



Management Presentation

Invest Securities BioMed Event
January 30, 2024





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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**
- Design production and commercialization of medical devices for **cytology**
- **Ikoniscope20** digital fluorescence microscope system - A combination of **proprietary instrument, software applications and reagents** covered by numerous international patents
- **CYTOfast** – the leading liquid-based cytology **mono-layer standardized preparation**

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

 Milano & Florence - Italy
AI, software, commercialization
 , **ISO13485** Medical Device Manufacturer

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

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

We offer a unique fully-automated solution for diagnostics laboratories

- Ticker: ALIKO
- ISIN: FR00140048X2
- Listing date: July 19, 2021
- # of shares outstanding: 10,451 M
- Market Cap: 15 M€
- Equity Research:





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**



Francesco Trisolini
COO

- CEO of **Hospitex International**
- Manager in **Hospitex Diagnostics** since the late '90, developing the opening of international markets
- Family Entrepreneur, a deep knowledge of the market's trends, an R&D vision and consolidated relationship in the scientific field, make him a visionary leader.
- **London School of Economics**
- European School of Economics – International Business



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**



Dr. Michael Kilpatrick
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



Alessandro Nosei
CDO

- 15 years as CEO in growth companies
- COO of **Hospitex International**
- He transforms the technology in Business Model, develops the strategy and the industrial plan and he is responsible of its execution, coordinating Operations, Marketing and Commercial.
- **UC Berkely California** – Strategic Marketing Management
- Nottingham Trent University – Finance



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**
- **MBA** at Munich University of Applied Sciences
- MSc in Environmental Sciences at Giessen University of Applied Sciences

Years of experience

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

2. MARKET & COMMERCIALIZATION

3. SUCCESSFUL BUSINESS MODEL AND
GROWTH STRATEGY

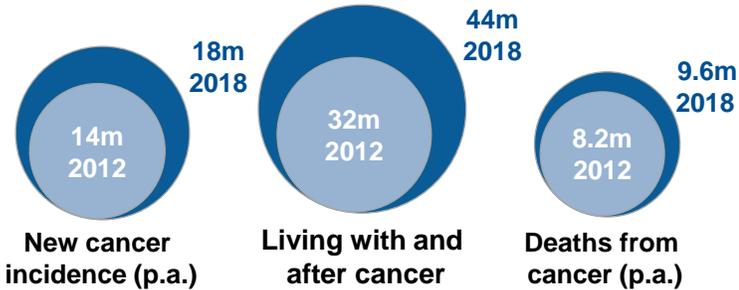
4. COMPANY HIGHLIGHTS





A clear need for fully integrated solutions in cancer diagnostics

Cancer: a deadly burden for humankind



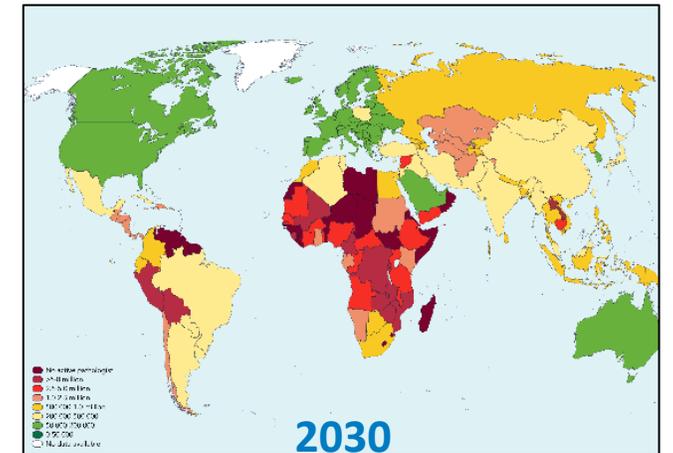
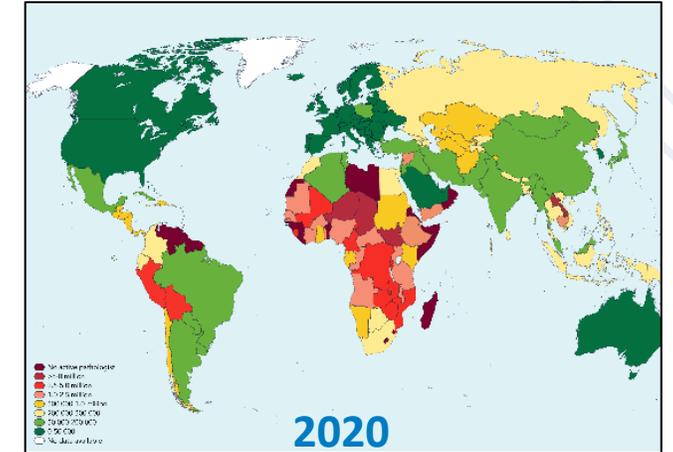
• **Survival rates** at 5 years, early stage vs late stage:

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

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

Shortage of pathologists is a bottleneck for diagnosis

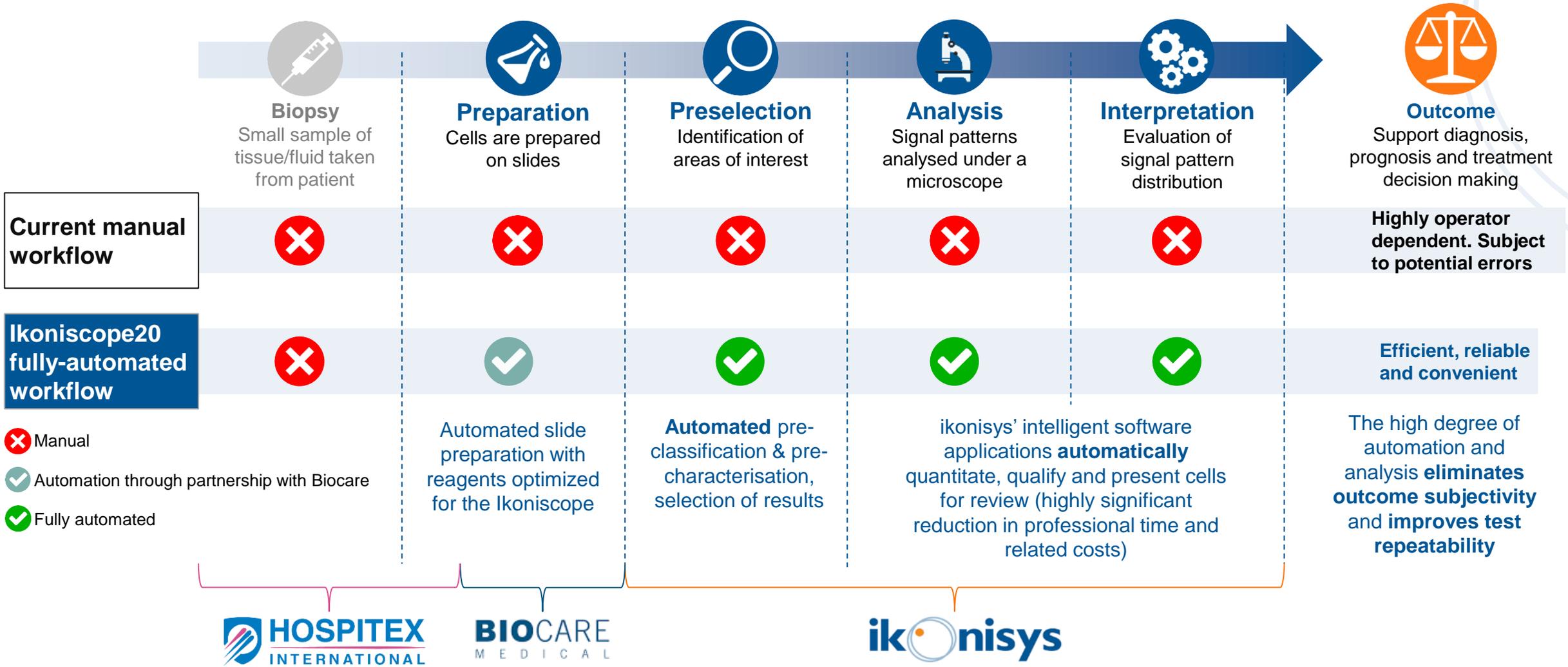
- 18%** • The decrease between 2007-2017 in the number of active pathologists in the US
- 63%** • The percentage of active US pathologists aged 55 years or more
- 44%** • The portion of active UK pathologists that already work overtime
- 24%** • The percentage of UK pathology labs that have to outsource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



Availability of pathologists, from dark green (high availability) to dark red (no pathologists available)



Ikonisys greatly improves the laboratory's workflow



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



CYTOfast: mono-layer standardized results

CYTOfast Plus solution



- **Patented Nephelometric Smart Technology (NST)**
- Thanks to the Nephelometric Reading designed in synergy with the Cytfast fixative, the system makes it possible to detect the presence of disturbing materials and manage them automatically in order to **produce 100% adequate, representative and always reportable cytology preparations.**
- Compared to competitor technologies that are only applicable to the Pap test, NST **can be applied to the entire cytology universe**, making it the most versatile product in the LBC (Liquid Based Cytology) market.
- **The only certified technology for all cytology tests** (competition only for the Pap test)



Reagents

Consumables

Needed for the preparation of slides with the CYTOfast Plus
In-house chemical and mechanical production of core components



Maintenance

Service agreements

Renewed yearly
Very high MTBF



Digitization, remote connectivity

Data driven

Networking with virtually any laboratory
Internet-based remote access



UNIQUE BENEFITS

- Bottle with multi-purpose fixative: cytology + molecular biology.
- Reading of the amount of cell available in the bottle.
- Slide in LBC with automatic **standardized cellularity.**
- Cellularity selection, multiple slide setup, residual sample storage.
- **Integrity of Cell Morphology.**
- These features make it the best LBC in the world for Digital Pathology, Morphological Analysis and the development of **Artificial Intelligence.**

› **The world's n°1 solution for thin layer liquid cytology**



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

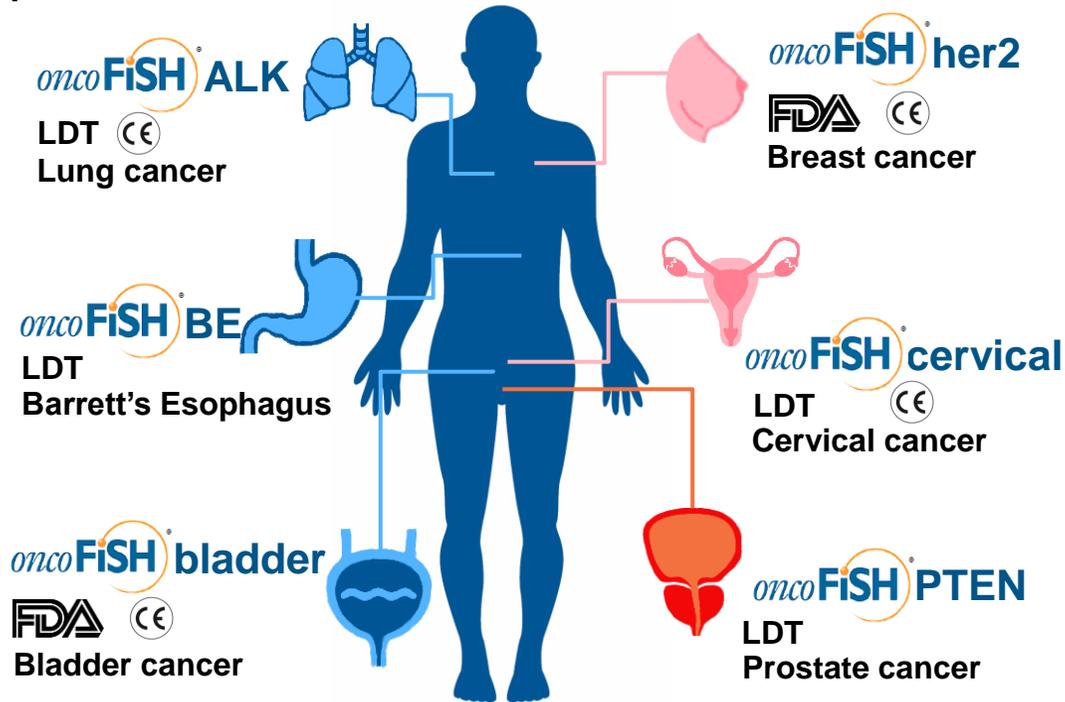
*In study



A wide current portfolio of solutions for cancer diagnostics

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

Cytology slide preparation & Urine24



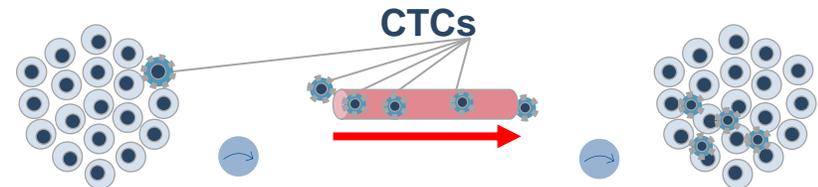
- **100% standardized thin layer** for:
 - samples free of obscuring elements
 - Ultra High Cellular Density
 - total fidelity of the sample represented.



- World's only **B2C product** for urology cancer screening

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**)
- **Full characterization of cells**
- **Cancer-specific applications** developed with Sheba Medical Center

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

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3. SUCCESSFUL BUSINESS MODEL AND
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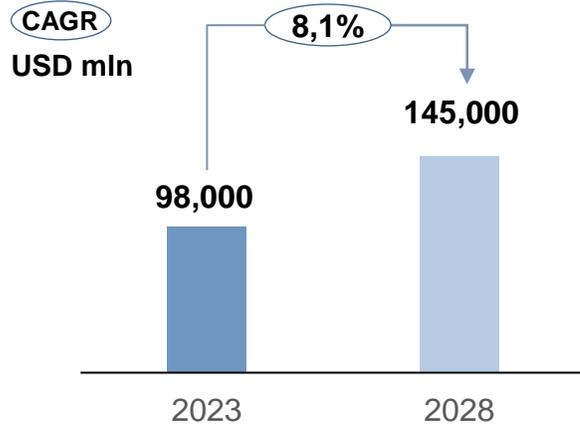
4. COMPANY HIGHLIGHTS



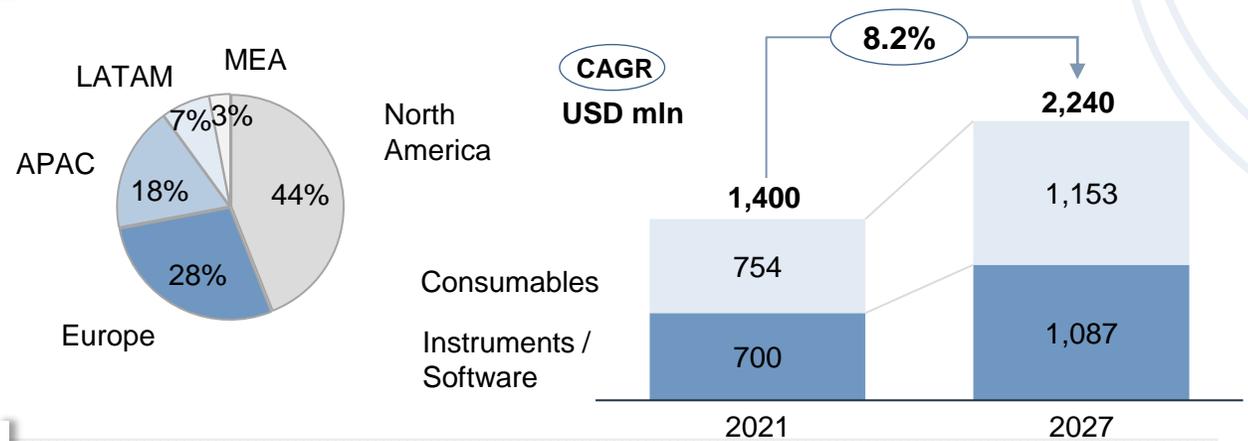


A vertical coverage of a fast growing market

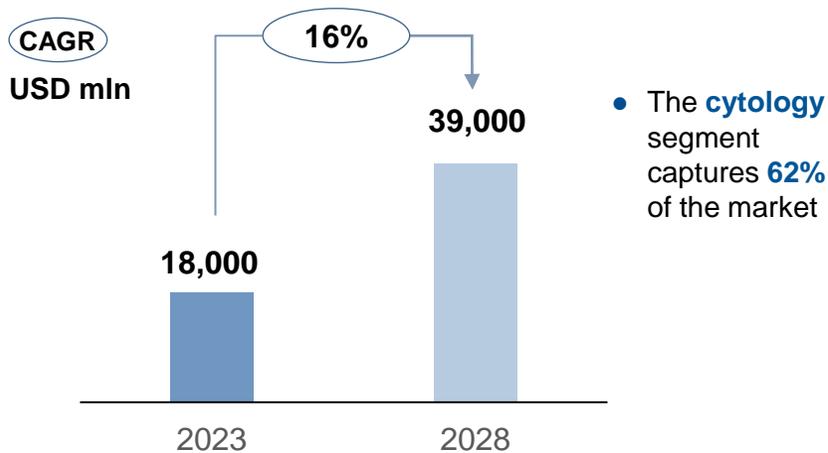
Cancer diagnostics - Market Overview



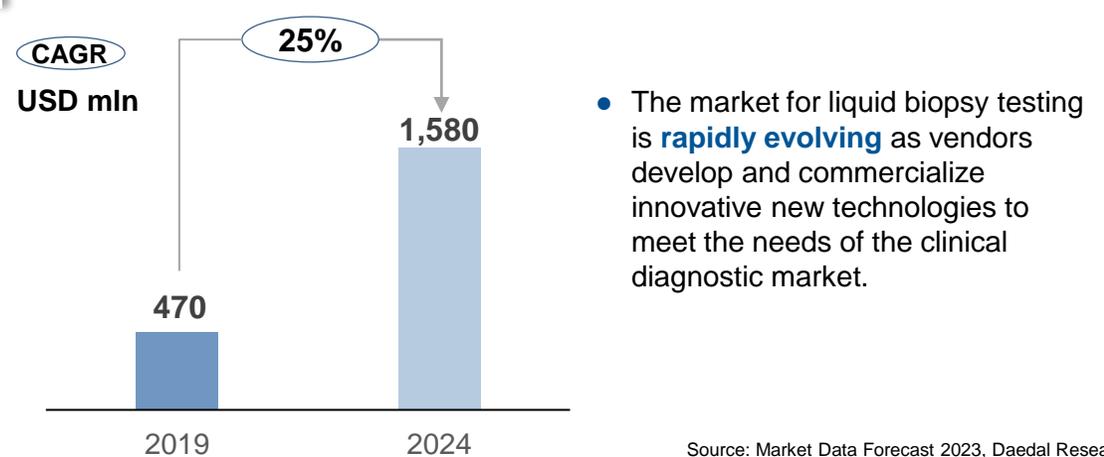
FISH – Market Overview



Histology and Cytology – Market overview



CTC (Liquid Biopsy) – Market Overview



Source: Market Data Forecast 2023, Daedal Research 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

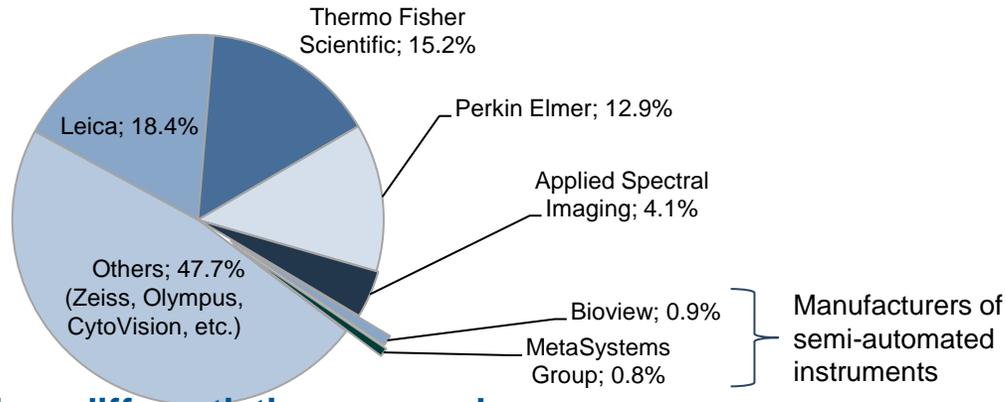
- **Europe:** Ikonisys-Biocare **coexclusivity**, including **sale of reagents**, with focus on "pay-per-test" model
- **Hospitex specialized sales network** with 20+ years of experience
- 24 month target Europe: **>10 instruments**
- **APA:** Biocare distributing the Ikoniscope, with Ikonisys receiving **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



Ikonisys unique and comprehensive positioning in an attractive market

Global FISH market and (semi-) automation

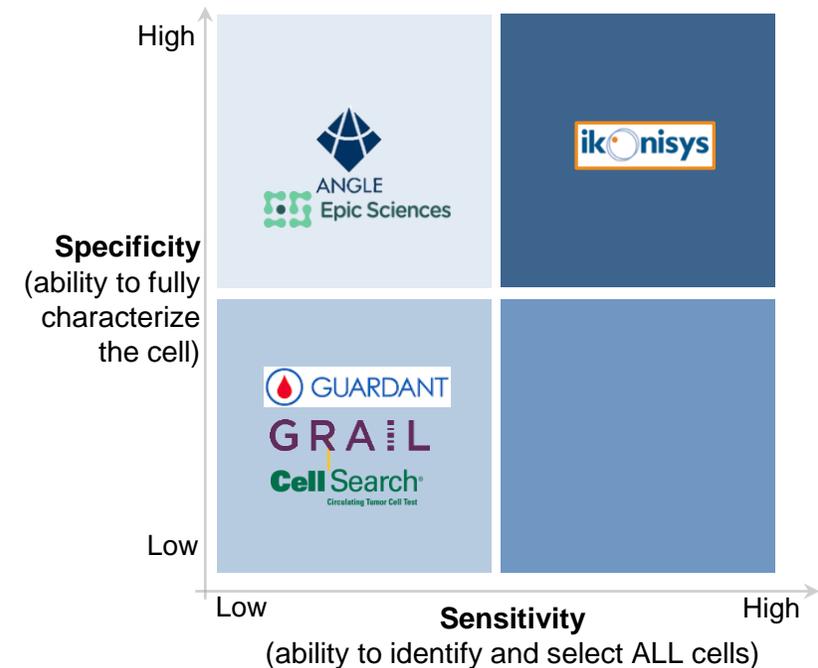


Ikonisys differentiating approach

- **Fully integrated & automated system**, enumerating, classifying and presenting diagnostically relevant cells without user intervention
- **Embedded standardized mono-layer cytology** for best quality preparation of slides and reduction of non-adequate results
- **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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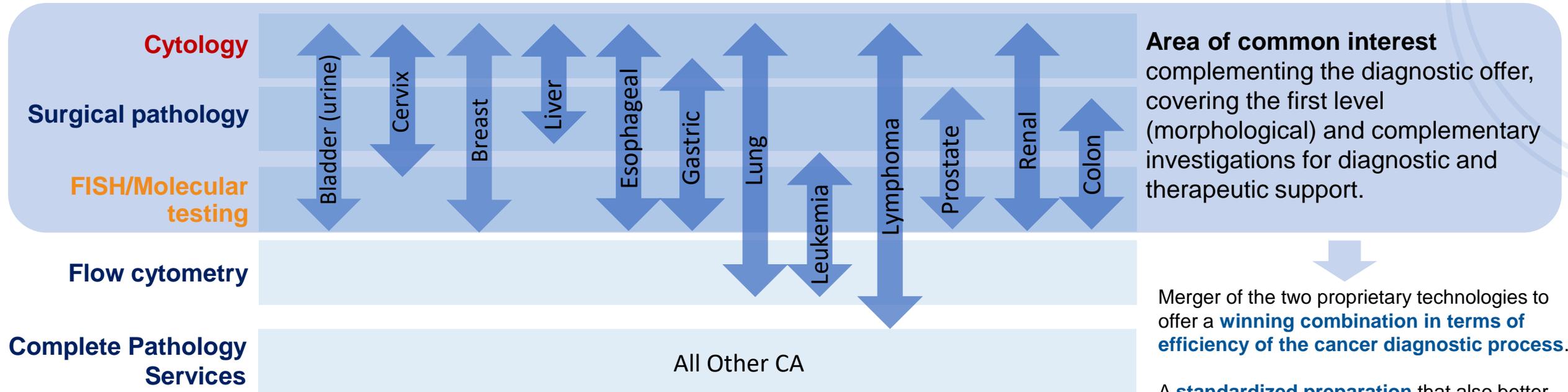
**3. SUCCESSFUL BUSINESS MODEL
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Hospitex and Ikonisys: premium efficient Cancer diagnostic



Area of common interest complementing the diagnostic offer, covering the first level (morphological) and complementary investigations for diagnostic and therapeutic support.



Merger of the two proprietary technologies to offer a **winning combination in terms of efficiency of the cancer diagnostic process.**

A **standardized preparation** that also better meets the needs of 'downstream' diagnostic testing, offering integrated solutions to the pathology laboratory.

The possibility of having residual specimen fixed, opens the way to its use for analyses linked to **predictive elements (AI and liquid biopsy).**

Hospitex expertise in efficient slide preparation

+

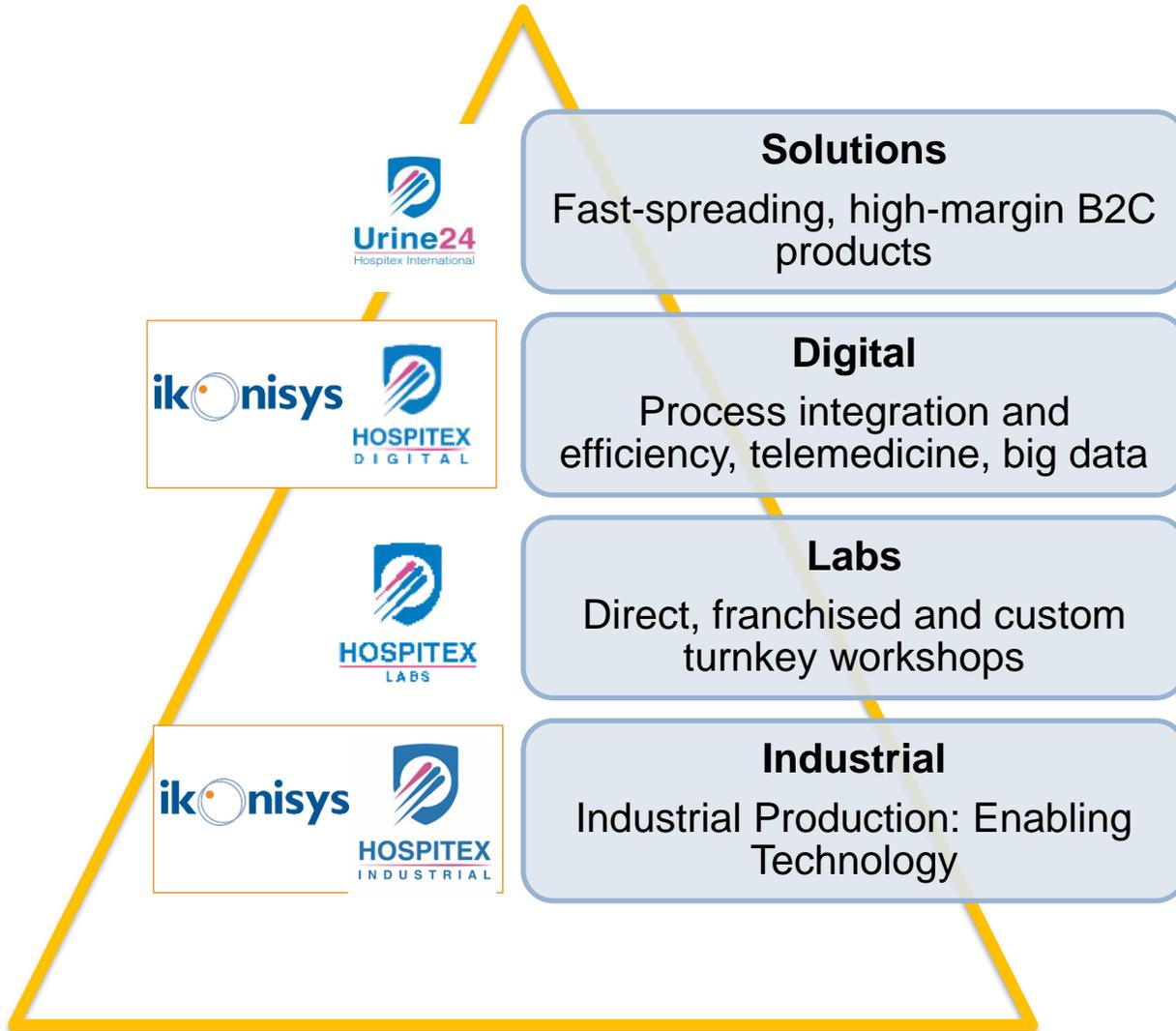
Ikonisys expertise in automated slide analysis

=

better and more efficient cancer diagnostic tests, including conventional cytology, FISH and immunocytochemistry



A fully integrated ecosystem: the pyramid of value



The integration of all heterogeneous variables is our **Sustainable Competitive Advantage**

We created an ecosystem of technologies and skills by integrating all the **complex variables to deliver the solution.**

Each level is the prerequisite to be able to integrate the higher level.

*The integration of complexity and the heterogeneity of all these factors make Ikonisys a unique player in the world for the **completeness of the offer in anatomical pathology.***



Business Model (1) - Instruments placements driving recurring revenues



Sales driver

- **Diagnostic 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 application to several
- Option to add additional slide components 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
- For Ikoniscope:
 - 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 + Digital pathology

- **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**



Business Model (2) – Urine24: the 1st B2C solution in cytology



- Bladder, kidney and ureter cancers are asymptomatic but account for 20% of cancer cases, especially in people over the age of 40. If caught in time they are curable.
- Urine24 is the world's first self-collected urology screening program.



Can be recommended by the pharmacist or by the urologist. It is an easy-to-use service that can save lives. Recommend it to those who complain of hematuria (blood in the urine), recurrent UTIs or discharge.



Promoting preventive screening of the urinary tract allows for the provision of a service of the highest quality, and at the same time reduces assistance costs.



Human capital is precious. Employees of companies that handle chemicals or other dangerous materials, are exposed to chemical agents regularly, over the long-term. Urine24 is the solution to get them tested easily, for them and for the company.



Directly sold online. The company takes care of everything, including logistics, for the simplest customer experience. (to be launched)



Governments can start a screening program on the outsourced population, providing top-level service to citizens and saving lives and money.

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2. MARKET & COMMERCIALIZATION
3. SUCCESSFUL BUSINESS MODEL AND GROWTH STRATEGY
- 4. COMPANY HIGHLIGHTS**





Take home message

1

Truly integrated cancer diagnostics solutions

- Based on standardized mono-layer preparation from liquid-based cytology
- Designed to expand applications in existing and new fields (FISH on cytology slides).
- 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

- Products 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

«We are in a market with an increasing demand and a decreasing offer, covering the gap is a precious opportunity that requires specific capabilities and network.

We do have that.

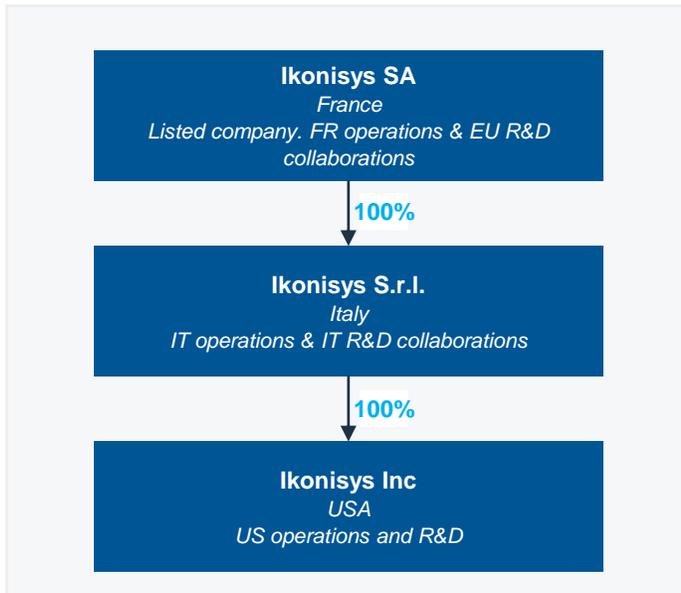
This is a disruptive opportunity in creating **the first integrated solution player**»



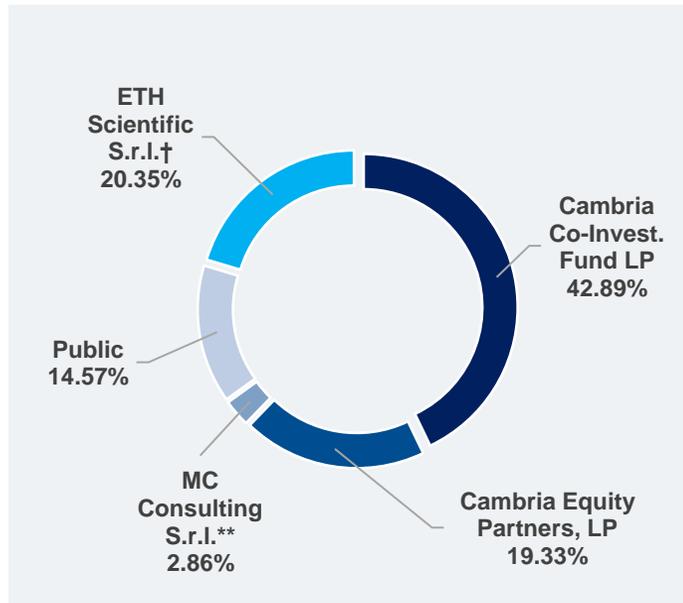
Company information

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

Corporate structure



Shareholders*



* Following the closing of the acquisition of Hospitex
 ** Holding company of Mr. Mario Crovetto, CEO of Ikonisys
 † Holding of Hospitex former shareholders

Stock information

- Listing date: July 19, 2021
- # of shares outstanding: 10,451 M
- Market Cap: 15 M€



Analysts' coverage





Historical Income Statement



<i>Euros</i>	(audited) 31/12/2021	(audited) 31/12/2022	(unaudited) 30/06/2023	(audited) 31/12/2021	(audited) 31/12/2022
Revenues	542,701	935,218	274,598	1,316,964	2,064,329
Cost of Goods Sold	(70,642)	(184,413)	(28,818)	(380,908)	(986,096)
Gross Margin	472,059	750,805	245,780	936,056	1,078,233
Operating expenses before D&A	(955,712)	(2,103,452)	(526,852)	(611,439)	(603,517)
EBITDA	(483,653)	(1,352,647)	(281,072)	324,617	474,716
D&A	(80,579)	(1,083,135)	(632,389)	(197,620)	(314,723)
Interest expenses	(5,107)	(13,537)	(55,465)	(36,129)	(88,265)
Income / (Loss) before Tax	(569,339)	(2,448,320)	(698,926)	90,868	71,728
Taxes	1,931	-	-	(4,045)	(10,041)
Net Income / (Loss)	(571,270)	(2,448,320)	(698,926)	86,823	61,687

IPO on July 19 2021

Beginning of commercialization of Ikoniscope20

Beginning of commercialization of Ikoniscope20max. First sales in H2



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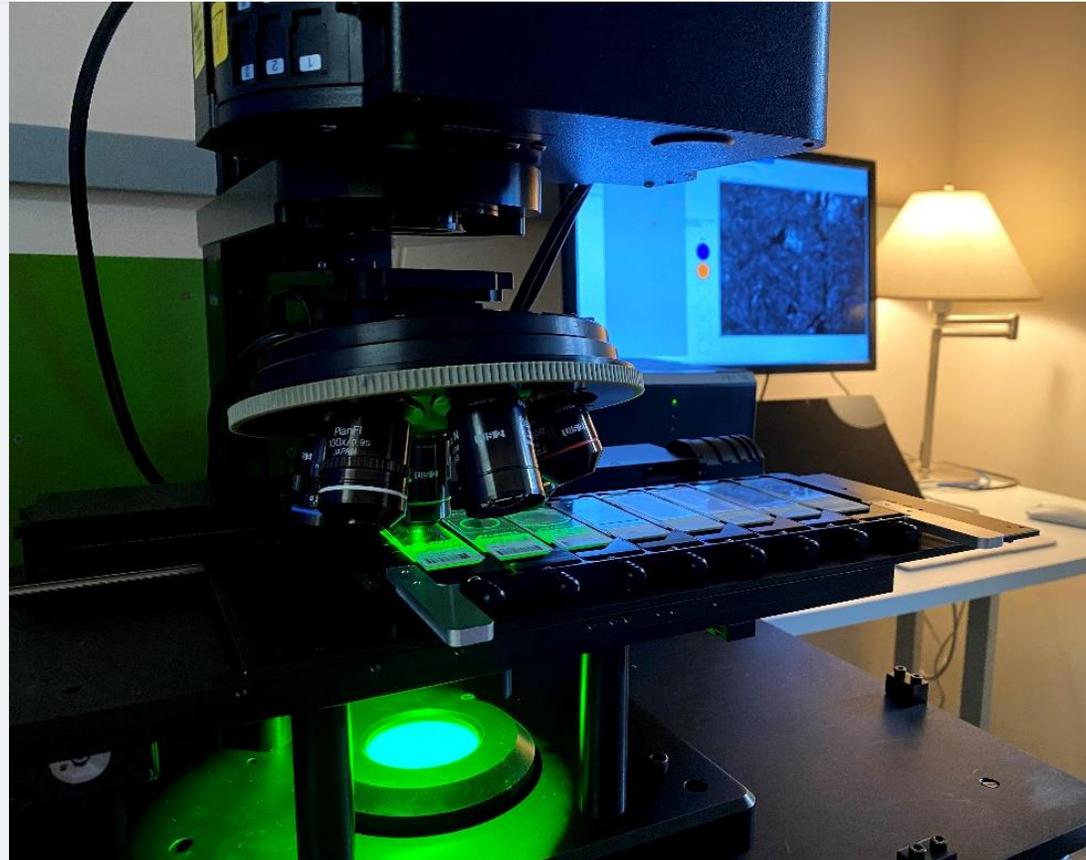
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Francesco Trisolini - COO

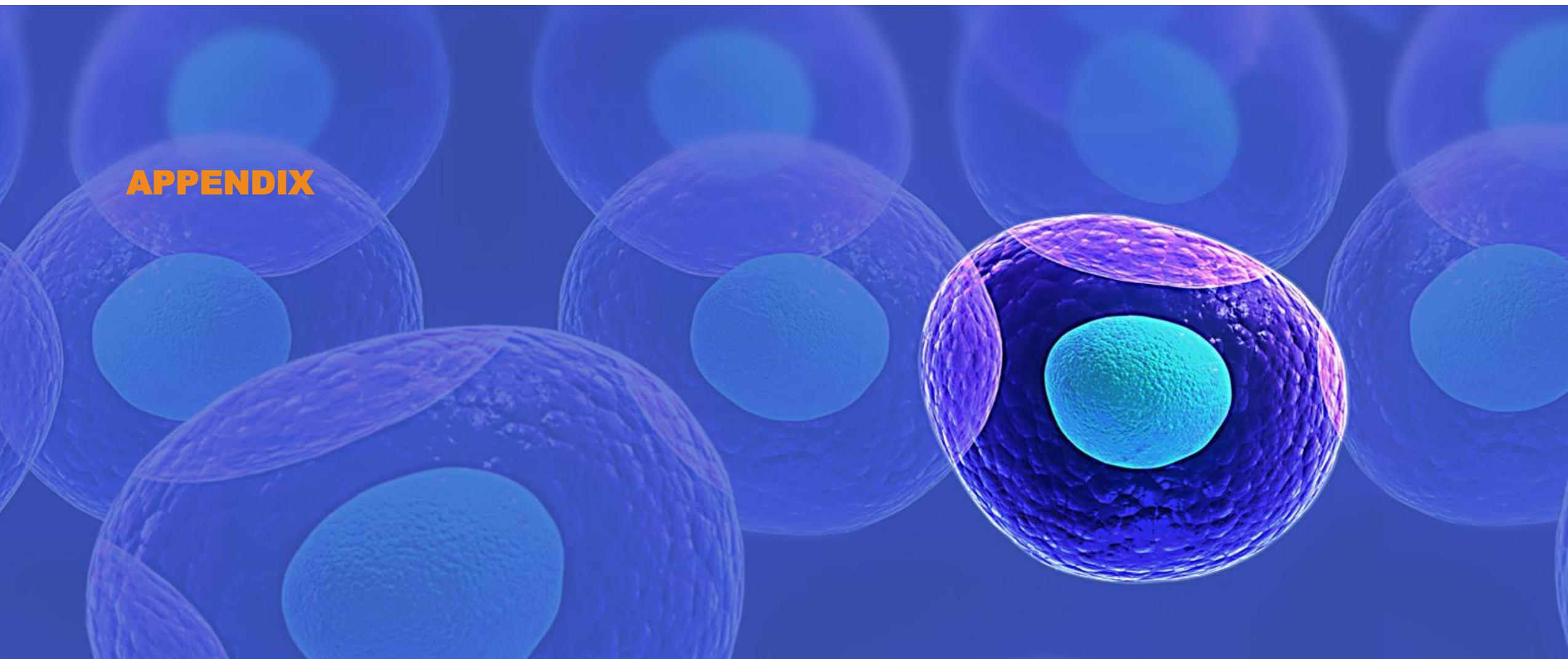
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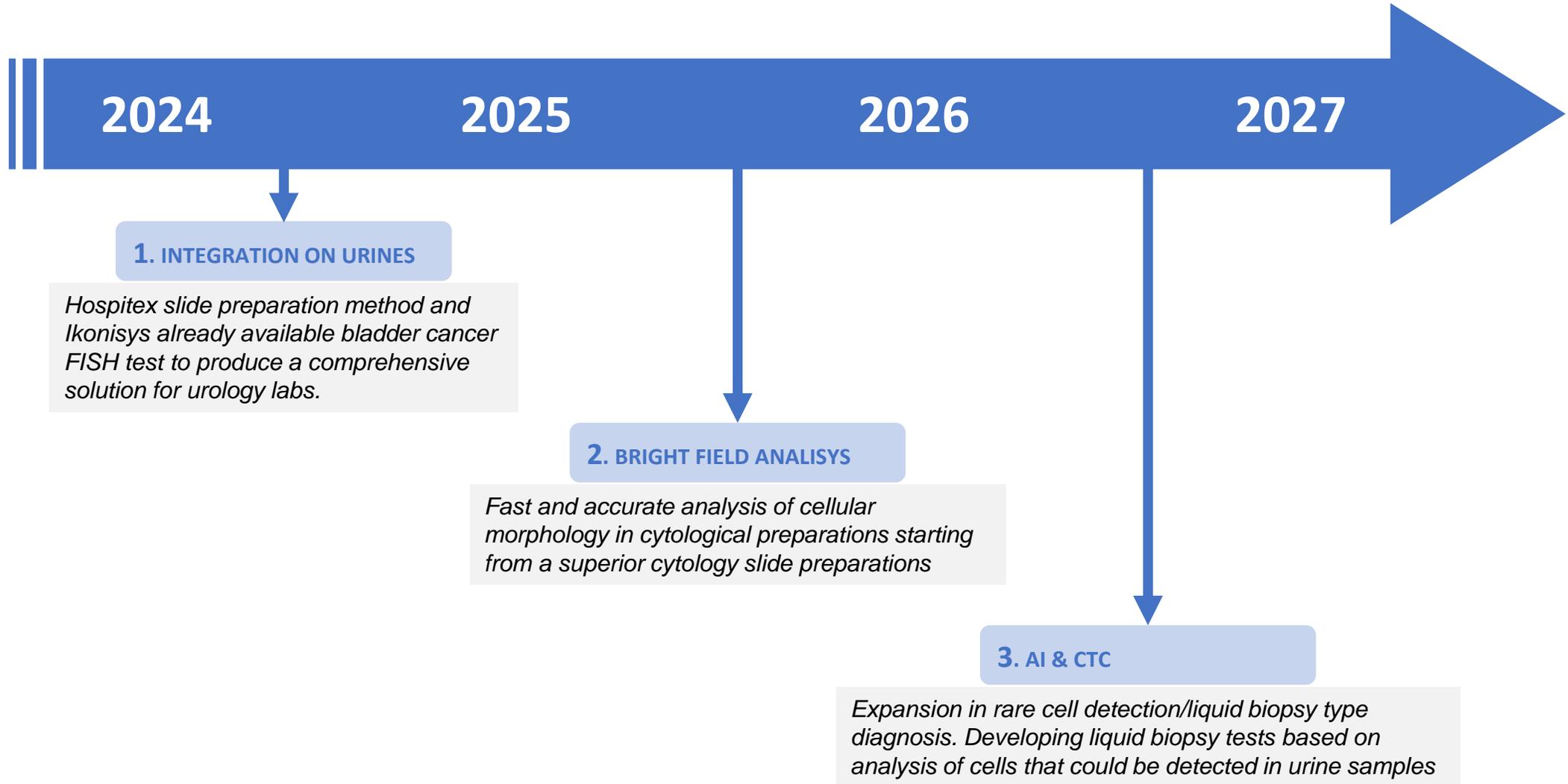
FINDING THE CELLS THAT MATTER

APPENDIX





Long term Product Strategy





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



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

Artificial intelligence: a tool in the hands of the pathologist



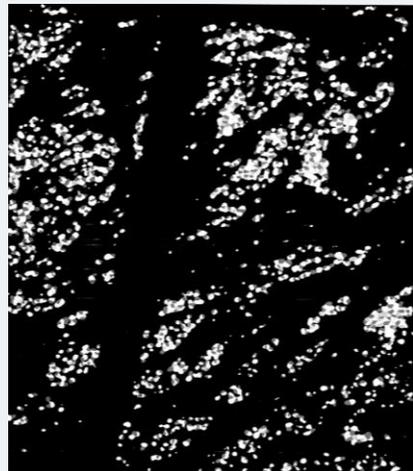
AI will be integrated in the pathologist's workflow, to enhance efficiency and expand possibilities

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**

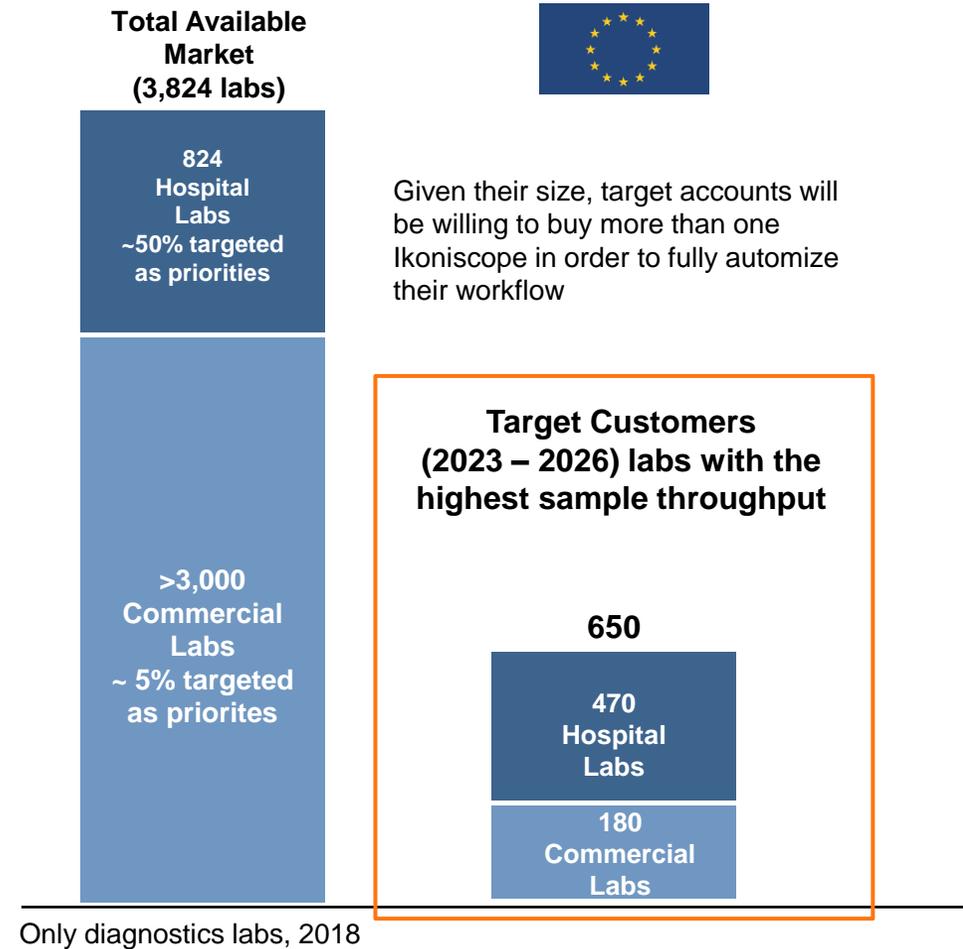
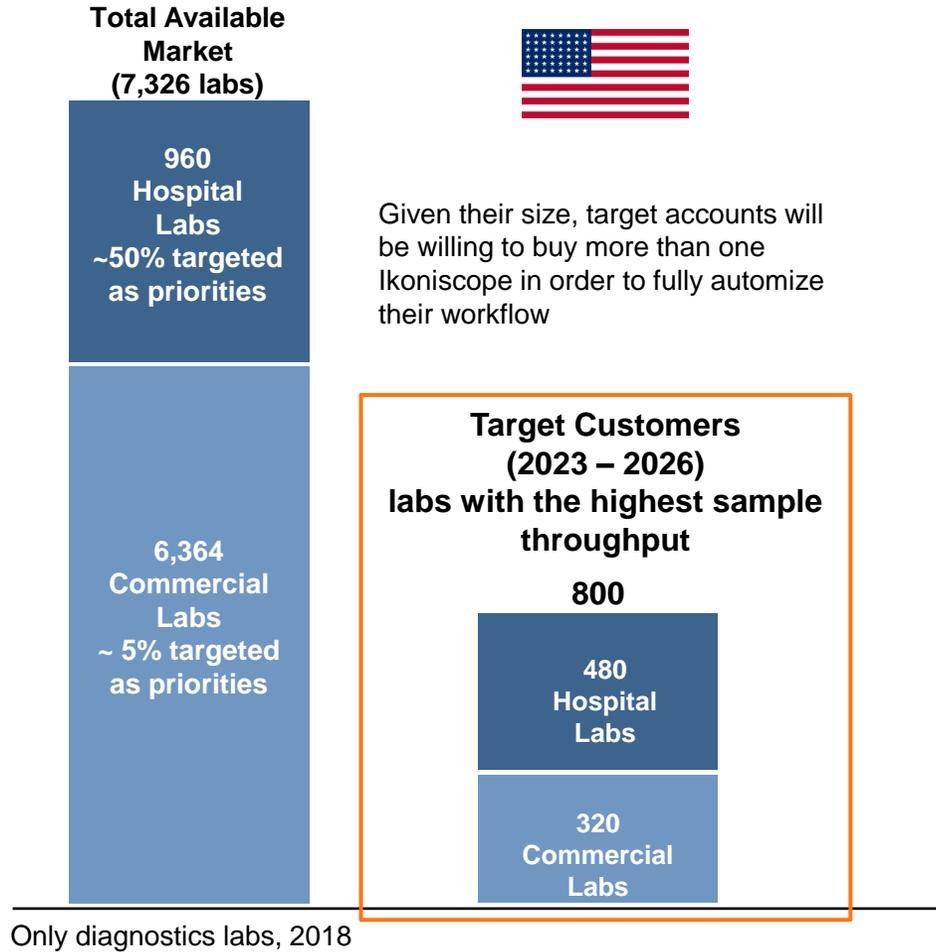
4 Data integration

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

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



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



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

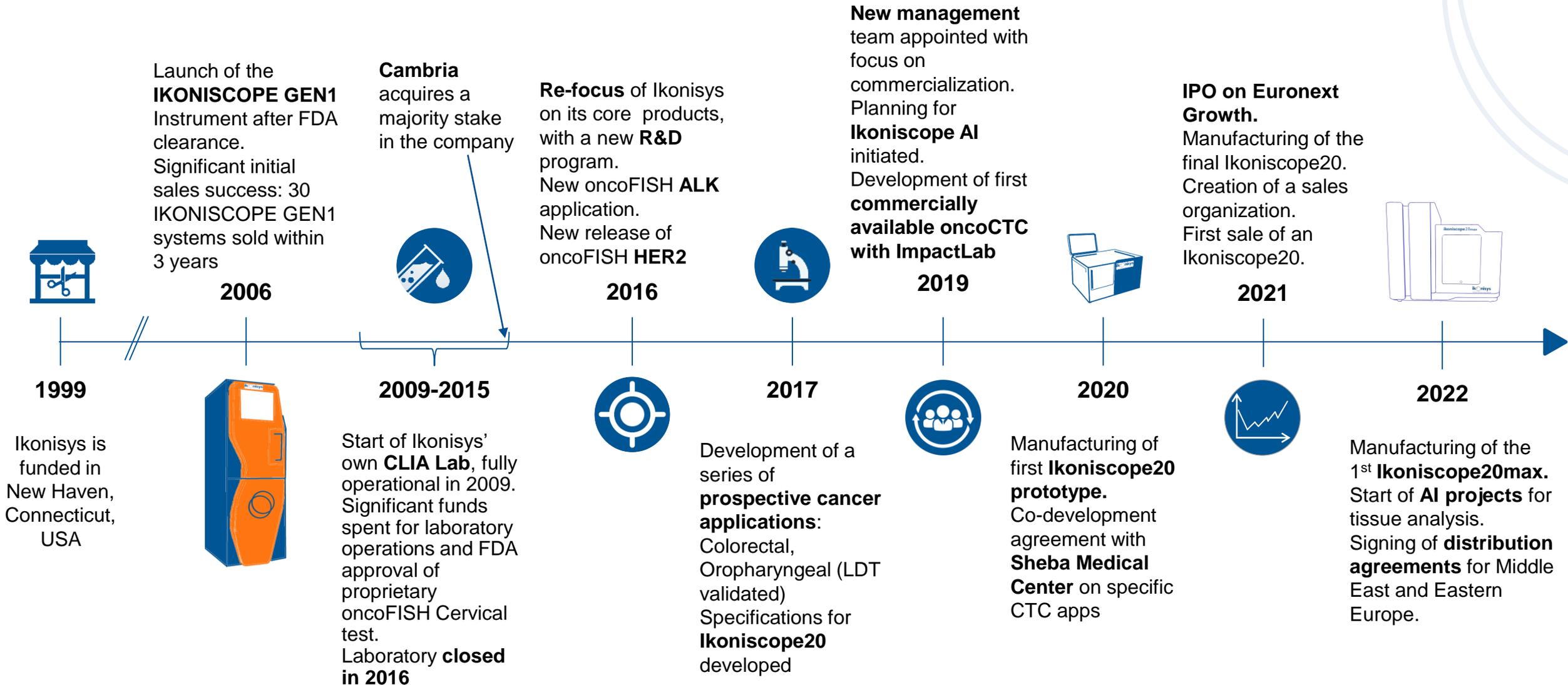
For the development of **cancer specific CTC-based test**

Full characterization

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



Brief company history





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**

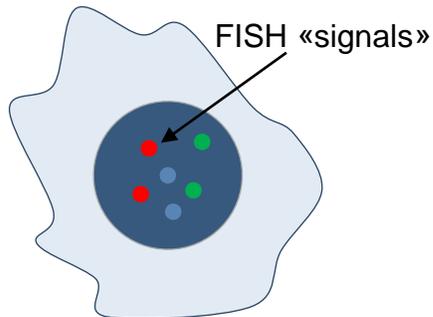


FISH at a glance

- 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

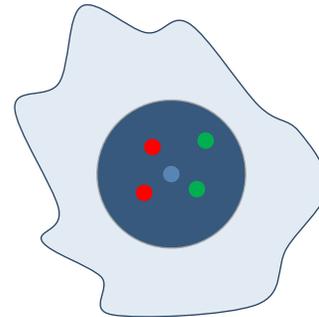
Example: measuring the number of copies of HER2 (Human epidermal growth factor receptor 2) in breast cancer to single out patients that are most likely to respond to Herceptin (trastuzumab) treatment.

Normal



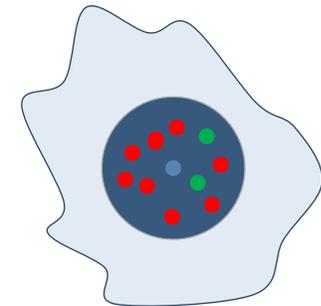
Normal copies (2 dots) of all targeted genes are present

Abnormal: HER2- Prognosis: Poor



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

Abnormal: HER2+ Prognosis: Favourable

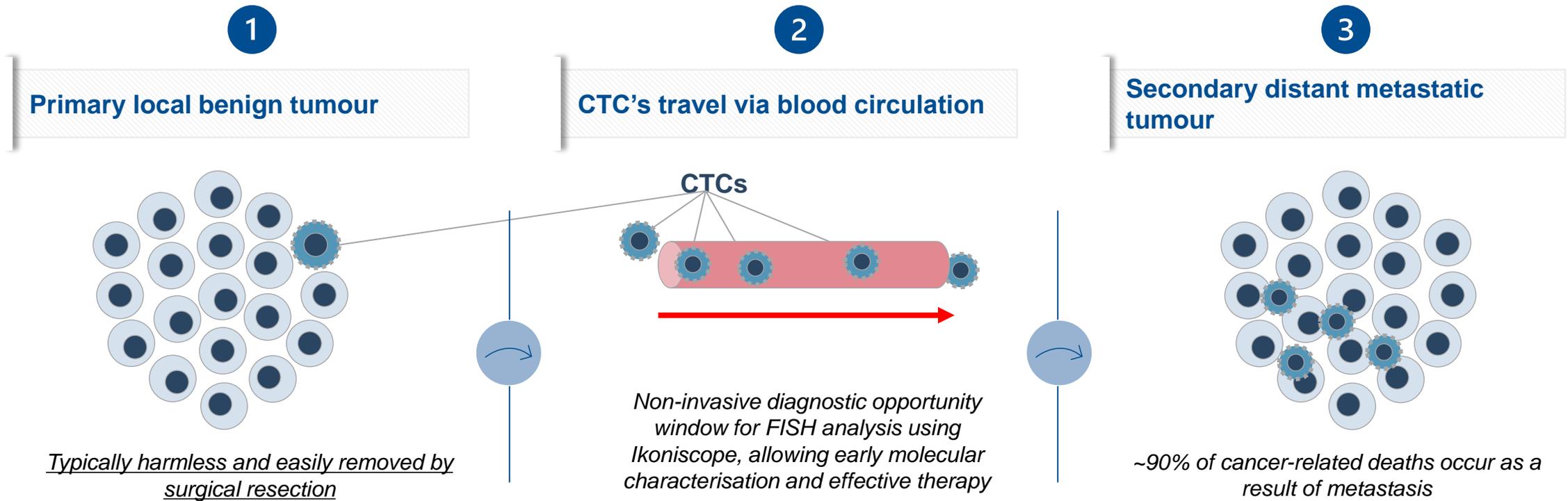


Hemizygous deletion causes cancerous growth, but HER2 amplification (8 copies) provides treatment target for trastuzumab



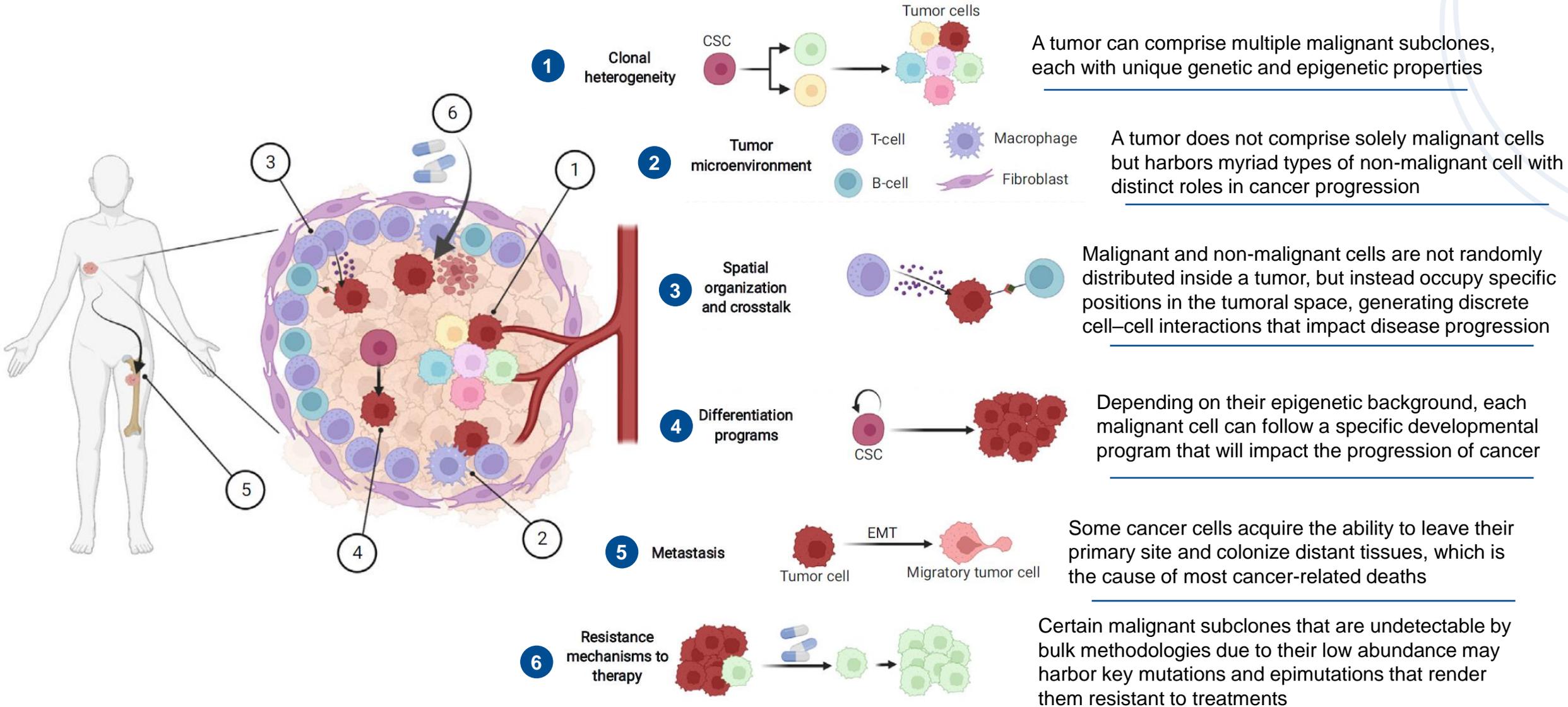
Circulating Tumor Cells (CTC) at a glance

- 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