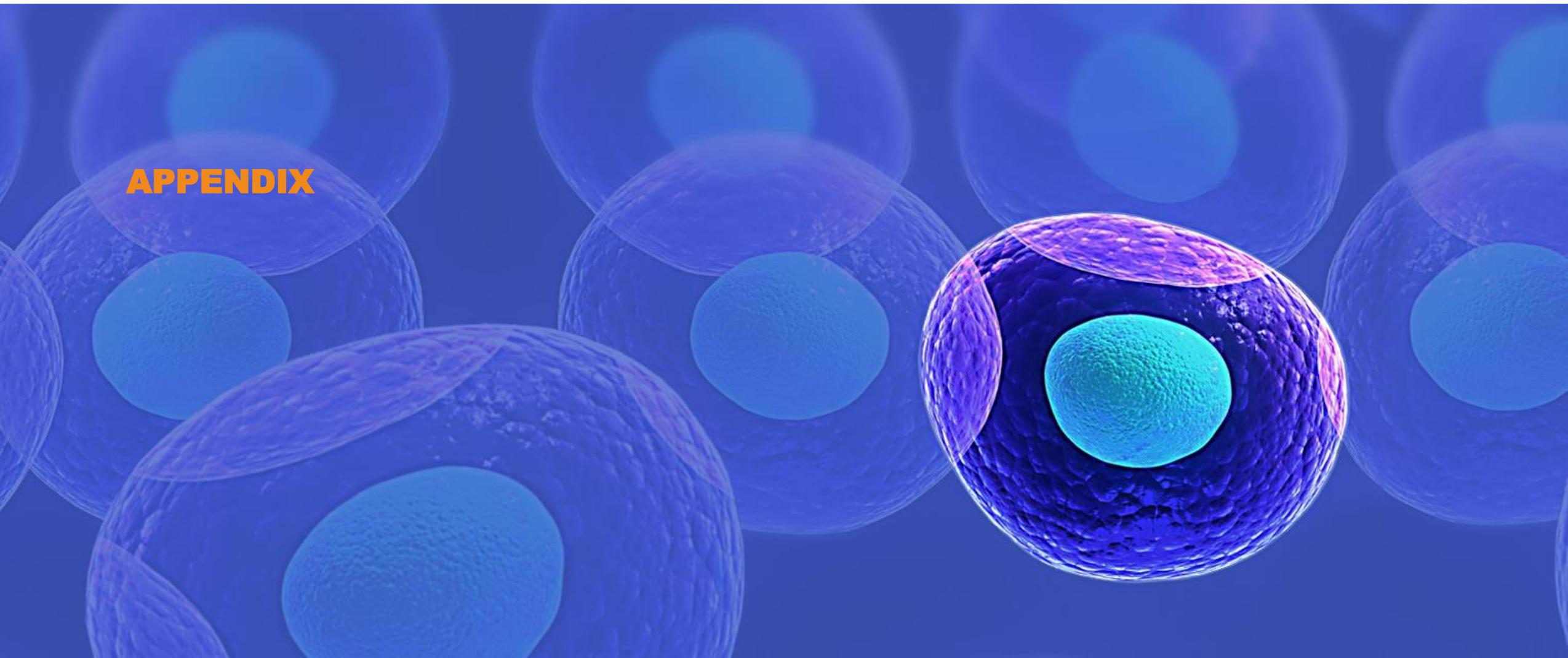
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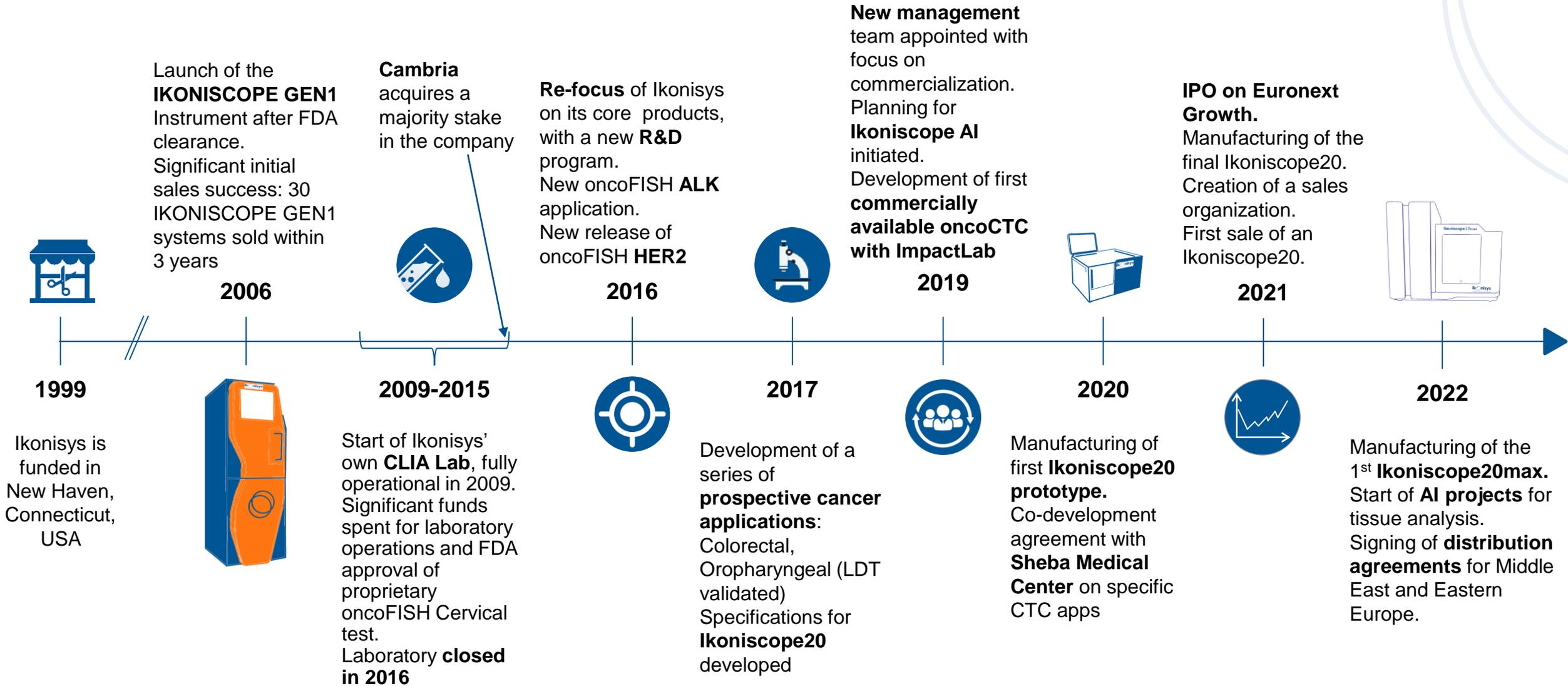
FINDING THE CELLS THAT MATTER

APPENDIX





Brief company history





FY 2022 simplified Income Statement

<i>Euros</i>	(audited) 31/12/2022	(audited) 31/12/2021
Revenues	935,218	542,701
Cost of Goods Sold	(184,413)	(70,642)
Gross Margin	750,805	472,059
Operating expenses	(2,103,452)	(955,712)
EBITDA	(1,352,647)	(483,653)
D&A	(1,083,135)	(80,579)
Interest expenses	(13,537)	(5,107)
Income / (Loss) before Tax	(2,448,320)	(569,339)
Taxes	-	1,931
Net Income / (Loss)	(2,448,320)	(571,270)



FISH testing: attractive reimbursement business for pathology labs

Favorable reimbursement rates are available in the US and Europe

- FISH testing at hospitals and clinics is mostly covered by the pathology lab's budget and reimbursed by DRG coding
- FISH testing at outpatient clinics and at doctor's offices is usually covered by country specific reimbursement catalogs
- Examples:

Reimbursement of FISH Testing		
	USA:	Bladder cancer 488 USD
	Germany:	Any FISH application 377 EURO
	Italy:	Any FISH application 450 EURO

- › **Customers have a clear incentive in automating their workflow, optimizing and increasing their throughput with an instrument that will allow them to increase the yearly net contribution margin from FISH testing**

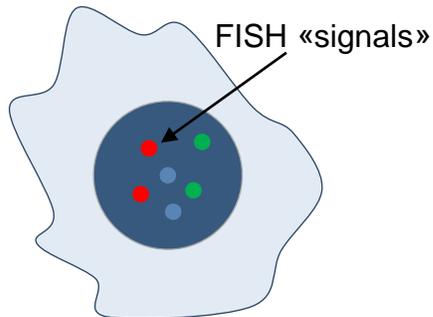


FISH at a glance

- FISH (Fluorescence In Situ Hybridization) is a technique that identifies and quantifies specific genes in cells or tissues
- By way of example a test for the HER2 gene can determine whether breast tumor cells have an increased number of copies of the HER2 gene (HER2 gene amplification)
- As HER2 amplified breast tumors are responsive to the drug herceptin a FISH test that determines the HER2 status of a breast tumor is of great value as a companion diagnostic test in determining the appropriate treatment for a patient with breast cancer

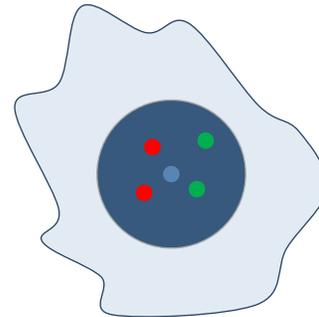
Example: measuring the number of copies of HER2 (Human epidermal growth factor receptor 2) in breast cancer to single out patients that are most likely to respond to Herceptin (trastuzumab) treatment.

Normal



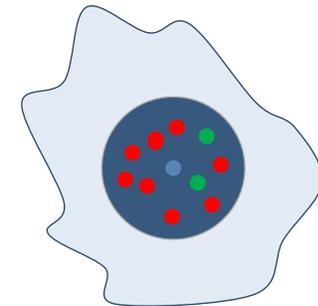
Normal copies (2 dots) of all targeted genes are present

Abnormal: HER2- Prognosis: Poor



Hemizygous deletion (1 copy) of oncogene causing cancerous growth, HER2 numbers unaffected

Abnormal: HER2+ Prognosis: Favourable

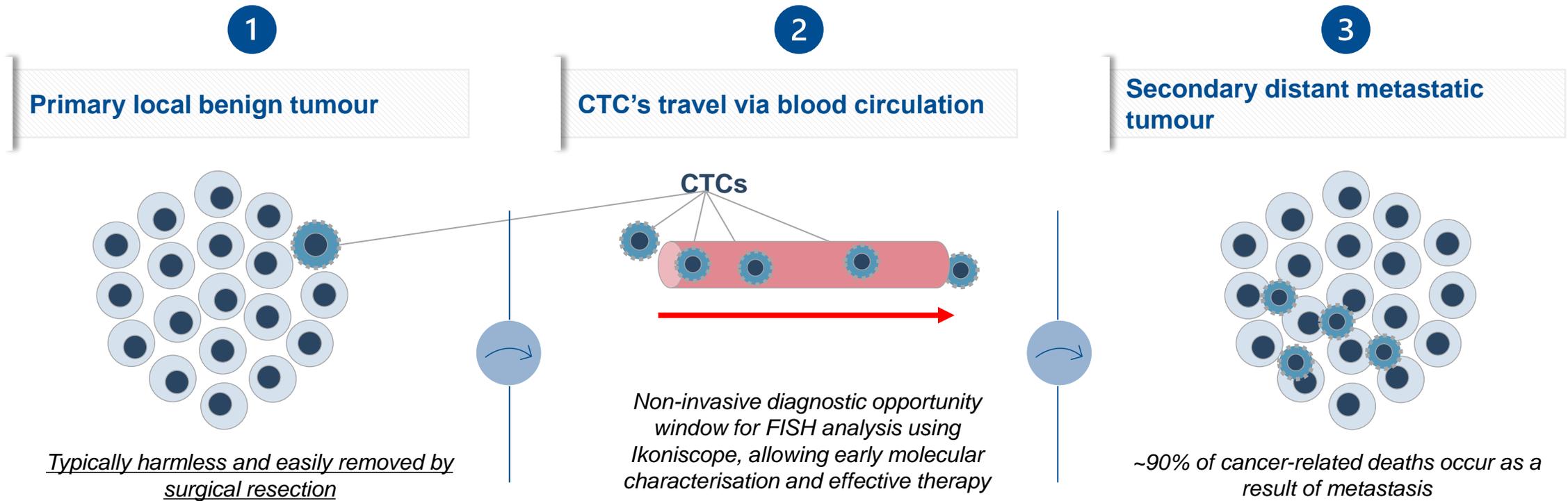


Hemizygous deletion causes cancerous growth, but HER2 amplification (8 copies) provides treatment target for trastuzumab



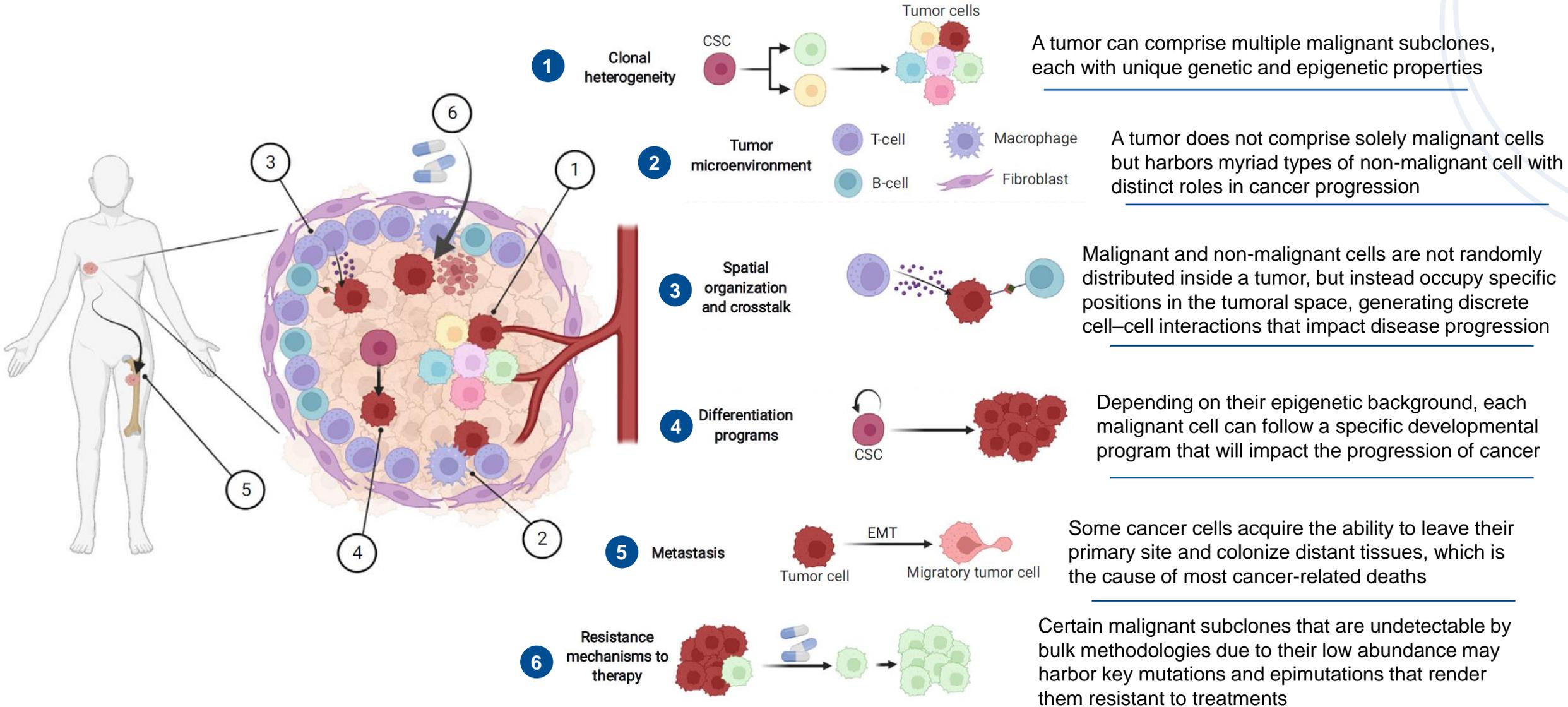
Circulating Tumor Cells (CTC) at a glance

- CTC are cells that detach from a tumor and circulate in blood, it has been known for more than 100 years
- These cells offer a source of tumor material for diagnosis, treatment monitoring and even screening for a variety of cancers
- Clearly being able to access tumor material on an ongoing basis through liquid biopsy rather than having to biopsy the tumor itself has great value
- A major challenge however is the rarity of these cells – which is addressed by the Ikoniscope





Tumor heterogeneity and the importance of single-cell analysis



Source: Single cell cancer epigenetics, Casado-Pelaez et al., Trends in Cancer 2022