

## Al supported diagnostics drives the digital transformation in pathology

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Jukka Tapaninen, CEO

Aiforia Technologies Plc

## The challenge

Population in relation to the number of pathologists<sup>1</sup>

**Pathologists Per Million** 

## ... with no reduction of sample volumes in sight

Rising rates of disease like cancer, ...

**30% increase in cancer rates** in the US in past 50 years

...create a huge burden on pathologists, an already dwindling medical specialty...



## 2.03% drop to 1.43% in pathologists

as a % of total physicians in past 10 years

#### 41.73% workload increase





The shortage of pathologists makes the job stressful and require in some cases overtime work frequently. The pathologists retiring early further exaggerates the shortage problem. Estimated global cancer increases cases 2020-2040<sup>4</sup>



The growing cancer incidence rates, estimated to increase by 49.7% during 2020-2040, will lead to increasing number of pathology tests. Constantly increasing number of new diagnostic tests increase the workload and require new expertise.

## Digital transformation in pathology is becoming mainstream



## Adoption of AI in pathology is accelerating Clinical pathology workflow with AI supported diagnosis



## Report for the clinician treating the patient



#### Benefits and result:

- Automates manual tasks such as cell counting
- Produces objective and accurate data
- Improves workflow efficiency, brings results faster for the benefit of the patient

Only certain Aiforia® Clinical AI models and the Aiforia® Clinical Suite Viewer are CE-IVD marked for diagnostic use in EU and EEA countries, see here for the full list: <u>www.aiforia.com/aiforia.clinical-suite</u>. In all other countries, the use is limited to Research Use Only, not for use in diagnostic procedures.



## Gartner forecast: Between 2023 and 2027, \$3 trillion will be spent on AI

#### By 2027

GenAI will represent 36% of total AI spending.

#### By 2030

- Every dollar of GDP created anywhere on the planet will be influenced by AI
- 100% of global IT spending will be directly on AI or indirectly supporting AI
- 100% of IT development will incorporate AI in the design development, testing or supporting production



## **Overview of Aiforia Technologies**

#### Medical software company, founded in 2013

- Equips pathologists and scientists in clinical, pre-clinical, and academic labs with powerful deep learning AI and cloud-based technology
- The diverse team includes experienced pathologists, medical scientists, AI and software developers, and a dedicated commercial team
- Listed on Nasdaq Helsinki First North Growth Market

#### Our mission

Aiforia's mission is to transform pathology image analysis with AI, enabling better care for each patient.



#### **Global organization**

- ~ 100 team members
- HQ Helsinki, Finland
- US Offices in Cambridge, MA and Rochester, MN
- Sales & commercial teams in Finland, the US, the UK, the Netherlands, France, Hungary, and Norway

#### Main customer segments

#### **CLINICAL DIAGNOSTICS SECTOR,**

including hospitals, health systems and clinical diagnostic companies

#### **PRE-CLINICAL SECTOR,**

including pharma and biotech companies, contract research organizations and academic research

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## **Recent clinical deals and collaborations**



#### MAYO CLINIC

- Breast cancer diagnostics
- +70 pathologists using Aiforia Platform in translational research
- +30 ongoing research projects utilizing the Aiforia's technology at the Mayo Clinic
- An exclusive licensing agreement to globally commercialize an AI model that improves prediction of colorectal cancer recurrence



#### **FIMLAB LABORATORIES**

- 6 year framework contract
- First order confirmed for breast and prostate cancer diagnostics

#### CASTILE AND LEÓN REGION HEALTH MANAGEMENT

- 3 year contract
- Breast, prostate and lung cancer diagnostics

#### VENETO REGION HEALTH AUTHORITY

- 12 hospital units
- 3 year contract
- Breast, prostate and lung cancer diagnostics

#### CATANIA REGION HEALTH AUTHORITY

- 1 hospital unit
- 3 year contract
- Breast and prostate cancer diagnostics



#### PATHLAKE PLUS CONSORTIUM / NHS

- 3 year framework contract for lung and prostate cancer diagnostics
- First deal signed with a NHS Trust for lung cancer diagnostics

## **One cloud-based platform for multiple needs**





#### Al model development tools to

create, customize and validate proprietary deep-learning AI models, both for research and clinical use cases Ready-to-use CE-IVD certified AI models and Clinical Suites that are easily integrated with existing laboratory IT infrastructures

Aiforia currently provides regulatory approved AI models for some of the most prevalent cancers worldwide, including prostate, breast, and lung.

# Aiforia<sup>®</sup> Create enables different types of image recognition and classification in pathology



### Object detection

in breast cancer tissue

Instance segmentation in nerve tissue





## **Semantic segmentation** in liver tissue

#### **Multi-class Object detection**

Positive and negative cells, pathogens, etc.

#### Instance segmentation

- Object detection and semantic segmentation simultaneously
- True cell borders, their sizes and dimensions

#### **Multi-class Semantic segmentation**

- Detection of tissue, different classes of tumors, cells, artefacts
- Typically the first layer of detection to find the area of interest

#### Regression

 Detection of continuous values, e.g. staining intensity aiforia

## Thousands of AI models have been built with Aiforia Create for research and discovery

	Breast Cancer Ki67		Breast Cancer Estrogen Receptor Detection of positive and negative ER cells		Lung Cancer PD-L1 Exp Analysis quantifying pos & neg cells in NSCLC tumor epithelium
	Breast Cancer Progesterone Detection of positive and negative PR cells		Breast Cancer HER2 Analysis quantify HER2 pos & neg cells and HER2 scoring	Carlos and	Prostate Cancer Gleason Grading
	Breast Cancer Grading - Mitosis Scoring	1 4 11	Liver parenchyma & cytokeratin quantification		Malaria infected red blood cell analysis healthy / malaria infected / white blood cell
	<b>Kidney glomeruli counting</b> quantify the number of viable and sclerotic glomeruli in kidney biopsy		Liver non-alcohol related steato-hepatitis & fibrosis scoring	The Art	<b>Rat motor neurons</b> detect and quantify motor neurons in rat brain tissue samples
	Acid Fast Bacteria Myco- bacterium tuberculosis mZN		Liver steatosis, inflammation, ballooning & fibrosis classification		Rat microglia iba1 analysis detection & quantification microglia in spinal cord tissue
States A	Mouse liver lobular fibrosis Collagen-I IHC		Mouse Lung NSCLC tumor grading		Multi-Channel IF Neuron Culture Intensity analysis in the nuclear & somatic compartments
	Mouse Liver Steatosis Quantification Classification		Mouse Lung tuberculous granulomas detection		Atlantic salmon skin segmentation of Connective Tissue/Dermis/Epidermis/Adipose Tissue
	Human brain thionine glial cells & neurons counter in a thionine stained human brain		<b>Mouse alpha-synuclein</b> detect and count neuron cell bodies with Lewy bodies in a mouse brain	A Carl	Rat astrocytes counter GFAP identify and quantify astrocytes in GFAP stained rat spinal cord sections

& many more

## Aiforia<sup>®</sup> Clinical Suites

#### **Breast Cancer**

 ✔ Aiforia<sup>®</sup> Breast Cancer Ki67 (CE-IVD)

✓ Aiforia<sup>®</sup> Breast Cancer ER (CE-IVD)

✓ Aiforia<sup>®</sup> Breast Cancer PR (CE-IVD)



#### Lung Cancer

✓ Aiforia<sup>®</sup> Lung Cancer PD-L1 (CE-IVD)



#### **Prostate Cancer**

✓ Aiforia<sup>®</sup> Prostate Cancer Gleason Grade Groups (CE-IVD)



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## Future of pathology image analysis: prognostic AI models

Prognostic AI model **Aiforia® Colorectal Cancer QuantCRC** identifies important histological features of colorectal cancer and provides a recurrence prediction estimate useful for treatment decisions.

The AI model was developed and validated in collaboration with the Mayo Clinic.

Aiforia® Colorectal Cancer QuantCRC is currently for Research Use Only (RUO) and for Performance Studies Only (PSO) in all market areas.





## Strong scientific and regulatory validations

Aiforia's products have been referenced in **over 80 scientific articles and posters** 

Aiforia holds several globally recognized quality and security certifications such as **ISO13485, ISO27001 and SOC 2 Type II** 

Multiple patents in the US related to processing and analysis of images of pathology specimens

Aiforia complies with applicable HIPAA regulations

Aiforia has initiated a path to secure regulatory approval for its first product in the United States, **application to the FDA** anticipated in 2024.

Aiforia has six CE-IVD marked products in its portfolio

From research use to clinical: customer-validated Lab Developed Test (LDT) pathway



# For more information

www.aiforia.com

#### Contact

Jukka Tapaninen, CEO jukka.tapaninen@aiforia.com +33 61 041 6686

