25 November 2021 11:24 GMT



# COMPANY NOTE

# **Ikonisys** (ALIKO-FR)

Opening the door to Al-digital and liquid pathology

#### **KEY TAKEAWAY**

The new load-and-walk Ikoniscope20 digital pathology platform looks an ideal solution for tissue and liquid biopsies in cancer pathology. It allows rapid identification of individual tumour, immune and other rare cells in solid tissue and liquid biopsies, facilitating diagnosis and treatment monitoring / precision therapy. Guided by a new commercial management, compatible with existing workflows, the Ikoniscope20 should generate growing consumable and other recurrent revenues from an expanding installed base. The system has broad application; initially in FISH (fluorescence in situ hybridisation), but increasingly in CTC (circulating tumour cell) based liquid biopsies, immunotherapy, and infectious disease. The global market for FISH analysis is expected to be c.\$1.8bn in 2024E. A 30% penetration of higher volume pathology units could generate revenues >€100m p.a. from FISH alone. An enhanced Alenabled IkoniscopeAl is expected from 2023E. We initiate coverage of Ikonisys SA OUTPERFORM with a €10 / share target price.

System launch based on validated platform - The existing >40 GEN1 lkoniscope installed base includes large US commercial pathology labs, processing tens of thousands of FISH tests per year. The compact new lkoniscope20 will make the technology available to >10,000 US / EU pathology labs. Saving up to 65% of current hands-on analysis, lkonisys' unique load-and-walk image processing and interpretation platform aims to remove a bottleneck by providing an automated digital solution in tissue and CTC liquid biopsy.

**Robust adoption expected for Ikoniscope20** - Long experienced in healthcare CEO Mario Crovetto has assembled a team with extensive experience in diagnostics sales and marketing well-equipped to execute a launch. Many current GEN1 customers are keen to upgrade, with a strong appetite for integrated load-and-walk solution within in pathology market. Easily integrated into existing workflow, we anticipate robust adoption of the Ikoniscope20 system in the US and EU with global installed base >500 by 2026E.

**Recurrent revenues from installed base** - Expanding installed base should generate recurrent revenues from maintenance, software, and own-brand consumables optimised for platform. Assuming 30% adoption by 1,450 high volume cancer pathology labs, we estimate c.€43m revenues by 2026E and >€70m by 2030E based on FISH alone; with further upside expected from CTC and other applications.

**Growing market for FISH gold standard** - While we expect growing use of liquid biopsies, combining molecular diagnostics with clinically critical cellular pathology, FISH remains the gold standard for diagnosis and cancer care. The FISH market is expected to approach \$1.8bn by 2024E.

Substantial opportunity in CTC liquid biopsy and beyond - With proven capability in blood rare cell detection and analysis, Ikonoscope20 is ideal for CTCs liquid biopsies, with no enrichment on standard blood smears. Adaptable to new imaging markers, it has broad application for patient immune cell analysis for targeted immunotherapy and infectious pathogen detection.

2020A	2021E	2022E
1	1	5
0	(1)	(1)
(2)	(1)	(1)
0.0	2.2	0.5
	1 0 (2)	1 1 0 (1) (2) (1)

Source: Ikonisys SA, goetzpartners Research estimates. Warning Note: Past performance and forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations

# **OUTPERFORM**

Target Price €10.00 Current Price €2.73

0.9

4.306

#### FINANCIAL SUMMARY Net Cash/Debt (M): 4.00 MARKET DATA Current Price: £2 73 Target Price €10.00 52 Week Range: €4.70 - €2.70 Total Enterprise Value: 24 Market Cap (M): 26 Shares Out (M): 95

Float (M):

Average Daily Volume:

# **EQUITY** RESEARCH

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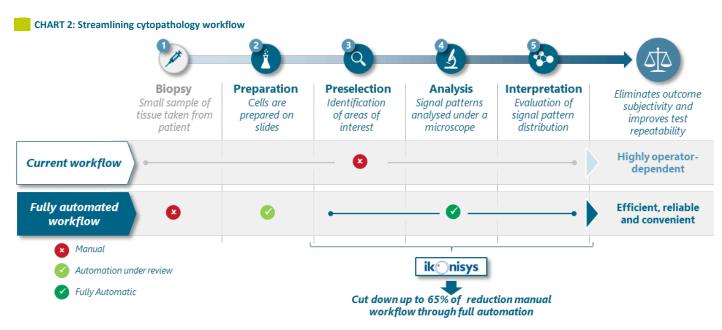
Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

# Key investment highlights

The proposed \$8bn acquisition of Grail by Illumina highlights the potential for gene-based liquid biopsies to accelerate the detection of cancer. While early detection will save lives, it is critical that early diagnosis is accompanied by the diagnostic and prognostics tools required to guide, optimise and, crucially, when necessary, avoid therapy. Efficiently combining molecular diagnostics with cytopathology, digital molecular pathology will become central to tumour management; particularly with the increasing use of Al and machine learning able to provide reproducible diagnosis from complex data sets.

Founded in 1999 in New Haven USA, now headquartered in Paris with offices in Italy, Ikonisys is a commercial stage medical technology focused on developing fully automated solutions to meet the new challenges facing digital and molecular pathology. The Ikonisys Ikoniscope platform allows the rapid identification of individual tumour, immune and other rare cells in solid tissue as well as in liquid / blood biopsies. The platform facilitates diagnosis, prognosis, and treatment decision-making by streamlining already well-established diagnostic approaches, as well as opening the door to novel technologies. This includes circulating tumour cells ("CTCs") as well as the cancer directed immune cells, enabling the analysis of both the patient's tumour and crucially the specific immune response to it. Reducing the mounting pressure on increasingly stretched pathology departments in hospitals and private labs, the Ikoniscope robotic microscopy platform provides automated slide handling, slide scanning, image capture as well as analytics capabilities, increasing reliability with a 65% reduction in hands-on workflow (CHART 2).

The first generation GEN1 Ikoniscope is both clinically and commercially validated through an existing international installed base in major commercial and clinical pathology labs. Ikonisys is now rolling out the Ikoniscope20 in 2021, a more advanced and compact version of the Ikonisys platform, which is based on the same technology underlying the success of GEN1, thus significantly de-risking the launch of this new device. We anticipate first uptake in 2021, catalysed by a recently strengthened management team with a high level of expertise in commercial execution in the field of molecular diagnostics. Ikonisys recently recruited a Head of Sales for the US market, who has not only extensive experience in diagnostic marketing, but also was previously with Ikonisys and instrumental in the adoption of the GEN1 system by US market leaders. The resulting increase in installed base will pave the way for a recurring stream of revenue from kits, software, and maintenance (CHART 1). Using multiple valuation techniques including a discounted cash flow ("DCF") analysis, we derive an equity value of €92m − €157m.



Source: Ikonisys, goetzpartners Research



# Key strengths and risks

#### **Strengths**

- Proven platform
- Endorsed by leading players
- Substantial unmet need
- Growing market
- Complementary to current diagnostic workflow
- Flexible open platform
- Multiple and recurring revenue streams
- Multiple applications
- Experienced management team

#### **Risks**

- Commercial infrastructure to be further built
- Ikoniscope20 yet to fully launch
- Established competition
- Significant execution risk

# Core competence: Revolutionising clinical pathology

Ikonisys has developed fully automated rare cell detection equipment that is set to significantly improve the working efficiency of clinical pathologists, who are increasingly front and centre in cancer care. Rapid advances in our molecular understanding of cancer are allowing earlier diagnosis and better targeting and personalisation of cancer therapies. Constrained by the use of largely manual procedures, pathology departments are increasingly overwhelmed by the rapidly rising demand for cytopathological techniques, particularly FISH (fluorescent in-situ hybridisation) testing for cancer-related markers such as HER2, to improve diagnosis, prognosis as well as disease management. Based on its established technology and ability to automate and seamlessly integrate into existing cytopathological workflows, the Ikoniscope looks ideally placed to relieve this burden and exploit a substantial opportunity in this growing market.

Manual approaches to scoring cells under a microscope are labourintensive, time-consuming, and inefficient. The Ikoniscope can help alleviate pressure on understaffed pathology departments

# Launch of new model this year the key catalyst

Ikonisys' first generation Ikoniscope automated digital pathology platform has already been validated and optimised through an existing and long-established installed base of 46 systems across the US and Europe. Providing digital read-out with up to an 65% reduction in manual input, the Ikonisys GEN1 system has become the prime workhorse for FISH analysis in leading commercial and larger US pathology laboratories for a number of major cancers. Fully automated and darkroom-free, the launch of the optimised, compact benchtop Ikoniscope20 in 2021 makes this technology broadly available to the increasing number of hospitals and larger private labs struggling to cope with the growing demand for molecular pathology. With molecular pathology expected to play an increasing role in the personalisation and targeting of immunotherapies, this self-contained benchtop platform will provide pathologists with a valuable and reliable resource. There are significant additional opportunities outside cancer such as infectious disease, a miniaturised third generation IkoniscopeAl platform, planned for launch in 2023E, is expected to significantly extend image collection and processing to a full range of molecular and cytopathological markers supported by Al-based data management.

# CHART 3: Selected clients to date LabCorp CPKO PathGroup Comprehensive Urology MHP





Source: Ikonisys

# \$0.9bn \$1.1bn \$1.8bn \$0.9bn \$1.1bn \$2014 \$2018 \$2024E \$2018 \$

Source: Frost & Sullivan

# Rapid system adoption to drive recurring revenue

Complementary and non-disruptive to conventional cytopathology workflows, the Ikoniscope20 system should achieve rapid adoption within its overburdened target market, particularly given the increased pressure on labs to carry out a high volume of coronavirus testing at present. Aside from the short-term impacts of COVID-19 on customer budgeting, buyer uncertainty is unlikely to materially constrain commercial development as the majority of competing systems fail to provide a similar degree of automation and analytical sophistication. In addition, the growing installed base should generate multiple recurrent revenue streams through maintenance, software, and own-brand diagnostic kit sales. While demand is expected to grow driven by the increasing use of FISH cytopathology, a market expected to reach \$1.8bn by 2024E (CHART 4), the platform has broad additional application including detection and analysis of CTCs as well as any other fluorescent probes that might emerge to complement or displace FISH.

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Circulating tumour cells allow non-invasive tumour detection and profiling

Experienced management team well-positioned to roll-out the already proven digital pathology platform

# Large commercial potential in high-growth CTC market

While FISH-mediated characterisation of solid tissue samples is Ikonisys' current core competence, the same technology can be applied to the analysis of circulating tumour cells extracted from patients' blood. CTCs have increasingly moved to the centre of attention of molecular diagnostics due to their large potential in non-invasive tumour detection and profiling, which has fuelled growth of a number of prominent players in the field. Avoiding the need for CTC pre-enrichment and potential bias of competing technologies, the Ikonisys platform has the substantial advantage that it can be used on whole blood samples. Ikonisys is well-positioned to benefit from the fast expansion of the liquid biopsy industry, expected to grow at a 25% CAGR (2019 - 2024E, Brandessence, 2018), thus representing additional upside to future performance. To harness this opportunity, Ikonisys has entered into a collaboration agreement with Sheba Medical Centre, the largest hospital in the Middle East, to develop a range of CTC tests for the Ikoniscope platform.

# Leveraging the molecular pathology of immune cells

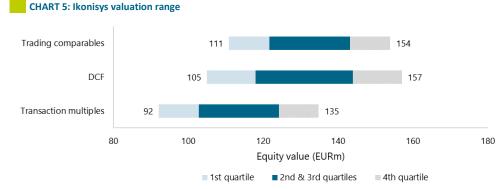
There is increasing evidence that analysis of the response of immune cells may provide a powerful means in diagnosing and guiding therapy in both cancer and infectious disease. Ikonisys has already entered into a collaboration with UConn to look at how specific T-Cells in blood respond to various immunological challenges. The company recently announced its success in the detection of cancer antigen-specific CD8 T-cells, which could provide an important handle on key patient anti-cancer immune responses. More recently the company entered into a MoU to provide Dr Ehsan Ghorani of Imperial College with Ikoniscope20 systems to investigate the potential of digital morphology not only in cancer, but in a range of other diseases including infectious, cardiovascular, and connective tissue diseases. This project will be taken forward when Ikonisys has sufficient financial resources.

# Management team with expertise in commercial execution

Ikonisys is led by an ambitious and highly experienced management team that was recently reinforced by the addition of a number of members with a strong track record in molecular diagnostics. Led by healthcare veteran CEO Mario Crovetto, the leadership team includes CCO Juergen Schipper, who brings expertise in managing large-scale commercial and marketing strategies from major diagnostic players, including Luminex and Omega Diagnostics. The company also recently recruited Manny Iglesias as Sales Director for the US. A highly experienced diagnostics marketeer, Iglesias was previously with Ikonisys and played a key role in the adoption of the GEN1 system by major pathology laboratory service providers in the US. The company is consequently well-positioned to deliver an effective commercial roll out of their already proven digital pathology platform.

# Indicative valuation based on multiple valuation techniques

Ikonisys is an established medtech company with a commercial track record, however, revenues are still relatively modest. We feel that the valuation methodology that best captures the long-term growth potential is a discounted cash flow ("DCF") analysis, which we further complement with an analysis of trading comparables as well as transaction multiples from recent M&A deals in the space in which Ikonisys is active. Finally, we performed a sensitivity analysis on the various valuation methods to provide alternative valuation scenarios, which yield the valuation ranges shown in CHART 5 suggests an average valuation range of  $\epsilon$ 0. Given the inherent uncertainly associated with product roll out we estimate a target price of  $\epsilon$ 10 / share.



Source: goetzpartners Research estimates

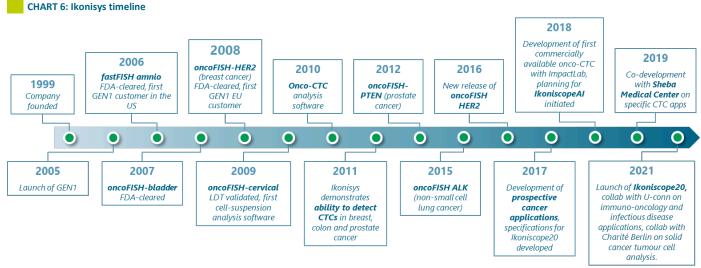


# Building sales and commercial infrastructure

Led by a newly installed commercial management team with an extensive background in healthcare and *in vitro* diagnostics, Ikonisys is using the €4m in gross proceeds from the IPO to build up their commercial and sales infrastructure and to finalise the launch of Ikoniscope20 in the US and EU, before raising additional funds to drive the development of the IkoniscopeAI platform in the future. We anticipate investments into sales and marketing to translate into rapid expansion of the Ikoniscope20 installed base, forming a solid foundation for sustainable top-line growth from 2022E.

## Company background

The Ikoniscope platform represents the core of Ikonisys' operations and offers fully-automated detection and analysis of tissue samples Ikonisys was founded in 1999 and is headquartered in New Haven, Connecticut. The company develops and markets fully automated diagnostic solutions for rare cell detection, analysis and interpretation in oncology and infectious disease. Their four current revenue streams are comprised of Ikoniscope fully automated digital microscope sales, reagent kits, software applications and maintenance services. The company is already generating revenues and the technology platform is validated by an existing installed base of 46 systems and a >10-year commercial track record (CHART 6).



Source: Ikonisys, goetzpartners Research

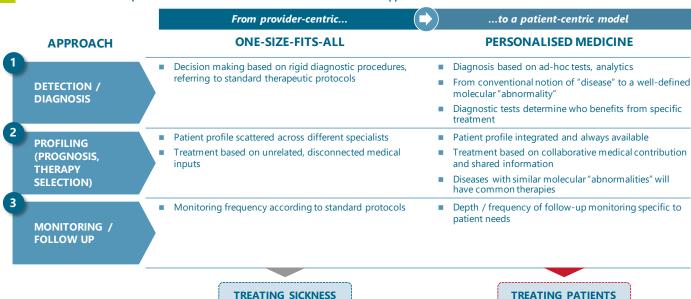
Tumour heterogeneity is a significant challenge, driving the need for accurate molecular profiling to enable tailored therapeutic regimens

# The importance of personalising cancer care

Substantial advances in the characterisation of the human genome have led to a much better understanding of the genetic mechanisms underlying different types of cancer. A key observation is the fact that cancer cells within the same tumour can display different genotypic, phenotypic, and morphological profiles (tumour heterogeneity), driven by their underlying genetic make-up. On one hand, tumour heterogeneity represents a significant challenge in designing effective treatment. However, an increased understanding and characterisation of tumour biology forms the basis of more accurate molecular profiling of individual patients, enabling better stratification and prognosis, thus paving the way for tailored therapeutic regimens utilising more refined treatment strategies with higher therapeutic yield and reduced risk of adverse events. Facilitated by the use of AI, molecular diagnostics and a growing repertoire of genetic markers used to guide treatment are playing an increasingly important role in the personalisation of cancer therapy by facilitating the differentiation between aggressive and benign pathology, allowing patients to receive the most effective treatments for their specific cancer or to avoid the discomfort and expense of unnecessary or ineffective interventions.



#### CHART 7: The benefits of personalised medicine vs. the traditional one-size-fits all approach



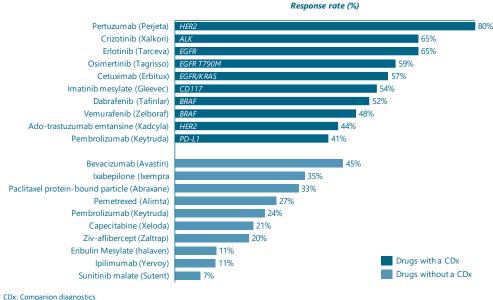
Source: Ikonisys, goetzpartners Research

Improved understanding of tumour genetics and biomarkers has driven development of targeted therapies that improve therapeutic outcomes

# Targeted therapy with specific mutant-directed drugs

Many companion diagnostics are based on biomarkers linking a drug to a specific genotypic marker that defines the sensitivity of the cancer to a particular drug (CHART 8). Sequencing efforts have identified about 140 genes known to be drivers of the oncogenic phenotype, and they are closely linked to disease mechanisms that support oncogenesis and determine cell fate, cell survival, and genome maintenance. Improvements in genome sequencing technology and increased efforts on advancing our understanding of tumour genetics are expected to drive the positive impact of personalised cancer care on therapeutic outcomes and improving patient survival.

CHART 8: Response to targeted therapies with and without companion diagnostics



CDx: Companion diagnostics Source: Jorgensen & Hersom, 2016



Numerous molecular diagnostic techniques allow analysis of tumour cells outside their biological context

# Tumour molecular diagnostics: FISH, PCR and NGS

Molecular diagnostics ("MDx") describes a number of techniques used to measure and analyse DNA and RNA at the molecular level in vitro, i.e., outside of their normal biological context, with the aim to signify changes in biochemical pathways. Key factors driving the importance of these molecular diagnostic techniques are their specificity, scope of application and quick turnaround time. Continuous progress in our understanding of genetic markers and their role in disease is expected to open a huge opportunity for the use of MDx in companion diagnostics. Current approaches include:

- Fluorescent *in situ* hybridisation ("FISH") uses fluorescent markers that recognise and visualise specific genetic sequences *in situ*, i.e., in their original location within cells;
- Polymerase chain reaction ("PCR") amplifies specific DNA sequences that can then be quantified using several methods including gel electrophoresis;
- Next generation sequencing ("NGS") is a quantitative method used to sequence whole genomes at high speed and at low cost.

Huge promise seen these NGS analytic techniques, but molecular pathology is still vital for therapeutic decision making As previously mentioned, the proposed \$8bn acquisition of Grail by Illumina illustrates the progress and promise of NGS analysis of circulating tumour DNA. However, while this appears to provide the means to detect cancers at an early stage, it does not necessarily provide information as to the nature of the tumour cells from which the DNA is derived. Given the innate heterogeneity of cancer cells, such information may be vital for choosing the most appropriate therapy and most importantly avoiding inappropriate or unnecessary therapy in an increasing number of early diagnosed patients. A rapid, effective means of performing digital / molecular pathology on both tissues as well as circulating tumour cells will be critical.

# **FISH in cancer diagnostics**

Detection of chromosomal rearrangements by FISH is well-accepted as a reliable technique for the diagnosis of a number of different types of cancer. Using FISH, genetic changes associated with cancer can be visualised under a microscope, providing pathologists with molecular intelligence on genotype as well as cell morphology – two determining factors for prognosis and therapeutic intervention. While FISH is a well-established and powerful tool for cancer detection, manual approaches to scoring cells under a microscope are labour-intensive, time-consuming, and inefficient, thus increasing pressure on already stretched cytopathology departments. Despite this, the FISH market is one of the fastest growing segments of the overall molecular diagnostics market, currently estimated at \$1.1bn and projected to exceed \$1.7bn by 2024E, fuelled mainly by a growing demand for accurate and rapid cytogenetic techniques for the molecular characterisation of cancer.

FISH allows visualisation of genetic changes in cancer cells, which helps determine prognosis and chose appropriate therapeutic interventions

#### CHART 9: Common FISH probes

Probe	Disorder
CEP3,3,17; p16	Bladder carcinoma
HER-2/CEPI17	Breast cancer
TOP2A	Breast cancer
TERC/CEP3	Cervical cancer
EWSR1	Ewing sarcoma
EGFR	NSCLC
ALK	NSCLC
ROS1	NSCLC
PTEN	Prostate cancer
PHLPP1	Prostate cancer
ERG	Prostate cancer

Source: Hu et al. Biomarker Research (2014)

### FISH at a glance

#### FISH for cancer detection

FISH is a cytogenetic test used to map the pattern of gene expression in human cells. FISH can detect abnormalities such as deletions and amplifications of certain genes associated with cancer (CHART 9), making it a powerful diagnostic tool. In addition to facilitating cancer diagnosis, a FISH test may also provide useful additional information on patient prognosis and can help determine how likely a patient is to respond to different types of treatment such as chemotherapy.

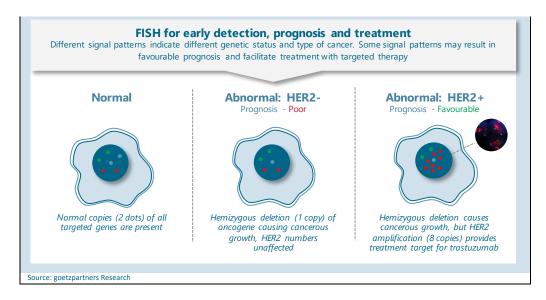
#### HER2 testing for breast cancer prognosis

For example, a FISH test can measure the number of copies of the Human epidermal growth factor receptor 2 ("HER2") gene in breast cancer tissue removed during a biopsy. HER2 is a common receptor found in all breast cells, but extra copies of the gene can stimulate breast cancer growth and spread. However, cells expressing larger numbers of the HER2 receptor are more likely to respond to Herceptin (trastuzumab) treatment, which downregulates tumour growth by acting on the HER2 receptor. Since Herceptin only has a beneficial effect in breast cancers where HER2 is overexpressed (only 20% - 30% of early-stage breast cancers), FISH can help single out patients that are most likely to respond to therapy and spare others from undergoing unnecessary treatment.

#### FISH technology at a glance

Special fluorescent labels that recognise genetic markers associated with certain cancers attach to specific parts in the tissue under investigation and emit a coloured signal that can then be visualised using a fluorescent microscope, allowing pathologists to visualise cancer-promoting abnormalities.





FISH offers more comprehensive cyto-pathological characterisation of tissue samples

#### FISH benefits from a number of advantages compared with other IVD approaches

While NGS and PCR can accurately confirm the presence of particular markers, a key advantage of FISH is its compatibility with the provision of more detailed information on the cells under investigation. This offers pathologists a more comprehensive insight into underlying disease pathology, which forms an essential part of optimising patient outcomes given the high degree of complexity and heterogeneity of tumours. FISH's ability to provide detailed information not only on the existence of specific markers, but also on their spatial distribution within a tumour have made it an indispensable part of the rapidly developing field of personalised medicine despite being a relatively low-throughput cytogenetic test. This has led to the development and commercialisation of a range of FISH probes for a variety of different cancers (CHART 9). In addition, FISH benefits from high resolution, a relatively simple preparation protocol, and the ability to visualise multiple abnormalities simultaneously.

#### CHART 10: FISH's positioning in the diagnostic landscape and advantages over IHC, qRT-PCR and NGS

	IHC	FISH	qRT-PCR	NGS
Method	Identifies protein overexpression	Uses gene amplification	Analyses mRNA determination	High-throughput sequencing
Results type	Subjective	Semi-quantitative	Quantitative	Quantitative
Hands-on time	Significant	Significant	Minimal	Significant
Time to results	Hours	Days	Hours	Days
Cost	Low	Low	High	High
Accuracy	Low	High	High	High
Variability	High	Low	Low	Low

IHC: Immunohistochemistry, FISH: Fluorescence in situ hybridization, qRT-PCR: Quantitative reverse transcription polymerase chain reaction, NGS: Next-generation sequencing Source: goetzpartners Research

FISH combines qualitative and quantitative data, whilst is reliable, simple, and accurate, meaning it will remain integral for cancer diagnostics

#### Molecular detection technology progressing rapidly, but FISH expected to remain on top

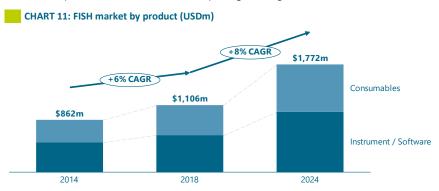
FISH evidently forms a vital component of personalised medicine in today's diagnostic landscape, however, the increasing speed of technological progress in the field of biomarker detection raises the question of whether a classical assay, such as FISH, can withstand the potential threats from new high-throughput molecular tests such as next generation sequencing technologies. We believe quite the opposite will hold true: its unmatched reliability, simplicity and accuracy have made, and will continue to make FISH an integral part in the clinical diagnosis of cancer, especially given its ability to combine qualitative and quantitative data — a hurdle that is unlikely to be overcome by faster tests that solely focus on quantitative output, forming a natural barrier to market erosion. Furthermore, FISH itself continues to develop as a diagnostic technique and does not remain a stationary technology, with efforts to improve image resolution and quality still advancing among fluorescent probe producers. Moreover, we see NGS as a complementary technology to FISH that can be used to discover mutations that can then be tested for using FISH.



The FISH market will witness strong growth due to rising sample volumes and increasing demand for cancer diagnostics in an ageing population

# Market for FISH expected to exceed \$1.7bn by 2024E

The FISH market is one of the fastest growing segments of the overall molecular diagnostics market, expanding at an 8% CAGR and projected to exceed \$1.7bn by 2024E (CHART 11). Despite being an established market, the accelerating CAGR is testimony to the clinical importance and diagnostic validity of FISH. We anticipate the FISH market to witness strong growth fuelled mainly by rising patient sample volumes due to population ageing as well as growing demand for accurate and rapid cytogenetic techniques for the molecular characterisation of cancer, which accounts for >40% of the total market (CHART 14). With the FISH market reaching a stage of maturity, the risk of erosion by disruptive technologies such as NGS is reduced, especially since NGS should be considered complementary to FISH and does not provide the same level of morphological insight.



Source: Ikonisys, goetzpartners Research estimates

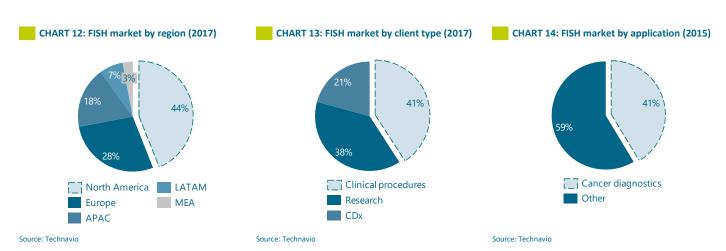
Fastest growth will be seen in Europe and APAC as the US market is mature and saturated

#### North America the largest market but higher growth expected in EMEA and APAC

North America dominates the global FISH market with a 44% market share, followed by Europe and APAC with 28% and 18%, respectively (CHART 12). North America benefits from a large customer base with chronic conditions; however, the US FISH market is mature and quite saturated, with existing vendors providing FISH solutions to a relatively static number of healthcare facilities, which is likely to drive growth deceleration in the mid to long-term. In contrast, Europe and APAC are likely to witness the fastest growth (6.6% and 9.8% until 2025E, respectively), driven by growing awareness of personalised medicine and increases in government initiatives such as FP7 and Horizon2020 that provide funding to promote the opening of new diagnostic centres.

#### FISH market by end-user

Clinical uses account for the majority of the FISH market (41 % in 2017), followed by research studies (38%), and companion diagnostics (21%) (CHART 13). The high share of clinical procedures can be attributed to the large number of diagnostic centres and their widespread use of FISH for diagnostic and prognostic purposes. The companion diagnostics segment is expected to witness the fastest expansion, growing at a >8% CAGR until 2020E (Grand View Research, 2019), fuelled by increasing demand for personalised medicine and an extension of the scope of application of FISH probes to new genetic variations.



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#### Probe market dominated by a few large players

The global FISH market is characterised by strong competition between a few prominent diagnostic players and Abbott has retained its position as market leader since the beginning of FISH assays in clinical diagnostics. Other prominent players include Agilent, Roche Diagnostics, Thermo Fisher Scientific, Leica and Genemed. With the exception of Roche Diagnostics, the largest players are predominantly US-based, but provide good global coverage of FISH probes. Market consolidation and intense competition provide a barrier to entry for smaller innovative players wanting to compete on a global stage. Furthermore, competition arising from smaller players is often dismantled by very aggressive acquisition / partnership strategies conducted by larger players, resulting in a consolidation of their global footprint (Thermo Fisher: 10 acquisitions between 2016 and 2018 – 4 of which in the molecular diagnostics and electronic microscopy sector).

#### FISH manual workflows create bottlenecks

Despite playing an integral part in the diagnostic landscape for cancer, FISH carried out manually is very time-consuming and heavily operator dependent. The human element in FISH analysis represents one of the main limitations to throughput, accuracy, cost, and reproducibility while also restricting the extent of tissue that can be examined. Furthermore, increasing screening rates and cancer incidence are expected to contribute to mounting pressure on already stretched pathology departments that require better solutions to be able to shoulder the increasing burden associated with cancer diagnosis. The estimated additional cost from covering current workforce gaps is estimated to amount to £27m (\$35.5m) annually across the UK – money that could be invested in better diagnostic equipment.

Limitations in throughput and operator-dependency mean FISH is time-consuming when carried out manually

#### Overworked pathology departments unable to cope with current and future demand

Rising pathologist shortages are causing severe delays in diagnosis and treatment. A survey by the Royal College of Pathologists found that only 3% of pathology departments in the UK had enough staff to cope with demand, and that departments with inadequate staff have to outsource work, use temporary staff, or require existing staff to work overtime. In addition to dramatically increasing the risk of diagnostic and medical error as fatigue sets in, these solutions are expensive, unsustainable, and unable to meet increasing future demand, especially in light of the limitations on pathologists' workload set by regulatory bodies. Furthermore, the fact that a quarter of pathology staff in the UK are aged 55 or over implies an imminent retirement crisis, highlighting the large need for digital, automated systems that deliver better outcomes in less time.

Demand for pathology services has grown significantly in recent years but pathology departments are inadequately staffed to meet workloads

#### Other factors currently constraining the FISH market

In addition to shortages in people sufficiently skilled to conduct analysis and interpretation of results, the FISH market is constrained by three other main factors. First, the fact that FISH data analysis is still carried out manually and subject to human judgment — mostly due to a lack of efficient digitalisation solutions and software support — leaves significant room for improvement in the standardisation of care. Second, current systems lack advanced automation capabilities, requiring sporadic human intervention to help along the process, which results in material time inefficiencies and introduces variability. Finally, diagnostic capabilities are unequally distributed, leading to large geographic variations in diagnostic quality.

Manual data analysis is subject to human bias, variability, and time inefficient

#### Advances in probe technology will improve FISH resolution

At present, FISH is only suitable for detecting large chromosomal changes. While the technology is sufficiently powerful to yield significant therapeutic benefits in its current form, future advances in research and design of more sophisticated therapeutics will increase the need for probes with a higher resolution that can accurately identify small mutations. NGS and PCR are currently used to detect these small genetic changes, including deletions and insertions as well as point mutations, thereby representing complementary technologies to FISH. Other main limitations of FISH are the need for a darkroom, although not required by the Ikoniscope platform, and the fact that the sequence of the gene under investigation has to be known to allow pathologists to choose the correct probe.

# Ikonisys differentiates itself from other companies such as BioView and MetaSystems by:

- 1. Higher level of automation
- 2. Better degree of analysis
- 3. Darkroom-free operation

#### Overcoming hurdles – a large commercial opportunity

The fact that there is an established but constrained market for FISH technology represents a large opportunity for vendors developing solutions to alleviate current bottlenecks. While both larger as well as more innovative players have attempted to overcome limiting factors, no system other than the Ikoniscope offers true walk-away functionality that requires no human input from the initial sample loading, at the same level of convenience and sophistication. Semi-automated platforms offered by Leica, PerkinElmer and Olympus offer digital solutions allowing on-screen analysis of slides, however they lack FISH analytical capabilities and require additional handling, thereby limiting throughput

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(CHART 15). More automated solutions such as the Duet-3 platform (BioView), Metafer (MetaSystems) and HiFISH (ASI) offer a larger degree of automation, but still rely on manual guidance to define tumour regions, in addition to requiring oil immersion and dark-rooms to operate.

#### **CHART 15: FISH automation competitive landscape**

	Large imag	ing players focuse	ed on optics		Walk-away		
Manufacturer	Leica	PerkinElmer*	OLYMPUS	<b>Oio</b> view	MetaSystems	APPLIED SPECTRAL IMAGING	ikenisys
System	CytoVision	Vectra 3	VS120	Duet-3	Metafer	HiFISH	Ikoniscope
Full Automation	0	0	0	Р	Р	Р	Р
Data analysis	0	0	0	Р	P	Р	Р
Data interpretation	0	0	0	0	0	0	Р
Darkroom-free	0	0	0	0	0	0	Р

Increasing digitalisation and analytic automation

Source: goetzpartners Research

#### CHART 16: Ikoniscope20



Source: Ikonisys

# **Ikonisys offers digital pathology solutions**

With an established installed base, including some the largest commercial and academic pathology laboratories, the first generation Ikoniscope GEN1 offers fully automated slide handling, scanning and real-time image capture, with 175-slide capacity and the ability to analyse up to 2 million cells on a single slide.

The just launched Ikoniscope20 (shown in CHART 16) provides a high-resolution imaging solution with fully integrated mechanical, optical, IT hardware, and software modules in a self-contained benchtop unit using components from leading players. The platform is capable of multiple applications, but most significantly in cancer the localisation and molecular analysis of tumour cells in tissue biopsy sections as well as circulating tumour cells in liquid biopsies. The key value proposition of the platform is that it offers fully automated slide handling, cell recognition, classification, data capture and data storage solutions combined with highly sophisticated image analysis capabilities. As a result, the Ikoniscope20 can be used to free up valuable resources and help alleviate the high pressure placed on pathology departments at present, while at the same time increasing the amount / quality of time spent on image interpretation by pathologists.

Moreover, the Ikoniscope20 also boasts LAN and WAN connectivity to further improve pathology department efficiency by 1) optimising use of available pathologist manpower (located anywhere with internet connection), 2) allowing another pathologist to offer a second opinion remotely, and 3) providing remote service and support.

We anticipate fast adoption of the Ikoniscope20 driven by a growing need for more efficient solutions that increase FISH throughput. Adoption will also be supported by existing commercial validation for the system from an established installed base of 46 the predecessor Ikonisys systems in major hospitals and private labs and a strong >10-year track-record together with great approval ratings de-risking the device. The system provides a clear benefit in the fact that it improves the precision of image acquisition and analysis and promotes overall workflow efficiency, throughput and cost effectiveness in hospitals and labs.

### FISH automation – a more efficient and reliable alternative

The benefits of automated FISH probe analysis compared with manual procedures are well-documented in scientific literature. Comparative studies have shown equivalent levels of clinical accuracy in identifying and classifying genetic markers between the two methods (>95% concordance, C. Ohlschlegel *et al.*, 2013). Automatic analysis is considered to be at least as reliable as its manual alternative, removing the need for time-consuming case-by-case manual interpretation. The benefits of this are two-fold: 1) automatic procedures are not subject to human judgement – which is intrinsically subjective and potentially misleading – resulting in a fully objective and unbiased classification of cells; 2) the analytical power of automated platforms relies on pre-defined, predictable parameters and is therefore highly replicable – which could contribute to the standardisation of FISH overall, while reducing the need for highly-trained technicians and the impact of inherent variability.



#### A simple 4-step process:

- 1. Load slides into cassettes
- 2. Place cassettes into Ikoniscope
- 3. Initiate run
- 4. Review results and issue report

#### **Ikoniscope system advantages**

Ikonisys markets a number of different software packages for different cancer types with specifically tailored algorithms that recognise relevant features of the sample under investigation, requiring no additional input. The Ikoniscope is unique in the fact that it provides a fully integrated platform that can automatically recognise diagnostically relevant cells and establish parameters that optimise analytical outcome considering factors such as tissue type, cell morphology, chromosome shape, FISH probe type as well as fluorescent intensity. In addition, the Ikoniscope differentiates itself from other platforms in the fact that it is a self-contained unit that does not require a darkroom to work, allowing utilisation of valuable lab space otherwise dedicated to FISH imaging. High-resolution imaging using dry lens optics improves handling and forms the basis to generating clean data, while compatibility with existing technologies ensures seamless integration of the Ikoniscope into existing workflows (CHART 17).

#### **CHART 17: Unique advantages of the Ikoniscope**



Substantial efficiency gains and improved diagnostic output

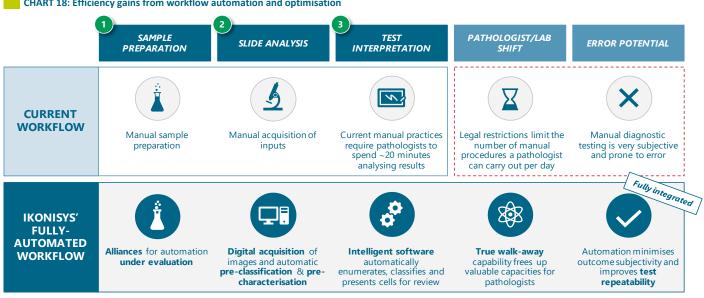
Source: goetzpartners Research

Automation and associated workflow optimisation increase quality and volume of diagnostic output

#### Ikoniscope optimises workflow inefficiencies that currently constrain the FISH market

The Ikoniscope high level of automation combined with a large loading capacity of 96 slides when paired with its optional slide loader (currently under development) for the Ikoniscope20 creates true walkaway functionality that offers unattended processing from start to finish. As a result, slide processing can be carried out overnight or on weekends, resulting in substantial efficiency gains as reflected in faster turnaround times, increased throughput, and improvedcost-effectiveness. Increasing capacity without increasing staff is a key value proposition that directly addresses the growing problem of staffing shortages, while provision of a multipurpose platform reduces CAPEX needs and frees up valuable resources by offering significant time-savings for high-value operators. In terms of diagnostic value, system automation can reduce the risk of human error associated with fatigue, and contribute to standardisation of diagnostic results, higher consistency, and increased sensitivity (the higher the volume of cells reviewed, the higher the probability of identifying rare cells).





Source: Ikonisys, goetzpartners Research



#### Ikoniscope20 new features:

- 1. Updated software
- 2. Increased speed and throughput
- 3. Smaller size
- 4. Configurable loading capacity
- 5. Improved remote access
- 6. Lower maintenance

The IkoniscopeAI is in development and will harness big data and selflearning algorithms for superior data interpretation

Ikonisys will launch at least two applications per year to test additional cancer types

#### Ikoniscope20: Further extending Ikonisys' technological lead

The introduction of next-generation Ikoniscope products will expand Ikonisys' arsenal with more evolved versions of the already highly sophisticated GEN1 platform. Ikoniscope20, a beta version installed with the first customer in Q4/2020E, incorporates all functionalities of the previous model, while adding an updated operating software as well as improved slide-handling capabilities through more sophisticated robotics systems that will further increase speeds and enhance throughput. The smaller size has obvious advantages related to easier shipping, handling, maintenance and set up, whilst the ability for customers to configure the loading capacity up to 96 slides provides the opportunity for customisation according to each lab's particular throughput. The remote access capabilities of the platform have also been improved, in addition to hardware updates that help to lower maintenance requirements.

#### **Charité Collaboration**

In November 2020, Ikonisys formed a collaboration with the Institute of Pathology (Molecular Diagnostics) at Charité, University Medicine Berlin, to evaluate the performance of the Ikoniscope20 platform in analysis of tumour cells in tissue samples of solid cancer, sarcoma and malignant lymphoma. The Ikoniscope20 will be used in a state-of-the-art routine diagnostic laboratory to analyse large numbers of cells for the quantification of clinically relevant cells from complex specimens, based on a combination of markers. Following the successful introduction of the Ikoniscope20, Charité aims to integrate the system into their daily routine testing of cancer tissue samples.

#### IkoniscopeAI: Harnessing the power of big data

Features for the third-generation product, IkoniscopeAI (launch planned for 2023E), are currently under evaluation, but the system is expected to further leverage Ikoniscope20's competitive edge. This includes the addition of powerful big data analytics tools, a self-learning AI algorithm for superior speed and accuracy in data interpretation, access to cloud computing for data management, and direct imaging technology for analysis of both dark field (FISH and immunofluorescence) and bright field (H&E, IHC) microscopy. The company has already entered into an agreement with Hub Innovation Trentino / Bruno Kessler Foundation regarding the design and development of IkoniscopeAI's intelligent software and more recently with an AI group in Latvia.



Source: Ikonisys, goetzpartners Research

#### **Current Ikonisys software solutions**

At present, Ikonisys offers a range of specific applications for bladder cancer, breast cancer (HER2 amplification), cervical cancer, lung cancer (ALK), prostate cancer (PTEN), Barrett's Oesophagus as well as haematological cancers. The company intends to develop and launch a minimum of two additional applications per year based on market demand for new types of tests. While FISH analysis of solid tumours represents a substantial commercial opportunity with a large unmet medical need, the Ikoniscope's ability to automatically detect, analyse and quantify rare fluorescently labelled cells within a sample allow its use to be extended to other applications such as the characterisation of CTCs as well as infectious pathogens using FISH or immunofluorescence.



Outsourcing kit manufacture allows Ikonisys to scale up other applications and focus on development of the platform

#### Outsourcing of FISH kit manufacturing offers commercial flexibility

While Ikoniscope hardware and software are proprietary and developed by Ikonisys directly, the company relies on the expertise of existing probe providers for the manufacturing and supply of FISH consumable kits, which allows consumables revenue to be generated with low CAPEX. While agreements with selected partners have yet to materialise, Ikonisys' previous commercial activities in the market facilitate access to companies offering contract development of FISH reagents as well as to existing probe manufacturers that are open for original equipment manufacturer ("OEM") collaborations. The company can therefore focus its attention on the production and development of the platform, allowing it to scale up its applications in other indications and testing methods while retaining the ability to provide a sufficient supply of high-quality consumables.

#### Expansion into additional areas will be relatively simple, showing promise for long-term commercial

prospects

#### Large potential to expand beyond FISH and cancer

While FISH for cancer detection represents a key market entry point and large driver for Ikoniscope validation and penetration, use of the platform to improve detection of CTCs in liquid biopsy samples, as well as detection and characterisation of infectious diseases, which account for c.17m annual deaths worldwide, provide promising long-term commercial prospects. Expansion would merely be a matter of developing software solutions adapted to reflect changes in underlying test and tissue characteristics. This would allow Ikonisys to offer its unique advantages to a much wider range of laboratories and markets, allowing smaller laboratories carrying out a variety of tests to also benefit from fully scalable workflow optimisation. The IPO of Guardant Health in late 2018, raising \$238m (valuing the company at \$1.6bn and paving the way for an impressive share price performance since, CHART 20), as well as the recent proposal by Illumina to acquire GRAIL for \$8bn, further exemplifies the hype around liquid biopsies for the early detection of cancer. While both Guardant Health's and GRAIL's lead assets focus on the detection of circulating tumour DNA ("ctDNA"), Ikonisys focuses on providing physicians with more comprehensive molecular intelligence by characterising whole CTCs, combining molecular diagnostics with cytopathology.



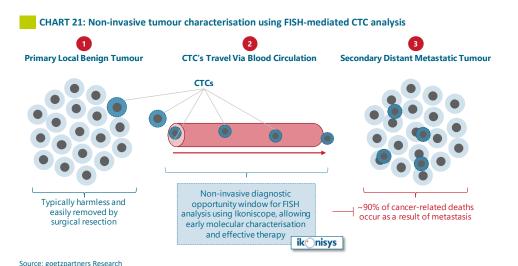
Source: FactSet as of 21<sup>st</sup> December 2020, goetzpartners Research. Warning Note: Past performance is not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

#### Liquid biopsies allow detection of CTCs through a simple blood test, although further analysis is required to guide treatment decisions

#### Characterising blood for the presence of solid tumours using CTCs

Usually, a solid biopsy is performed at the suspected source of the cancer, but this is invasive, expensive, and inconvenient. Liquid biopsies on the other hand provide a non-invasive and more cost-effective alternative to surgical biopsies, enabling physicians to detect cancer simply by testing a patient's blood for the presence of circulating tumour cells – cells that have detached themselves from the primary tumour and circulate in the bloodstream. CTCs are early precursors of distant metastases not found in healthy individuals, but only in patients with cancer, and CTC status is a reliable indicator for disease prognosis. The use of CTCs has a number of advantages over physical biopsies: in addition to being less invasive, it provides a systemic approach that enables physicians to distinguish between *in situ* tumours and invasive cancer and to identify the source as well as the type of the cancer without having to know its exact location to guide surgical biopsy. As such, it can be used early on in the diagnostic process, thus increasing the probability of beneficial therapeutic outcomes, given that sufficient pharmacological interventions are in place to exploit the actionable diagnostic intelligence afforded by FISH.

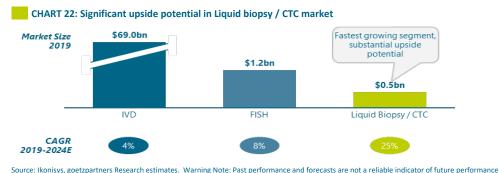




Utilisation of CTCs for diagnostic purposes requires cost-effective, easy-to-interpret and highly sensitive clinical tests such as the lkoniscope

#### Ikonisys – unlocking the potential of CTC and immune cell analysis

The previously discussed advantages of FISH in terms of its ability to perform genetic interrogation at single-cell resolution while retaining cellular architecture and structural integrity also apply to the characterisation of CTCs, and other non-invasive techniques such as MRI and CT scanning or analysis of protein-specific markers simply do not provide the same degree of molecular insight. While CTC analysis has great potential to transform the diagnostic landscape in cancer, it has been limited by the extreme rarity of these cells, as a 10ml sample of blood typically contains less than 10 CTCs. Technologies that are more sensitive to picking up small signals, such as the Ikoniscope, are clearly at an advantage when it comes to increasing the probability of finding rare cells by being able to screen a much larger number of cells than possible manually. Furthermore, Ikonisys can be used with any desired enrichment approach, or even without enrichment, making it a leading technology that may play a principal role in unlocking the potential of CTC characterisation in optimising cancer care, paving the way for widespread implementation of scalable solutions for reliable early detection and monitoring. With anti-cancer immunity increasingly at the heart of oncology, the platform is also capable of detecting rare cancer-specific immune cells, which may be key to monitoring and directing individual patient cancer therapy.



source: ixonisys, goetzpartners research estimates. Warning Note: Past performance and forecasts are not a reliable indicator of ruture performance or results. The return may increase or decrease as a result of currency fluctuations.

#### Partnership with Sheba Medical Center-ARC

Ikonisys has recently teamed up with Israel's leading cancer research centre, the Sheba Medical Center-ARC, to identify novel biomarker sets that can be used on the Ikoniscope platform. The biomarkers will be matched against full sets of data and medical records collected from cancer patients with a view to the development of CTC-based diagnostic.

The platform was also recently endorsed by Sir William Bodmer Head of the Cancer and Immunogenetics Laboratory in the Weatherall Institute of Molecular Medicine at the University of Oxford.

"The Ikoniscope rare cell detection and analysis platform has great potential in the development of CTC-based clinical testing, an area of increasing relevance in oncology. It can be especially useful when coupled with DNA based tests for cancer early detection. The platform has the capability to analyse large numbers of cells, with no requirement for the expression of a particular cell marker by the CTCs of interest. This flexibility, coupled with the ability of the platform to analyse protein (antibody), DNA and RNA, will allow the development of a variety of CTC-based tests."



FISH can be used in infectious disease to analyse drug resistance patterns and visualize mycobacteria

Collaboration agreement to develop the Ikoniscope for immunology applications, such as characterisation of tumourassociated immune cells

Well-established client base and high customer satisfaction paves the way for rapid uptake of the new system

Installed base of 46 systems and over 440,000 performed tests

#### Infectious disease diagnostics market expected to exceed \$19bn by 2022E

The same concept applies to FISH-mediated identification of infectious disease, where rapid profiling of microbial pathogens is essential for efficient antibiotic selection, especially in light of increasing drug resistance patterns. FISH is easy, fast and offers the significant advantage of providing an image of the infectious organism being detected, thus allowing analysis of spatial architecture and morphology. On-going automation of systems such as the Ikoniscope accelerates the time-to-result and improves reliability. With respect to potential applications for infectious disease, visualisation of specific mycobacteria by FISH would greatly facilitate detection and identification of bacteria in both clinical as well as environmental samples, such as sputum or drinking water. A FISH based diagnostic approach offers the significant advantage over a PCR-based assay of providing an image of the infectious organism being detected.

#### Collaboration agreements with University of Connecticut and Imperial College

In July 2020, Ikonisys and the Neag Comprehensive Cancer Center at the University of Connecticut formed a collaboration agreement to further develop the Ikoniscope for use in CTC and immunology applications. More specifically, the Ikoniscope20 will be utilised in complex specimen samples to identify and quantify rare cell populations in I-O and infectious disease. For example, the identification and characterisation of tumour-associated immune cells should provide important information as to the susceptibility of individual tumours to different I-O strategies. This collaborative research agreement with a 'Commission on Cancer'-accredited centre not only further validates the Ikoniscope as a technology platform but will also allow Ikonisys to generate clinically relevant data to support their expansion into new fields. The collaboration has already established the ability of the Ikoniscope20 to detect very rare cancer antigen specific CD8 T-cells that are central to effective immune responses to both infectious pathogens and cancer cells. A more recent MoU was signed with Dr Ehsan Ghoran at Imperial College to look at combined morphological and molecular changes in cells in cancer as well as infectious, cardiovascular, and connective tissue diseases, which will be taken forward when the company has sufficient resources.

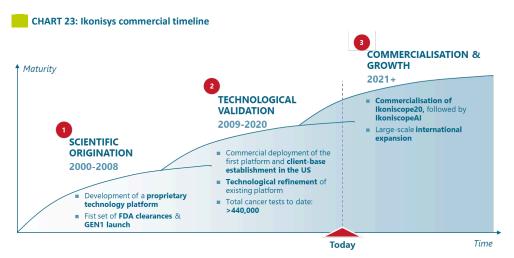
#### De-risked commercial strategy

A large, well-established, and reputable client base combined with high customer-satisfaction rates and a focus on a clinically validated technology for cancer characterisation significantly de-risk commercialisation of the system. In addition, existing regulatory clearance and a strong patent portfolio will pave the way for rapid uptake and provide a barrier to sales erosion by the competition. Most competing systems are semi-automatic, making them obsolete in a context where the need for automatic, practical, and time-efficient procedures is paramount. The handful of systems that are in fact fully automatic do not possess the same data interpretation capabilities and still require a darkroom to function — two barriers that are exclusively overcome by the Ikoniscope. Ikonisys intends to initiate marketing of Ikoniscope20 in the US and EU5 (France, Germany, Italy, Spain, United Kingdom) in 2021E, followed by expansion into Northern Europe, BeNeLux and Eastern Europe later in the year, before expanding into the APAC and LATAM markets via distributers from 2022E.

#### Widespread FISH use provides fertile ground for Ikonisys

One of the opportunities in the FISH market is that it is a widely accepted and understood technology: FISH is clinically validated and has therefore gained significant traction both among hospitals and private labs. However, the established FISH industry is characterised by a client base that has settled for highly imperfect, time-inefficient systems, primarily for lack of a better alternative. The fact that the sub-optimal performance of existing diagnostic equipment acts as a structural market constraint also represents a significant window of opportunity for Ikonisys, paving the way for quick market penetration and fast adoption due to elimination of existing deficiencies. Furthermore, the platform has been tested and been continuously used by major hospitals and private laboratories in the US and Europe. With an installed base of 46 systems and more than 440,000 cancer diagnosis tests performed to date, the Ikoniscope technology is clinically validated and reasonably well-established (CHART 23).





Source: Ikonisys, goetzpartners Research

# Target market of 800 clients in the US and 650 clients in Europe

#### Target market: hospital labs and private labs

The main target clients are hospital labs and private labs performing at least 6 / 7 FISH analyses per day to justify automation. In the US, 50% of the 960 hospital labs with more than 300 beds could benefit from Ikoniscope utilisation, which constitutes a potential market of 480 clients. Furthermore, 5% of the 6,364 private labs that perform diagnostic services for general practitioners, hospitals and clinics in the US are equipped with manual FISH capabilities, representing an additional target market of 320 clients (CHART 23). The overall estimated client-base over the next 5 years in the US therefore amounts to 800 hospitals and private labs. The European region also represents a substantial target, with a total addressable market over the next 5 years of 650 hospital and private labs, of which 400 are hospitals labs, 150 private labs, and 100 additional hospital and private labs from non-top 5 EU countries (CHART 23). The proportion of private labs equipped with FISH facilities is generally lower compared with hospitals, as investment in the equipment is only justified when reaching a certain threshold testing volume. Nonetheless, several current clients already perform less than 6 / 7 tests per day. Additionally, Ikonisys will also target labs that would like to perform FISH testing, but do not at present because of lack of personnel / resources

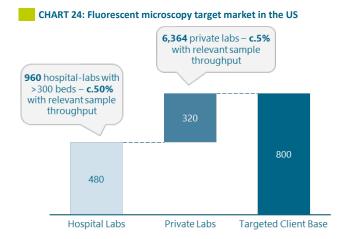


CHART 25: Fluorescent microscopy target market in Europe Other European >3,000 private labs markets: additional c.20% c.5% with relevant potential sample throughout >800 large hospitals c.50% with relevant sample throughput 650 400 **Hospital Labs** Private Labs Other non Top-**Targeted** 

5 FU countries

Client Base

Source: Ikonisys, goetzpartners Research

Source: Ikonisys, goetzpartners Research

#### Significant room for market penetration

Target market penetration is likely to be significant, as the adoption of this technology would provide sizeable upside to hospitals and private labs regardless of their current capabilities. On the one hand, the prospective clients that are relying on alternative systems for FISH probe diagnostics — mostly in Europe and the US — still have an incentive to upgrade their clinical and technological capabilities and are therefore likely to contribute to equipment sales. On the other hand, those who are not yet equipped with functional diagnosis platforms, but who have both the capacity and willingness to improve their clinical facilities — mostly APAC — are likely to be the largest sales contributors in the near future. Clearly, expected demand for the platform strongly correlates with the degree to which it is perceived as a valuable and superior alternative to existing solutions. However, the fact that most of the



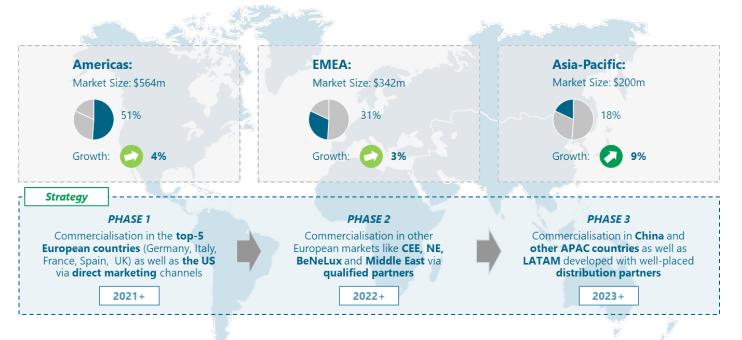
LATAM regions represents an untapped market opportunity, EMEA is seeing increasing investment into cutting-edge diagnostics and APAC has a high need for advanced diagnostic solutions

existing Ikonisys users have completely removed manual procedures from their diagnostic process gives reasonable indication for the commercial potential of the platform.

#### Expanding Ikonisys' commercial infrastructure to penetrate underserved markets

In the US, an abundance of healthcare capital, an accommodating regulatory climate, and an increasing need for personalised medicine should drive Ikoniscope sales provided that Ikonisys generates enough traction to convince end-users to deviate from competing technologies, which are particularly abundant in this region. The LATAM region represents a major untapped market opportunity, characterised by a clear lack of relevant diagnostic technologies currently in place. Similarly, the CEE / MEA region represents a high potential market due to increasing investment in cutting-edge diagnostic technologies and a growing awareness of the benefits of early diagnosis. Significant sales can also be expected from the EMEA region, and particularly from the top-5 European countries. Finally, the APAC region is likely to be one of the biggest sales contributors due to a very large population and a high need for advanced diagnostic solutions. Ikonisys is currently expanding its commercial infrastructure to initiate large commercial expansion into existing and new market (CHART 26).

#### CHART 26: Commercial strategy for international sale up via direct marketing and distribution partners



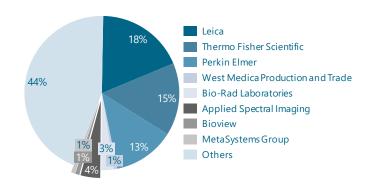
Source: Ikonisys, goetzpartners Research

The Ikoniscope is unique with advanced data interpretation functions and no requirement of a darkroom. These capabilities are protected by extensive IP.

#### Competitive landscape: A strong value proposition in an undifferentiated industry

The main competitors of Ikonisys are Leica, Thermo Fisher Scientific, Perkin Elmer, West Medica Production and Trade, Bio-Rad Laboratories, Applied Spectral Imaging, Bioview, and MetaSystems Group (CHART 27). The industry is also filled with a myriad of small players who are, for the most part, overshadowed by bigger players due to their lack of distinctive product differentiation. The majority of competing systems are semi-automatic, which makes them obsolete in a context where the need for automatic, practical, and time-efficient procedures is paramount. Furthermore, the few existing systems that are in fact automatic (made by Metasystems, BioView, or ASI) do not possess advanced data interpretation functions and require a darkroom — two barriers that are exclusively overcome by Ikonisys' system and protected by extensive intellectual property. The technological exclusivity on value-added functions increase the company's value proposition and the likelihood of strong market penetration.

#### CHART 27: Competitive landscape



Source: Ikonisys, goetzpartners Research

Approval for GEN1 in US and Europe significantly de-risks development and approval of the new models

#### GEN1 market authorisation to accelerate market entry of Ikoniscope20 and IkoniscopeAI

The Ikoniscope is a class II medical device and both FDA-cleared in the US and CE-marked in Europe, which significantly de-risks the device in a regulatory context and paves the way for rapid clearance of Ikoniscope20 and IkoniscopeAI: in order to obtain clearance, the company will only have to demonstrate substantial equivalence of the new models to the FDA-cleared GEN1 platform. The process consists of demonstrating a level of similarity between the new and the old product that is sufficiently high to be considered by regulatory authorities as having similar intended use, technological characteristics, and principal of operation. Technological differences are tolerated as long as they do not raise new issues of safety and effectiveness, leading us to believe that regulatory approval does not represent a barrier to successful commercial launch in the US and Europe.



Ikonisys holds 23 (19 granted and 4 pending) utility patents covering different aspects of the concept of automated microscopy including "automated cancer diagnostic methods using FISH", "automated cassette and slide handling system for an automated microscope" and the "detection of circulating tumour cells in peripheral blood with an automated scanning fluorescence microscope". In addition, Ikonisys' IP covers specific software applications focused on image processing and their specific use in cancer detection. Importantly, the body of issued patents at present exclusively covers applications in the US, while other patents are pending in Europe, China, Hong Kong, Japan, Korea, and India. While strong IP protection in the US reduces the risk of sales erosion by competition, patents in other areas of the globe are necessary to ensure Ikonisys can reach and maintain a leading position in this market.



Source: Ikonisys

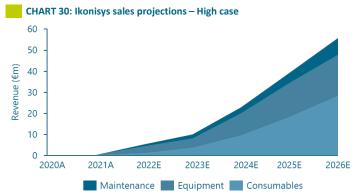


# **Financial Forecasts**

# Product revenues and assumptions

CHART 29 illustrates our base case revenue forecasts to 2026E, reflecting the long-term growth of the company as well as the evolution of its three core revenue drivers: 1) equipment sales), 2) consumable reagent kit sales, and 3) maintenance revenues (including software licenses). We expect equipment to be the biggest sales contributor following initial launch of Ikoniscope20 in 2021, followed by IkoniscopeAI in 2024E, respectively, but anticipate a progressive increase in recurring revenue from consumables, which we expect to surpass equipment sales as the leading source of revenue by 2027E.





Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future performance or results. The return may increase of decrease as a result of currency fluctuations.

Source: goetzpartners Research estimates.

Warning Note: Forecasts are not a reliable indicator of future performance or results. The return may increase of decrease as a result of currency fluctuations.

Our key forecast assumptions are outlined below and in CHART 31:

- Large target client base: We estimate a total addressable market of 2,600 hospitals and private labs globally, segmented into three regions:
  - US: Addressable market of 1,000 hospitals and labs. Expect fast adoption and penetration of >40% by 2030E;
  - Europe: Addressable market 800, c.35% expected penetration by 2030E;
  - RoW: Addressable market of 800, c.32% penetration by 2030E.
- Targeting larger hospitals initially: We assume that the proportion of customers buying 2 or 3 systems is 15% initially, but gradually increases to 30% by 2026E.
- A growing source of recurring revenue: We expect maintenance services and software licences to represent a recurrent and growing source of revenue over time as the demand for services increases proportionate to the total installed base offsetting potential equipment sales erosion by competitors. We assume maintenance contracts to amount to 20% of average machine selling price per year.

**Consumable reagents sales:** High margin (70% - 80%) consumable sales are expected to replace equipment sales as a leading source of revenue over the long-term as Ikonisys will supply a growing body of customers with reagent kits.

#### CHART 31: Overview of key assumptions underlying product sales forecast

Product launch	Ikoniscope ASP	Consumables ASP	Test volume	Installed base	System life span	COGS
Initial system launch: Ikoniscope20: 2020E IkoniscopeAI: 2022E	Average system selling price US: €120k EU: €100k RoW: €70k	Average kit selling price: €50.00	Avg. tests per machine per year: 2,000 initially, rising to 3,000 over three years	540 machines by YE2028E	6-year life cycle	<ul><li>Equipment: 65%</li><li>Kits: 20%</li><li>Maintenance: 10%</li></ul>

ASP: Average selling price

Source: goetzpartners Research estimates

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#### Base case vs. high case scenario analysis

Our product sales forecast consists of two different commercial scenarios – a base case scenario (CHART 29) and a high case scenario (CHART 30). The primary difference in assumptions underlying the two scenarios is a variation in the estimated sales of consumables: while the base case assumes that



only 35% of Ikoniscope users purchase their consumable kits from Ikonisys, the high case assumes that 50% of Ikonisys customers rely on Ikonisys to source their kits, which in our view is very achievable considering the increased convenience associated with purchasing all components from a single supplier. Even in the high case we assume Ikonisys kits would account for less than 20% of total kit sales within the company's target market.

#### **Profit and loss**

We would anticipate a minimal contribution from system sales in 2021E, but this should be expected to increase from 2022 onwards.

CHART 32: Profit and Loss Forecast

Profit & Loss Statement	2020A	2021E	2022E	2023E	2024E	2025E
Dec YE (EURm)	31-Dec-20	31-Dec-21	31-Dec-22	31-Dec-23	31-Dec-24	01-Jan-25
Net revenues	0.5	0.5	4.9	9.3	19.2	31.3
Total cost of goods	(0.0)	(0.1)	(2.0)	(3.5)	(7.8)	(12.6)
Gross profit	0.5	0.4	2.8	5.8	11.5	18.7
Gross Margin %	98%	73%	58%	63%	60%	60%
Sales and Marketing	-	(0.5)	(1.8)	(3.9)	(6.6)	(8.2)
G&A	(0.2)	(0.7)	(0.9)	(1.1)	(1.2)	(1.4)
Research and development expense	-	(0.6)	(0.6)	(0.7)	(0.9)	(1.2)
Other operating income	-	-	0.0	0.0	0.0	0.0
Other operating expenses						
EBITDA	0.2	(1.3)	(0.3)	0.3	3.1	8.3
Depreciation	0.1	(0.1)	(0.2)	(0.3)	(0.3)	(0.4)
EBIT	0.3	(1.4)	(0.5)	0.1	2.8	7.9
Financial income						
Financial expenses						
Net financials	(1.8)	(0.0)	0.0	(0.0)	(0.0)	(0.0)
Finance income/costs fair value meas.						
Net financials	(1.8)	(0.0)	0.0	(0.0)	(0.0)	(0.0)
Profit before tax and exceptionals	(1.5)	(1.4)	(0.5)	0.1	2.8	7.9
Exceptionals/other non op.	-	-	-	-	-	-
Tax	-	-	-	(0.0)	(0.6)	(1.6)
Net profit	(1.5)	(1.4)	(0.5)	0.1	2.2	6.3
Avg # of shares (m)	8.8	9.5	9.5	9.5	9.5	9.5
EPS p	(0.17)	(0.15)	(0.05)	0.01	0.23	0.66

Source: Ikonisys, goetzpartners Research estimates.

Warning Note: Past performance and forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations.

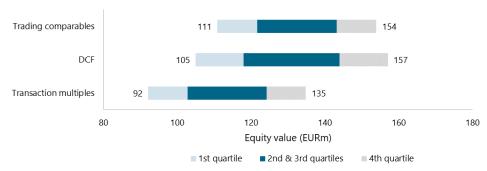


DCF valuation best captures the long-term growth potential of Ikonisys

# **Indicative valuation ranges**

Ikonisys is an established medtech company with a commercial track record, however, revenues are still relatively modest. We feel that the valuation methodology that best captures the long-term growth potential is a discounted cash flow analysis, which we further complement with an analysis of transaction multiples from recent M&A deals in the space Ikonisys is active in, whilst trading comparables analysis reflects upside potentials. Finally, we performed a sensitivity analysis on the various valuation methods to provide alternative valuation scenarios, which yield the valuation ranges shown in CHART 5 (and CHART 32 below) suggests a valuation range of €92.6m − €157m. This equates to a value per share of €9.6 - €16.5. Given the inherent uncertainly associated with product roll out we estimate a target price of €10 / share.

#### CHART 33: Ikonisys valuation ranges



Source: goetzpartners Research estimates

Footnote: The valuation ranges are based upon long term analysis and not short-term assessment of likely performance

Warning Note: Forecasts are not a reliable indicator of future performance or results. The return may increase of decrease as a result of currency fluctuations.

# DCF analysis captures long-term value

We have valued Ikonisys by DCF based on the cash flows generated in our forecasts. The DCF is based on ten-year forecasts with cash flows discounted using a weighted average cost of capital ("WACC") and a terminal multiplier applied to the year following the 10-year explicit forecast period. The terminal multiplier is calculated using a WACC equal to the return on invested capital; thus, at a WACC of 11%, the terminal multiplier is 9.1x. Our DCF analysis is shown in CHART 33.

CHART 34: Ikonisys discounted cash flow analysis – Base case scenario

Dec YE (€m)	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Revenues	0.5	4.9	9.3	19.2	31.3	42.9	51.6	59.8	65.4	72.8	78.4
sales growth	12%	792%	91%	107%	63%	37%	20%	16%	9%	11%	8%
EBIT	(1.4)	(0.5)	0.1	2.8	7.9	13.3	17.4	21.7	24.6	31.7	34.6
EBIT margin	-253%	-11%	1%	14%	25%	31%	34%	36%	38%	44%	44%
Tax on EBIT	-	-	-	-	(1.6)	(2.7)	(3.6)	(4.4)	(5.0)	(6.5)	(7.1)
NOPLAT	(1.4)	(0.5)	0.1	2.8	6.3	10.5	13.8	18.1	19.6	25.2	27.5
Net investments	(0.4)	(0.3)	(0.2)	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.0)	(0.0)
Chg in W/C dec/(incr)	(0.0)	(0.9)	(0.3)	(1.5)	(2.0)	(1.9)	(1.5)	(1.3)	(0.9)	(1.1)	(1.0)
FCF	(1.9)	(1.7)	(0.5)	1.1	4.2	8.5	12.2	16.8	18.6	24.1	26.4

WACC 11% Exit multiple 9.1x

Terminal value	65.5
Sum of PV of FCF	33.3
Enterprise value (E	98.8
Marketeable Securiti	4.0
Net debt	-
Equity value	102.8
Number of Shares	9.5
Value per share	10.8

Source: goetzpartners Research estimates.

Footnote: The valuation ranges are based upon long term analysis and not short-term assessment of likely performance. Warning Note: Forecasts are not a reliable indicator of future performance or results. The return may increase of decrease as a result of currency fluctuations.

#### Sensitivity analysis for key variables

We further conducted a sensitivity analysis to illustrate the impact of varying the exit multiple and WACC on the base-case (CHART 35) and high-case (CHART 36) scenarios. Our equity value range of €90m – €164m is derived from a combined scenario analysis with equal weighting of base case and high case.



CHART 35: Sensitivity of equity value to exit multiple and WACC - base case

WACC 13% 12% 11% 10% 9% 94 7 1x 84 86 88 91 **Exit multiple** 8.1x 91 93 96 98 101 9.1x 98 100 103 105 108 10.1x 105 107 110 113 116 11.1x 112 115 120 123

Source: goetzpartners Research estimates

CHART 36: Sensitivity of equity value to exit multiple and WACC - high case

		,	WACC		
	13%	12%	11%	10%	9%
7.1x	135	139	143	148	153
8.1x	147	151	155	159	164
9.1x	158	162	166	171	176
10.1x	170	174	178	182	187
11.1x	181	185	189	194	199
	8.1x 9.1x 10.1x	7.1x 135 8.1x 147 9.1x 158 10.1x 170	7.1x 135 139 8.1x 147 151 9.1x 158 162 10.1x 170 174	7.1x 135 139 143 8.1x 147 151 155 9.1x 158 162 166 10.1x 170 174 178	13%         12%         11%         10%           7.1x         135         139         143         148           8.1x         147         151         155         159           9.1x         158         162         166         171           10.1x         170         174         178         182

Source: goetzpartners Research estimates

# EV / Sales multiple analysis based on 2024E revenues

To conduct analysis of comparable trading companies we followed a similar valuation approach to our M&A analysis and first identified the median EV / Sales multiple of our primary peer group (CHART 35), then applied this to our 2023E revenue forecast. Our sensitivity analysis shows the impact of varying the forward sales multiple and probability rate (CHART 37) and forward sales multiple and WACC (CHART 38).

companies complete by again using the 2023E revenue forecast

Comparable companies selected

from the medical devices sector

with relatively modest revenues

Analysis of comparable trading

CHART 37: Sensitivity of equity value to sales multiple and overall probability of success

		Sales multiple								
		19.0x	19.5x	20.0x	20.5x	21.0x				
>	50%	132	136	139	143	146				
≝ ″	55%	119	122	125	128	132				
babi rate	60%	119	122	125	128	132				
Probability rate	65%	132	136	139	143	146				
۵	70%	159	163	167	171	175				

Source: goetzpartners Research estimates

CHART 38: Sensitivity of equity value to sales multiple and WACC

			Sales multiple						
		13.0x	13.5x	14.0x	14.5x	15.0x			
	13%	103	107	111	115	119			
ပ္ပ	12%	106	110	114	118	122			
WACC	11%	109	113	117	121	125			
	10%	112	116	120	125	129			
	9%	115	119	124	128	133			

Source: goetzpartners Research estimates

#### Primary peer group composed of established molecular diagnostics companies

Due to the unique positioning, Ikonisys does not have many close peers that are publicly traded. We therefore selected a range of small and midcap companies in the medical devices space that, in our view, bear similarities to Ikonisys in terms of focus on the production of equipment for the improved molecular diagnosis of cancer and retained companies that are 1) well-established in their respective industries and 2) have relatively modest revenues. (CHART 39).

**CHART 40: Comparable trading companies** 

Company	HQ	Currency	EV (€m)	EV (local) Rev	enues (local)	EV/Sales
Comparables 1: established companies, loss-m	aking to pro	ofitable				
Quidel Corporation	US	USD	3,823.2	4,572.1	1,862.4	2.5
Invitae Corp.	US	USD	5,667.2	6,760.9	319.0	21.2
Pacific Biosciences of California, Inc.	US	USD	5,687.0	6,786.0	92.3	73.5
NanoString Technologies, Inc.	US	USD	2,481.3	2,961.6	122.3	24.2
Fluidigm Corporation	US	USD	436.4	519.8	143.3	3.6
Biocartis Group NV	BE	EUR	257.6	257.6	43.1	6.0
Quanterix Corporation	US	USD	1,650.1	1,974.1	97.9	20.2
ChemoMetec A/S	DK	DKK	1,976.5	14,697.5	214.1	68.6
Abnova Taiwan Corp.	TW	TWD	114.4	3,802.0	470.9	8.1
Median						20.2x
Mean						25.3x
Comparables 2: early-stage, loss making						
Natera, Inc.	US	USD	8,372.6	9,989.6	449.3	22.2
Veracyte Inc	US	USD	2,103.6	2,513.4	123.1	20.4
Biocartis Group NV	BE	EUR	257.6	257.6	43.1	6.0
Quanterix Corporation	US	USD	1,650.1	1,974.1	97.9	20.2
NantHealth, Inc.	US	USD	423.9	502.4	71.2	7.1
T2 Biosystems, Inc.	US	USD	177.7	211.6	22.5	9.4
SQI Diagnostics Inc.	CA	CAD	48.5	71.4	1.0	69.7
Navidea Biopharmaceuticals, Inc.	US	USD	42.5	50.8	0.9	57.6
Median						20.3x
Mean						26.6x
Liquid biopsy						
Guardant Health, Inc.	US	USD	10,204.4	12,178.1	297.9	40.9
MDxHealth S.A.	BE	EUR	121.5	121.5	16.2	7.5
Pacific Edge Limited	NZ	NZD	517.0	875.5	7.7	113.7
Biolidics Ltd.	SG	SGD	43.1	68.9	8.9	7.7
Epigenomics AG	DE	EUR	7.8	7.8	0.7	11.1
Biocept, Inc.	US	USD	46.8	55.8	43.8	1.3
PlexBio Co., Ltd.	TW	TWD	58.1	1,910.1	101.3	18.8
Median		=				11.1x
Mean						28.7x
Source: FactSet, goetzpartners Research estimates.						

Values in millions. Market data as at European Markets close of business on 2nd October 2020

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#### Early-stage and liquid biopsy peers suggest additional upside

For indicative purposes only, we have also compiled two additional peer groups of companies (CHART 35) including early-stage molecular diagnostic companies (similar focus but different maturity stage), and liquid biopsy companies, an area that represents large potential for Ikonisys given the Ikoniscope's high applicability to CTC characterisation. While we have opted for a conservative valuation approach based on our primary peer group, we believe these scenarios illustrate realistic potential for additional future upside.

#### Trading comparables valuation reflects current market perception

This valuation produces a marginally higher estimate than the DCF and transactions analysis (below), reflecting EV / Sales values of comparators that we believe are elevated in the current market for two reasons. Firstly, a number of these molecular diagnostic companies also work in the infectious diseases space and have recently developed assays for COVID-19.

Secondly, growing interest in liquid biopsies has been driving increased valuation of related companies, despite revenues still being many years away, highlighted by the mean 28.7x EV / Sales value for companies in this market (CHART 41). Excitement has been steadily growing in the last year as the true potential of early cancer diagnosis is being discovered, epitomised by the \$8bn acquisition proposal of GRAIL by Illumina. This illustrates the huge momentum behind the liquid biopsy market at present and potential substantial upside for Ikonisys, if the company successfully executes its business plan.

High comparables valuation reflects huge excitement in liquid biopsies and some exposure to rises in the infectious disease market thanks to COVID-19

#### Precedent M&A deals

We also identified multiple M&A transactions involving companies operating in similar industries such as molecular diagnostics, liquid biopsy, and genetic testing - markets that Ikonisys already addresses or intends to target (CHART 41). As the company is a few years away from sustainable profitability, we feel a multiples-based valuation using 2020E revenues as would be common for a more mature, revenue-generating company is not appropriate. We therefore conducted an TV / Sales multiple analysis based on our revenue estimate for 2023E of €21.3m. We first identified the median TV / Sales multiple of relevant M&A transactions, applied this to our 2023E sales forecast for Ikonisys, then discounted this value back and finally applied a risk-adjustment of 80% to capture the commercial risk associated with Ikonisys achieving our forecasts. The average transaction multiple somewhat below our DCF, but this probably reflects the lack of transactions involving revenue generating targets since 2018 and does not reflect the substantial value of placed on diagnostic oncology exemplified by Illumina's \$8bn acquisition of Grail, which has yet to generate product revenues.

TV/Sales multiple analysis is based upon our 2023E revenue estimate

# CHART 41: Relevant M&A transactions

Date	Target company	Acquiring company	Currency	<b>Transaction Value</b>	Sales of target	TV/Sales
31/07/2018	Foundation Medicine	Roche Holding	USD	5,300	201	26.3x
07/07/2017	Epigenomics AG	Cathay Fortune	EUR	171	3	53.9x
08/06/2017	Oxford Gene Technology IP	Sysmex	USD	67	17	3.9x
04/11/2016	Cepheid	Danaher	USD	3,855	595	6.5x
07/08/2016	Advanced Cell Diagnostics	Bio-Techne	USD	325	25	13.0x
31/03/2016	Affymetrix	Thermofisher Scientific	USD	1,300	356	3.7x
Median						9.7x
Mean						17.9x

Values in local millions

Source: Mergermarket, FactSet, goetzpartners Research

#### Sensitivity analysis for key variables

We further conducted a sensitivity analysis to illustrate the impact of varying the transaction multiple and probability rate (CHART 42) and transaction multiple and WACC (CHART 43). Our equity value is derived from a combined scenario analysis with equal weighting.

#### CHART 42: Sensitivity of equity value to transaction multiple and overall probability

			Halisac	uon n	uiupie	
		8.7x	9.2x	9.7x	10.2x	10.7x
>	60%	91	97	102	107	112
Probability rate	65%	99	105	110	116	122
	70%	107	113	119	125	131
5 -	75%	114	121	127	134	141
_	80%	122	129	136	143	150

Source: goetzpartners Research estimates

#### CHART 43: Sensitivity of equity value to sales multiple and WACC

					.a.c.p.c	
		8.7x	9.2x	9.7x	10.2x	10.7x
	13%	117	123	130	137	143
WACC	12%	119	126	133	140	147
	11%	122	129	136	143	150
>	10%	125	132	139	146	153
	9%	128	135	142	150	157

Transaction multiple

Source: goetzpartners Research estimates

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# **Executive management and board members**

## Executive management

#### Mario Crovetto | CEO

Mario Crovetto became CEO of Ikonisys in 2018. He previously served as CFO of Eurand NV, a specialty pharmaceutical company which he successfully floated to NASDAQ in 2007. He also held multiple executive functions in the pharmaceutical and chemical sectors, including positions as CFO of the Recordati Group and Vice President at the Montedison Group. He currently serves as a director of OpGen Inc, after the merger between OpGen and Curetis NV, an international molecular diagnosis company based in Germany. Mr Crovetto holds an MSc in Business Economics from Harvard University.

#### Alessandro Mauri | CFO

Alessandro Mauri became CFO of Ikonisys in 2019. He has worked as a Portfolio Manager in Cambria, Ltd. a UK private equity firm. Before he had founded B10NIX, an innovative biotech start-up, for which he acted as CFO as well. Mr Mauri holds an M.Sc. in Global Finance from Fordham University (New York, USA), a Master in Corporate Finance from SDA Bocconi (Milano, Italy) and an M.Sc. in Engineering of Computing Systems (major in Robotics and AI) from Politecnico di Milano (Milano, Italy)

#### Juergen Schipper, MBA | CCO

Juergen Schipper joined Ikonisys as CCO in 2018. He has more than 20 years of experience in General Management, Business and Commercial Development. He is the Founder and Managing Director of Microbionix GmBH, a German company specialised in the development of Multiplex Assay Systems. He is also the Founder and CEO of Diagnostics & Life Science Consulting. Mr Schipper has occupied multiple interim management positions at companies such as Luminex Corporation and Omega Diagnostics GmbH and holds an MBA from Munich University of Applied Sciences.

#### Michael Kilpatrick, PhD | CSO

Michael Kilpatrick is CSO at Ikonisys and joined as one of the founders in 1999. He has been a prominent researcher in molecular genetics at University of Wisconsin-Madison, University of Alabama at Birmingham, the Imperial Cancer Research Fund laboratories in London, and University of Connecticut Health Center. He has more than 100 scientific publications in the fields of nucleic acid structure and function as well as human molecular genetics. His research has been funded by the Medical Research Council, the Wellcome Trust, NATO, the Arthritis and Rheumatism Council and the NIH. He holds a PhD in Chemistry from the University of Birmingham.

#### **Bill Kochiss | CTO**

Bill Kochiss joined Ikonisys as CTO in 2006. He has more than 25 years of experience in managing various manufacturing, purchasing, planning, and scheduling operations. He has occupied management positions in both multi-million-dollar publicly traded medical manufacturing corporations as well as biotech start-ups (Zetroz Inc, Bauer Inc, Diba Industries, Coopersurgical Inc). Mr Kochiss holds a BSc in Industrial Engineering and Plastics Engineering from University of Massachusetts.

#### Board of directors

#### Mario Mauri | Chairman of the Board

Mario Mauri is Chairman and CEO of Cambria Ltd, a private equity firm based in London. He has more than 25 years of experience in private equity and venture capital and is a Board Member of several public and private companies. He served as CFO of Mondedison Group, Chairman of the Financial Committee of Himont Inc, and Executive Director at A2A SpA and Edison SpA. Mr Mauri holds an MSc in Economics from Bocconi University of Milan.

#### Roberto Rettani, MBA| Deputy Chairman of the Board

Roberto Rettani serves as Chairman and Managing Director of Syneresis Srl, a consulting firm in the healthcare sector founded in 2010. He held various executive functions at major pharma and healthcare corporations, including positions as CEO of Bracco Imaging Group and Zambon Group. He has been an Adviser of CVC Capital Partners Limited since March 2014. Mr Rettani holds an MBA from SDA Bocconi and completed an MSc programme in Industrial Chemistry at Università degli Studi di Milano.

#### Vittorio Grazioli, MD | Scientific Committee Chair

Vittorio Grazioli serves as CEO of Impact Lab Srl and Chairman of Ikonisys. He has more than 30 years of experience in studying platform technologies, medical diagnostics and devices, quality assurance, and molecular biology. Previously, he served as Director of Clinical Lab at Centro Diagnostico Italiano and Istituto Clinico Humanitas. Dr Grazioli holds an MD in Medicine from Università degli Studi di Pavia.



#### Alberto Calvo, MBA | Independent Director

Alberto Calvo is a Partner at Value Partners Management Consulting. Over the last 20 years, he has gained extensive experience and international expertise in the consumer goods, energy, healthcare and utilities. Previously, he worked in the M&A division of UBS and was a Project Manager at CERN, Geneva. Mr Calvo holds an MBA from SDA Bocconi and completed an MSc in Nuclear Engineering at Politecnico of Turin.

#### Pramod Srivastava, PhD, MD | Independant Director

Pramod Srivastava is Professor of Immunology and Medicine and Director of the Carole and Ray Neag Comprehensive Cancer Center at the University of Connecticut School of Medicine. He is the co-founder of various biotech companies, including Antigenics and Life Science Pharmaceuticals. He is also the inventor of more than 200 awarded patents in the sector of immunology and a Member of the Scientific Advisory Council of the Cancer Research Institute. Dr Srivastava holds a PhD from the Centre for Cellular and Molecular Biology and an MD from University of Connecticut School of Medicine.

## Scientific Advisory Board

A scientific advisory board has been established by Ikonisys, led by Pramod Srivastava, and includes Dr Ehsan Ghorani of Imperial College London and Dr Zihai Li, Professor and founding Director of the Pelotonia Institute for Immuno-Oncology of the Ohio State University Comprehensive Cancer Center. The individuals bring a wealth of experience in healthcare and expertise in the diagnostics field, more specifically in the areas in which Ikonisys sees its next stage of development and expansion, namely immunological applications.

# Largest shareholders



Source: Ikonisys



# **Balance Sheet and Cashflow**

CHART 45: Ikonisys balance sheet model

Balance Sheet	2020E	2021E	2022E	2023E	2024E	2025E
Dec YE (EURm)	31-Dec-20	31-Dec-21 3	31-Dec-22	31-Dec-23	31-Dec-24	31-Dec-25
Goodwill	-	-	-	-	-	-
Intangible assets	8	8.0	8.1	8.1	8.1	8.1
Tangible assets		0.4	0.7	0.9	1.1	1.2
Investments and other	-	-	0.0	0.0	0.0	0.0
Inventories	-	0.1	1.0	1.2	2.5	4.0
Accounts receivable	-	(0.0)	0.0	0.2	0.5	1.0
Other	0.0	0.0	0.0	0.0	0.0	0.0
Cash & securities	0.0	2.2	0.5	0.0	0.6	4.8
Total assets	8	10.7	10.3	10.4	12.7	19.1
Shareholders equity	5.7	8.3	7.8	7.8	10.0	16.3
Debt and other liablilities	1.0	1.0	1.0	1.0	1.0	1.0
Creditors	1.1	1.1	1.2	1.2	1.3	1.3
Other liabilities	0.3	0.3	0.3	0.3	0.3	0.4
<b>Total Liabilities and Shareholders</b>	8.0	10.7	10.3	10.4	12.7	19.1

Source: Company data, goetzpartners Research estimates.

Historical financials: Pro forma, converted from USD into EUR using YE exchange rate: 0.8913 (31 Dec 2019)

Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

CHART 46: Ikonisys cash flow model

Cash Flow Statement	2020E	2021E	2022E	2023E	2024E	2025E
Dec YE (EURm)	31-Dec-20	31-Dec-21 3	31-Dec-22	31-Dec-23	31-Dec-24	01-Jan-25
Operating income	0.3	(1.4)	(0.5)	0.1	2.8	7.9
Depreciation	(0.1)	0.1	0.2	0.3	0.3	0.4
Tax paid	-	-	-	(0.0)	(0.6)	(1.6)
Amortization of stock options						
Change in working capital	0.2	(0.0)	(0.9)	(0.3)	(1.5)	(2.0)
Other items	0.0	0.0	0.0	0.0	0.0	0.0
Cash flow from operations	0.4	(1.3)	(1.2)	0.0	1.1	4.7
Capital expenditures	(0.2)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)
Cash flow from investing	(0.2)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)
Net interest	(1.8)	(0.0)	0.0	(0.0)	(0.0)	(0.0)
Net cash flow before financing	(1.6)	(1.8)	(1.7)	(0.5)	0.6	4.2
Share offerings	_	4.0	_	_	_	_
Increase/(decrease) in borrowings		-	_	-	-	-
Cash flow from financing	1.6	4.0	-	-	-	-
Change in liquid funds	0.0	2.2	(1.7)	(0.5)	0.6	4.2

Source: Company data, goetzpartners Research estimates.

Historical financials: Pro forma, converted from USD into EUR using YE exchange rate: 0.8913 (31 Dec 2019)

Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.t

The company has been supported using convertible debt provided by the current shareholders, The GPSL cash flow forecast assumes company had a zero cash balance at the time of IPO with the Shareholder debt converted to equity at the time of financing. For the purposes of the model the converted debt will amount to €2m.



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#### **COMPANY DESCRIPTION**

Ikonisys S.A. is specialized in the design, manufacture and marketing of medical diagnostic equipment. The company offers cell diagnostic products in the fields of cancer diagnosis, detection of genetic disorders, and fertility testing.

#### **SCENARIOS**

#### **Base Case - GP Investment Case**

Ikonisys achieves successful roll out of Ikonoscpe20 to fill need for effective flexible fully automated platform. Valuation of successful launch €9 - €16 / share.

# Bluesky Scenario

Downside risk

#### **SWOT**

#### Strengths

- # Proven platform
- # Endorsed by leading players
- # Substantial unmet need
- # Growing market
- # Complementary to current diagnostic workflow
- # Flexible open platform
- # Multiple and recurring revenue streams
- # Multiple applications
- # Experienced management team

#### Risks

- # Commercial infrastructure to be further built
- # Ikoniscope20 yet to fully launch
- # Established competition



# Important Disclosures: Non-Independent Research

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I, Dr. Chris Redhead, hereby certify that the views regarding the companies and their securities expressed in this research report are accurate and are truly held. I have not received and will not receive direct or indirect compensation in exchange for expressing specific recommendations or views in this research report.

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- (GENEMED)
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- (OLYMPUS)
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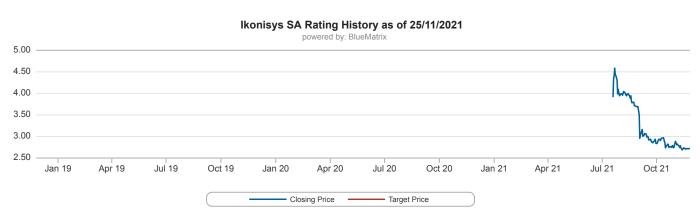
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