DECIPHEX

TRANSFORMING PATHOLOGY WORKFLOWS

DECIPHEX IS FOCUSSED ON THE DEVELOPMENT OF APPLICATIONS FOR CLINICAL AND VETERINARY PATHOLOGY THAT IMPROVE PRODUCTIVITY AND HELP PATHOLOGISTS FOCUS ON THE CRITICAL CONTENT.

DECIPHEX

SUMMARY OF INVESTMENT OPPORTUNITY

TECHNOLOGY

ARTIFICIAL INTELLIGENCE/
DEEP LEARNING

SECTOR

COMPUTER AIDED DIAGNOSTICS

MARKET OPPORTUNITY

1BN DOLLARS

SEED RAISE

1.5M EURO
TECHNOLOGY DEVELOPMENT
PHARMA PRODUCT LAUNCH

SERIES A RAISE

3M EURO
CLINICAL PRODUCT FDA VALIDATION
AND COMMERCIALISATION

PROJECTED SEED INVESTOR RETURN

100M-150M EURO EXIT
12-20 TIMES INVESTMENT
TIMELINE 3-5 YEARS

THE PATHOLOGY WORKFLOW

THE PROCESS FROM BIOPSY TO MICROSCOPE

$8-10BN GLOBAL SALARY COSTS!

CONSIDERABLE CAPITAL DEPLOYED TO MAINTAIN PATHOLOGY SERVICES

PATHOLOGY IN CRISIS?

Pathology facing a crunchpoint in a 10 year time horizon

01

MORE CANCER

70% forecasted increase in the next two decades. Particularly strong growth in China.

02

AGEING PATHOLOGISTS

Forecasted 23% drop in current US numbers in the next 20 years.

03

INCREASING COMPLEXITY

Greater demand for access to sub-specialist pathology capabilities

04

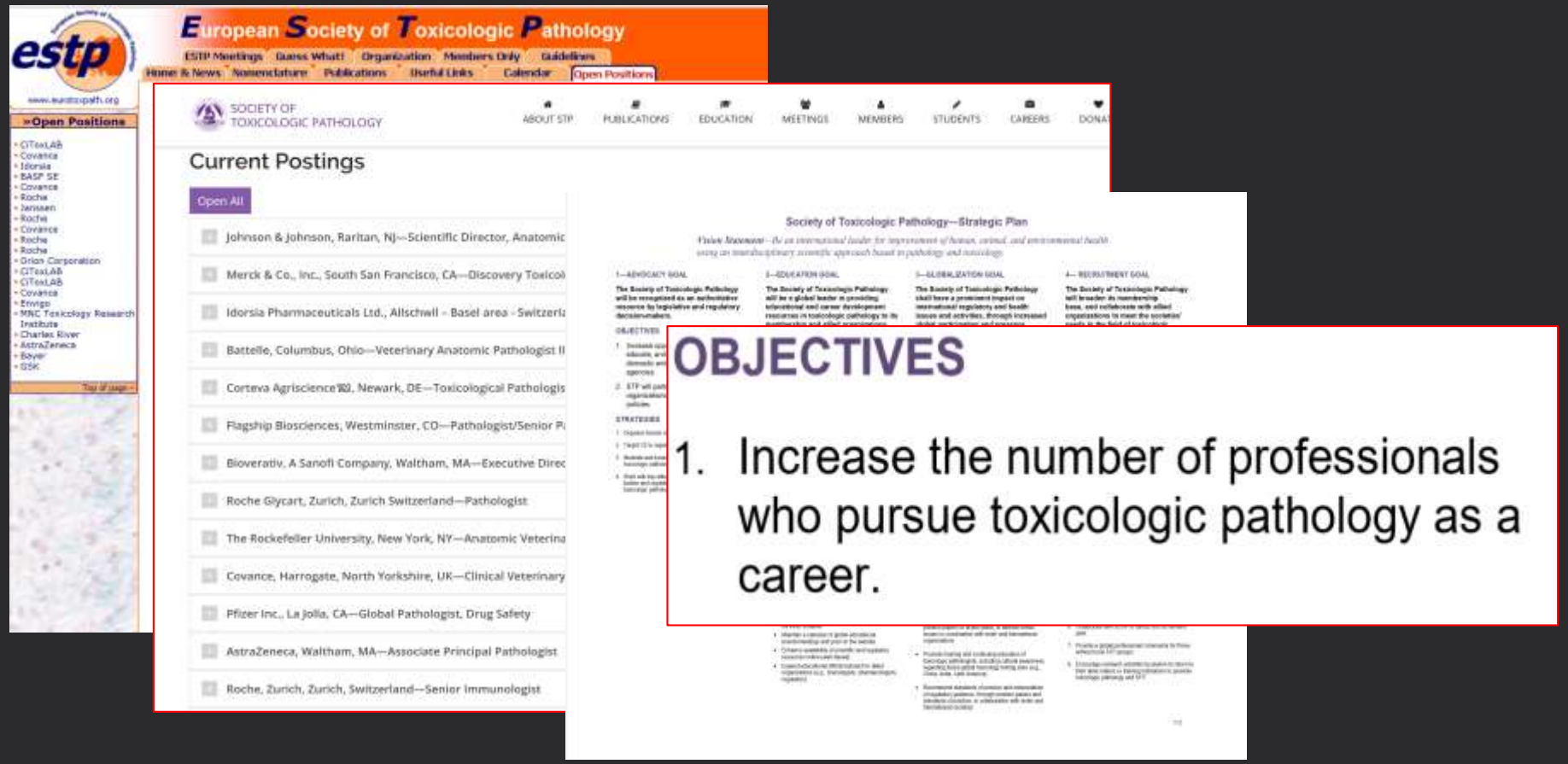
MORE TESTS PER PATIENT

Smaller biopsies, Growth in molecular pathology, Advent of companion diagnostics and prognostic/ predictive testing.

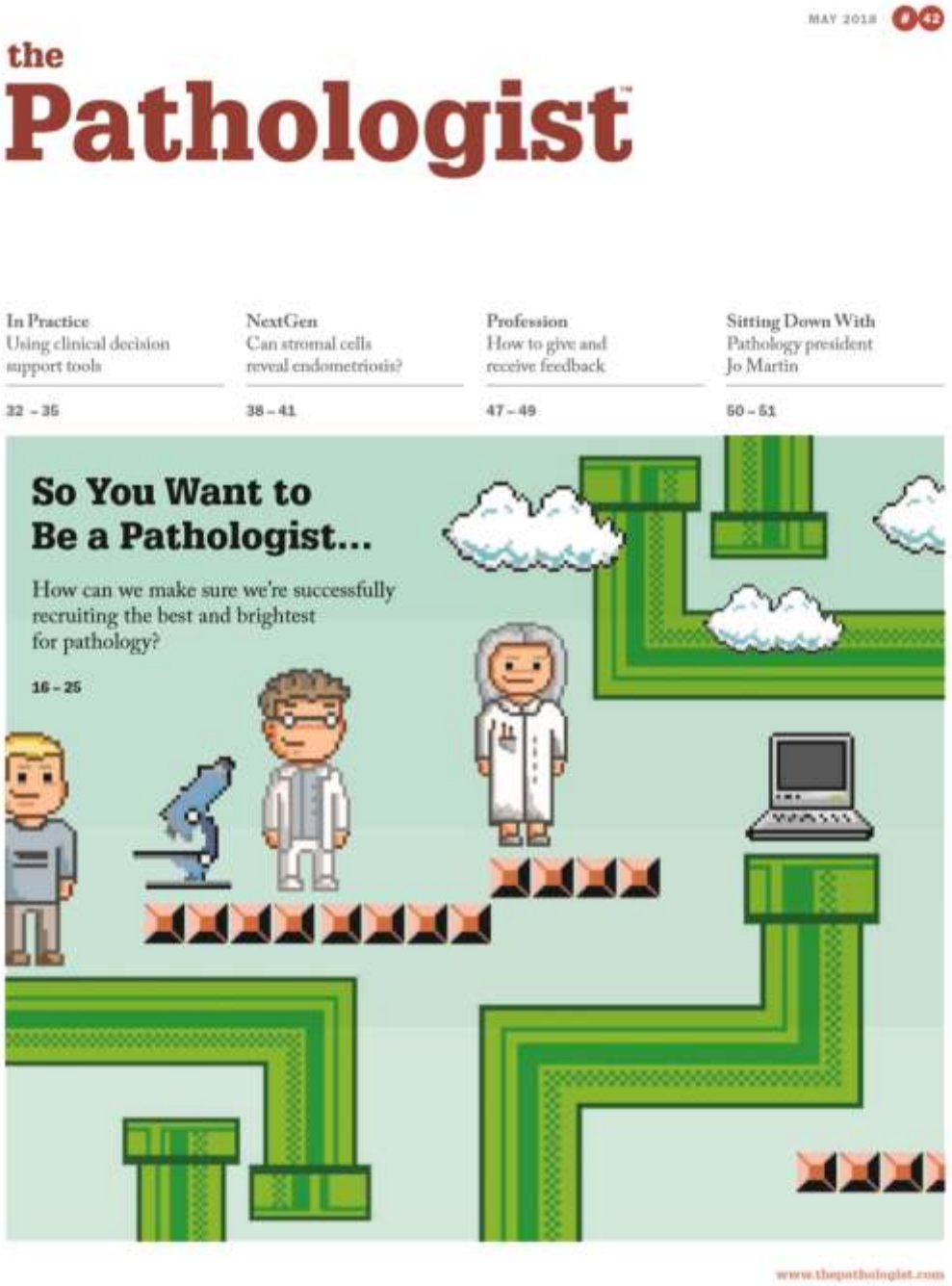
DEVELOPMENT OF STRONG SUPPLY DEMAND DYNAMICS

PATHOLOGY IN CRISIS?

Major Recruitment Issues Already Exist



PROBLEM PARTICULARLY ACUTE IN TOXICOLOGICAL PATHOLOGY



"this shortfall [in pathologist numbers] would extend through the 2020s."

"The field is ripe for benefiting from **AI to facilitate the work of diagnosticians, clinicians,** administrators, and community thought leaders."

"We are rapidly heading into a **future when neural networks will prompt diagnoses, treatments"**

Invited Review

Toxicologic Pathology, 41: 689-708, 2013

ISSN: 0192-6233 print / 1533-1601 online
DOI: 10.1177/0192623312466192

Toxicologic Pathology in the 21st Century

Robert A. Ettlin

Ettlin Consulting Ltd., Muenchenstein, Switzerland

Abstract

Toxicology is and will be heavily influenced by advances in many scientific disciplines. For toxicologic pathology, particularly relevant are the increasing array of molecular methods providing deeper insights into toxicity pathways, *in vivo* imaging techniques visualizing toxicodynamics and more powerful computers anticipated to allow (partly) automated morphological diagnoses. It appears unlikely that, in a foreseeable future, animal studies can be replaced by *in silico* and *in vitro* studies or longer term *in vivo* studies by investigations of biomarkers including toxicogenomics of shorter term studies, though the importance of such approaches will continue to increase. In addition to changes based on scientific progress, the work of toxicopathologists is and will be affected by social and financial factors, among them stagnating budgets, globalization, and outsourcing. The number of toxicopathologists in North America, Europe, and the Far East is not expected to grow. Many toxicopathologists will likely spend less time at the microscope but will be more heavily involved in early research activities, imaging, and as generalists with a broad biological understanding in evaluation and management of toxicity. Toxicologic pathology will remain important and is indispensable for validation of new methods, quality assurance of established methods, and for areas without good alternative methods.

Keywords: toxicologic pathology; alternative models in toxicology; animal models; biomarkers; computer data/image collection; discovery pathology; mechanisms of toxicity.

Introduction

In the three regional toxicopathology journals with over 4,000 scientific articles, the keyword "future" is used in more than 1,150 articles and the keyword "new trends" in close to 900 articles, while the term "21st century" is mentioned still relatively rarely in around 30 articles. In 2003, Bernhard A. Schwetz wrote an article entitled "Toxicologic pathology: looking ahead" (Schwetz 2003). He correctly foresaw that the pace of technologic change will accelerate and that new challenges will appear, including new pathogens.

Curiosity and wanting to be prepared are important reasons why people are interested in predictions, even though predictions often turn out to be wrong. The journal *Scientific American* (Pogue 2012) recently published a list of bad predictions, which included the following statement of Thomas Watson, Chairman of IBM in 1943: "I think there is a world market for maybe five computers." Similarly wrong were predictions regarding xenotransplantation using organs of transgenic pigs in the 1990s (Bach et al. 1996; Ferran et al. 1997) or concerning the future need for toxicopathologists: in Switzerland, around 20 years ago, a special program was initiated by the Basel pharmaceutical and chemical industry in collaboration with a Swiss veterinary faculty to train veterinarians in toxicologic pathology. However, the anticipated demand for toxicopathologists did not materialize. In 2007, the American College of Veterinary Pathologists, the Society of Toxicologic Pathology (STP), and the American Society for Veterinary Clinical Pathology undertook a survey regarding employment and future needs of veterinary pathologists (Owens, Marzano, and Yang 2008): the prediction for the period 2010 to 2013 was approximately 160 open positions for anatomic pathologists. By looking at the current job market and talking to colleagues, no shortage of toxicopathologists is evident. Various reasons have contributed to this development: the global financial crisis has partly dramatically lowered the fractions of government budgets dedicated to scientific projects

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Abbreviations: ADME, absorption/distribution/metabolism/excretion of xenobiotics; ADR, adverse drug reaction; CRO, contract research organization; CT, computer tomography; EC, European Commission; ECG, electrocardiography; ECHA, European Chemicals Agency; ECVAM, European Center for the Validation of Alternative Methods; EU, European Union; FDA, (U.S.) Food and Drug Administration; FRAME, Fund for the Replacement of Animals in Medical Experiments; GLP, good laboratory practice; ICCVAM, Interagency Coordinating Committee on the Validation of Alternative Methods; ICH, International Conference on Harmonization; ILSI, International Life Sciences Institute; IT, information technology; Kim-1, urinary kidney injury molecule-1; LIMS, laboratory information management system; NAS, (U.S.) National Academy of Sciences; NGO, nongovernmental organization; NHP, nonhuman primates; NICEATM, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods; NIH, (U.S.) National Institute of Health; NTP, (U.S.) National Toxicology Program; omics, generic term for genomics, proteomics, metabolomics, interactomics, etc.; 3R, reduce–refine–replace; R&D, research and development; REACH, Registration, Evaluation, Authorization and Restriction of Chemical Substances; STP, (North American) Society of Toxicologic Pathology.

"It appears unlikely that, in a foreseeable future, animal studies can be replaced by in silico and in vitro studies…"

"The number of toxicopathologists in North America, Europe, and the Far East is not expected to grow."

"Many toxicopathologists will likely spend less time at the microscope."

"more powerful computers [are] anticipated to allow (partly) automated morphological diagnoses."

OUR PRODUCT - PATHOLYTIX

We Will Use Artificial Intelligence to detect Abnormalities in Biopsies

Select Slides

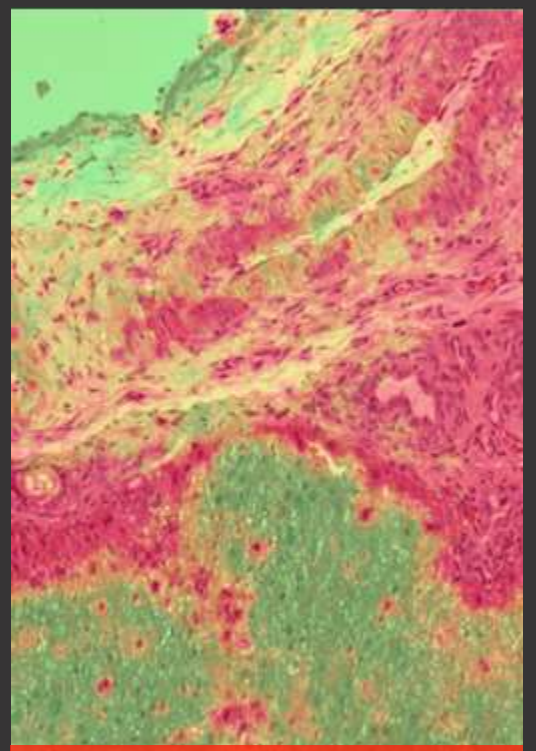
Normal biopises

Scan Content

Analog to digital

PATHOLYTIX

AI techniques applied

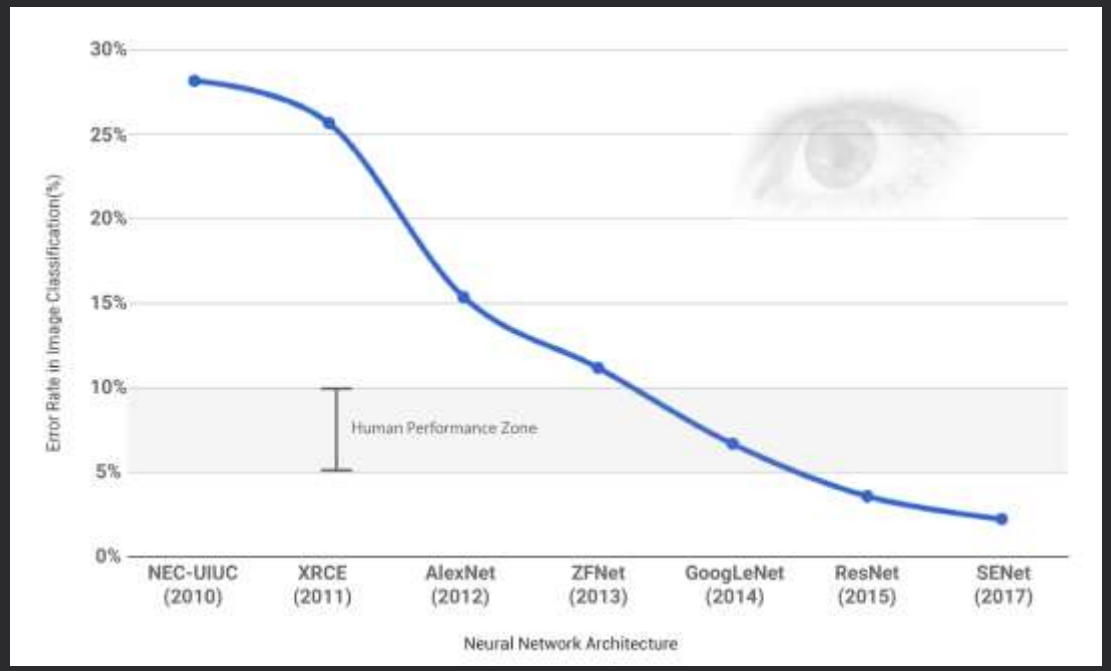


Insight

Areas of interest identified

ARTIFICAL INTELLIGENCE – THE TIME IS NOW

AI based Image recognition **exceeding** human capability in many academic trials.



Growing acceptance of the use of AI based image recognition in clinical diagnostics.

Opinion

VIEWPOINT

INNOVATIONS IN HEALTH CARE DELIVERY

Adapting to Artificial Intelligence
Radiologists and Pathologists as Information Specialists

Saurabh Jha, MBBS, MRCS, MS
Department of Radiology, University of Pennsylvania, Philadelphia.

Eric J. Topol, MD
Scripps Research Institute, La Jolla, California.

Editorial

Artificial intelligence—the mimicking of human cognition by computers—was once a fable in science fiction but is becoming reality in medicine. The combination of big data and artificial intelligence, referred to by some as the fourth industrial revolution,[1] will change radiology and pathology along with other medical specialties. Although reports of radiologists and pathologists being replaced by computers seem exaggerated,[2] these specialties must plan strategically for a future in which artificial intelligence is part of the health care workforce.

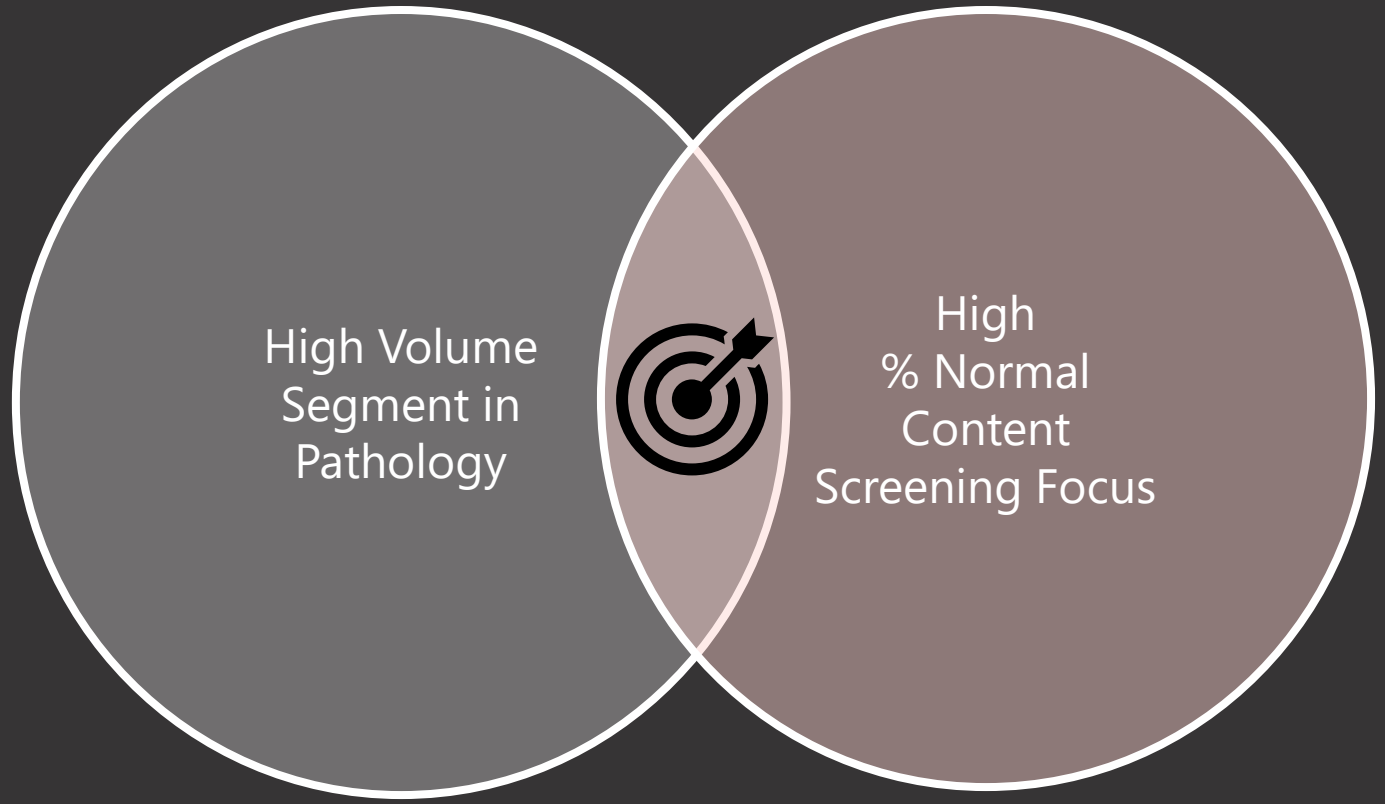
Radiologists have always revered machines and technology. In 1960, Lusted predicted "an electronic scanner-computer to examine chest photofluorograms, to separate the clearly normal chest films from the abnormal chest films."[3] Lusted further suggested that "the abnormal chest films would be marked for later study by the radiologists."[3] Lusted's intuitions were prescient: interpreting radiographs is pattern recognition; computers can

This progress in imaging has changed the work of radiologists. Radiology, once confined to projectional images, such as chest radiographs, has become more complex and data rich. Cross-sectional imaging such as CT and magnetic resonance, by showing anatomy with greater clarity, has made diagnosis simpler in many instances; for example, a ruptured aneurysm is inferred on a chest radiograph but actually seen on CT. However, this has come at a price—the amount of data has increased markedly. For example, a radiologist typically views 4000 images in a CT scan of multiple body parts ("pan scan") in patients with multiple trauma. The abundance of data has changed how radiologists interpret images; from pattern recognition, with clinical context, to searching for needles in haystacks; from inference to detection. The radiologist, once a maestro with a chest radiograph, is now often visually fatigued searching for an occult fracture in a pan scan.

AI IS READY FOR PRIMETIME IN CLINICAL USECASES

WHERE CAN WE ADD VALUE?

Where Volume and Normal Content Intersect

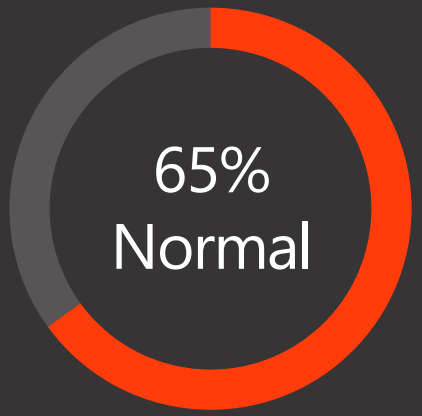


CERTAIN HIGH VOLUME APPLICATIONS HAVE A HIGH % NORMAL BIOPSIES.

DR KEITH KAPLAN
(EX MAYO CLINIC AND ARMED FORCES INSTITUTE OF PATHOLOGY)

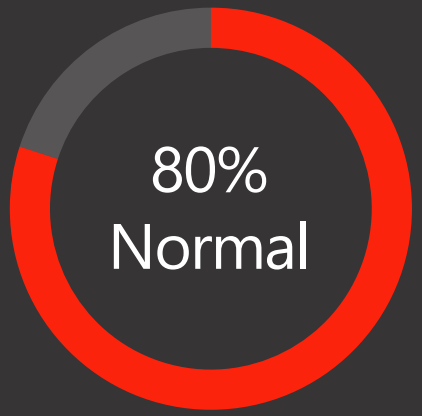
MARKETS AND OPPORTUNITY

Two Attractive Segments Identified with $1bn in Combined Opportunity



HUMAN GI PATHOLOGY SAM $0.5bn

15 million patients biopsied annually in the US. 65% “normal” endoscopic biopsies in current clinical practice. Growing incidence of endoscopic biopsies, declining numbers of global pathologists.



TOXICOLOGICAL PATHOLOGY SAM $0.5bn

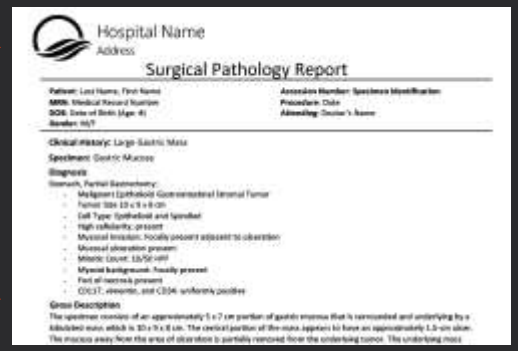
All candidate drugs go through drug safety assessment, driven by regulation. 100M slides reviewed annnually, 5500 pathologists globally deployed. 80% normal content.

OUR PLANNED APPROACH

TRIAGE CONTENT FOR HIGH PRIORITY REVIEW

35%

Pathologist reviews key content



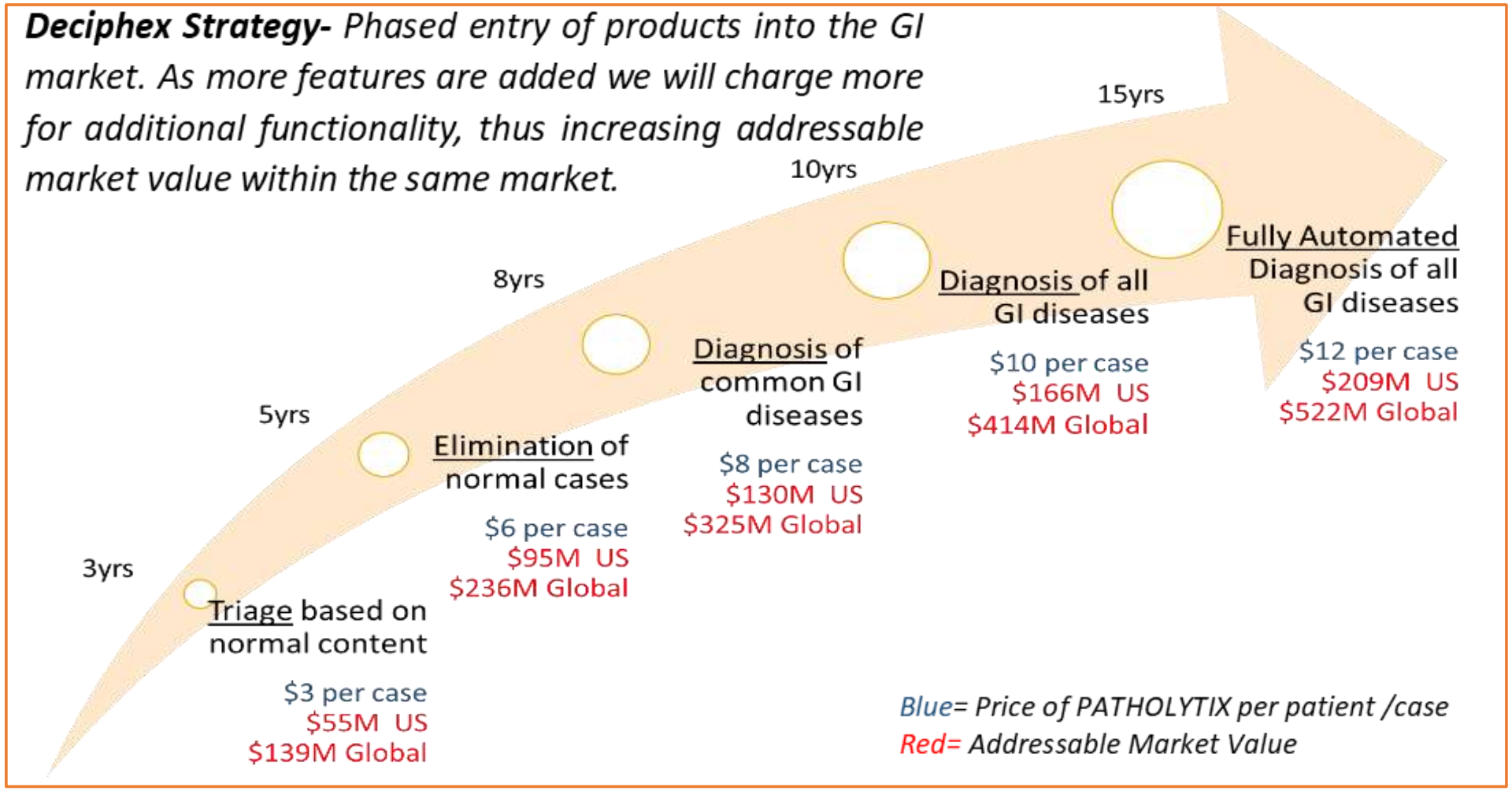
65%

Low priority content triaged out

ELIMINATING NORMAL CAN ULTIMATELY DRIVE **3X PRODUCTIVITY IN GI PATHOLOGY** AND **4X IN TOXICOLOGICAL PATHOLOGY**

Phased Market Entry as Capabilities Increase

Important to Build Confidence in Market through Incremental Technology Introduction



Key Achievements to Date

Great Progress in First Year of Operation

250k in convertible loan note finance.
550k in commitments for seed round.

2m EUR EU Fast Track to Innovation Grant Awarded. EU SME Instrument Phase 1, EI Feasibility Grant x 2.

Active collaborations with Janssen, Astra Zeneca, PDS, GI Partners of Illinois., Lasogen

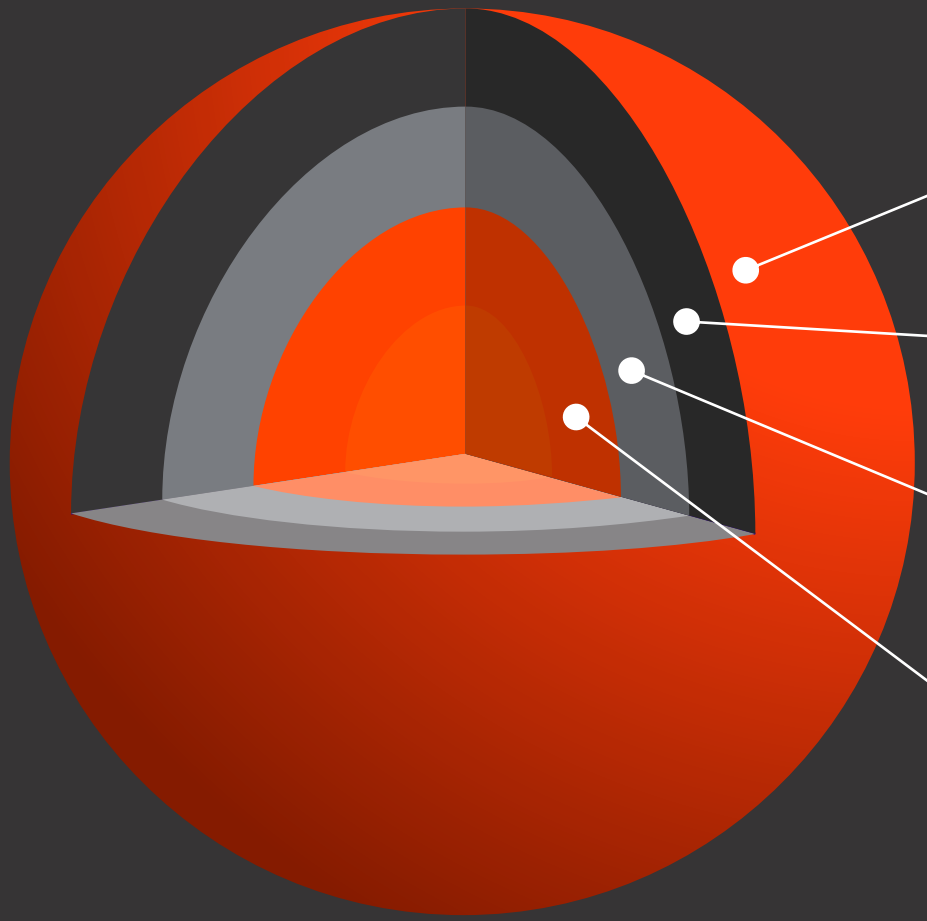
100,000 digital slides either in hand or contractually committed for development.

Working prototype engine, design specification for first pharma product.

2 US Patents Filed, detailed FTO assessment performed. Additional IP in-licenced.

Strong multidisciplinary team of 8 (Leica Biosystems, Amazon, Mastercard, Oncomark).

COMPLEX MULTIFACETED PROJECT



DEVELOP ERGONOMIC PRODUCT
DELIVER ON CUSTOMER EXPECTATIONS

DELIVER PERFORMING ENGINE
LEVERAGE LATEST TECHNOLOGICAL APPROACHES

BUILD HIGH QUALITY DATA REPOSITORY
HIGH QUALITY CONTENT WITH PATIENT CONSENT

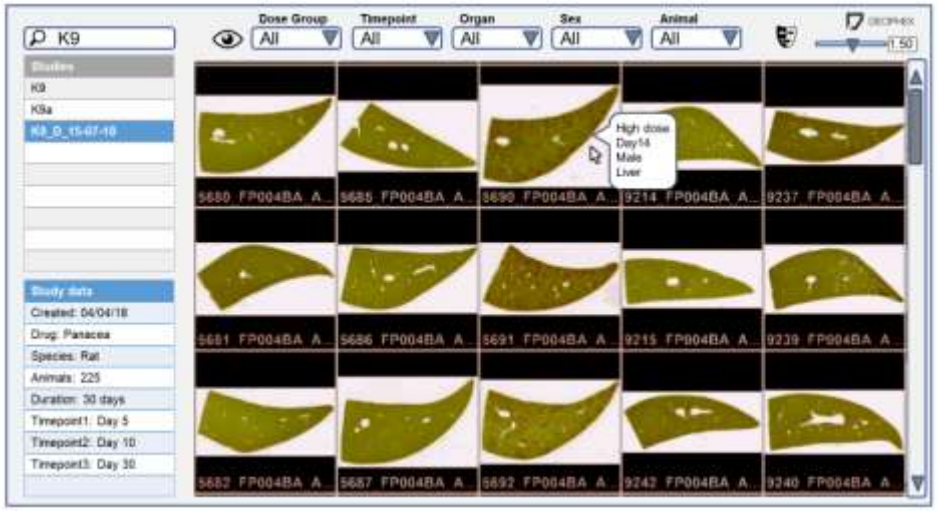
LEVERAGE CONTEXT FROM PATHOLOGISTS
SEVERAL THOUSAND ANNOTATIONS PER USECASE

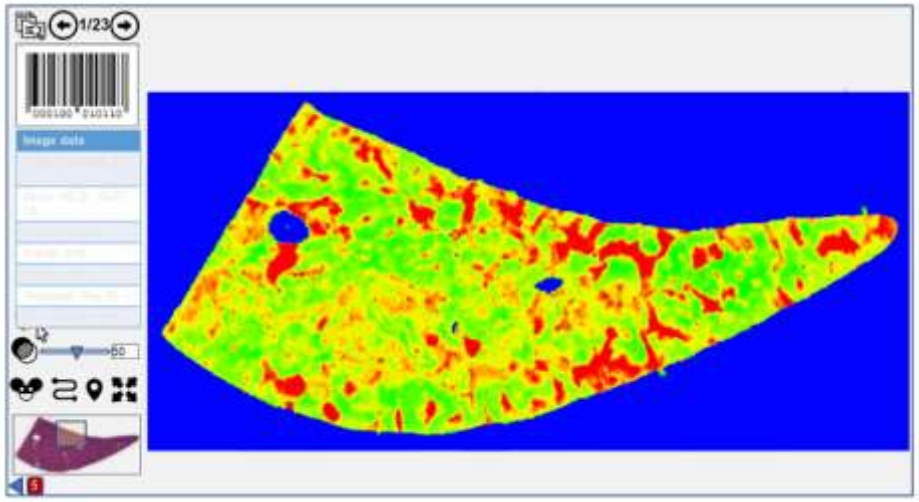
Deciphex will deploy validated, deep learning capability within ergonomic workflow and optimized business models

PRODUCT

Pharma Product Launch – Q4 18

Strong Funnel Already Established





janssen

charles river

AstraZeneca

Roche

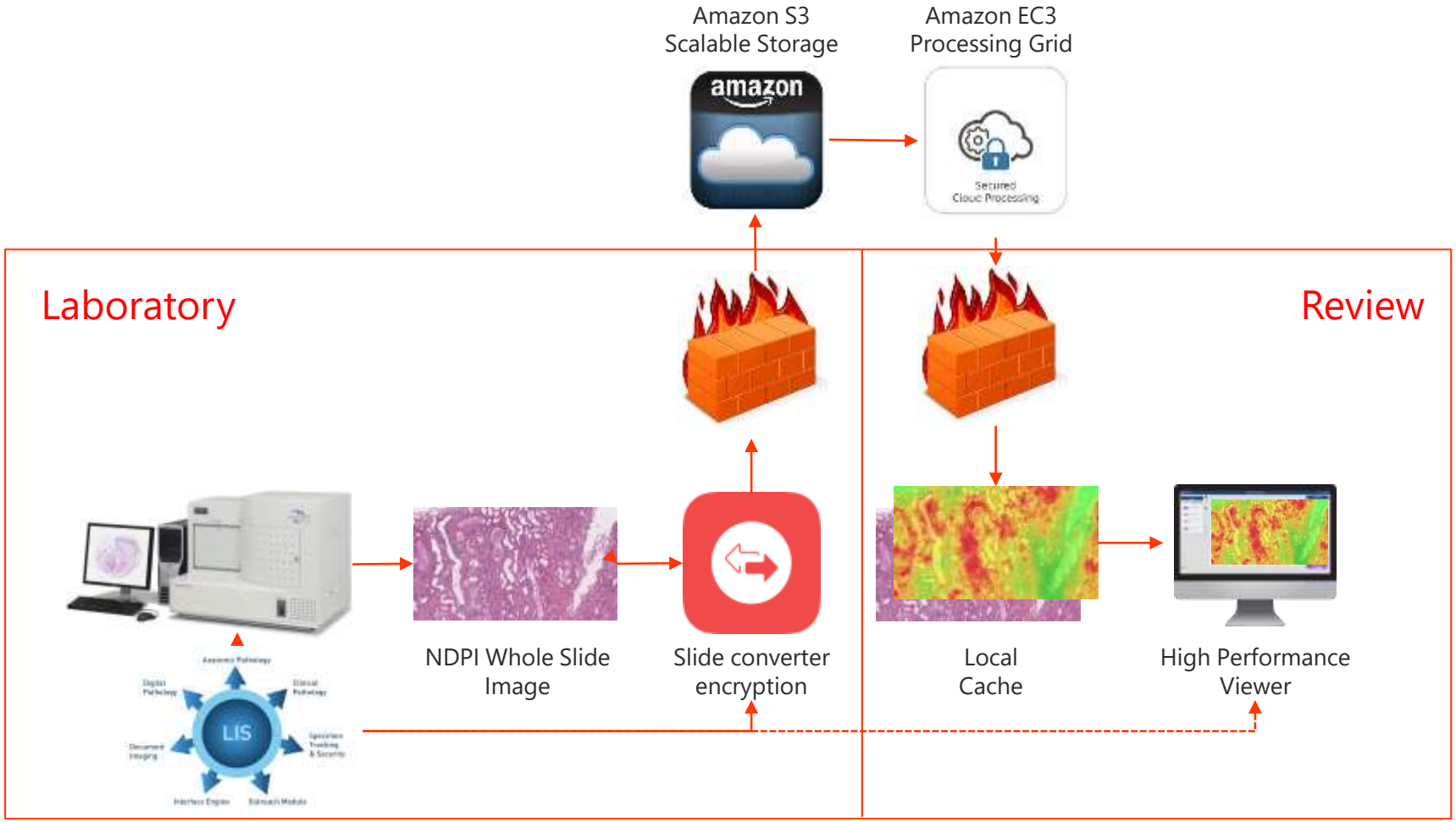
BAYER

COVANCE

NOVARTIS

High Level Overview of Patholytix

Image Processing in Pipeline/In Cloud



Key Design Criterion of Patholytix

SECURITY AND COMPLIANCE

01

Compliance with appropriate data standards 21CFR11, ISO27001,27017

ISO13485 software development processes

Encryption of identifiable data in transit and at rest.

SCALABILITY AND PERFORMACE

02

Scalable, secure, GPU powered microservice architecture in cloud.

Process slides as fast as they can be scanned.

Leverage state of the art models

ERGONOMY AND PRODUCTIVITY

03

User interface facilitating review of 300 slides per day with user ergonomy considered.

Product design in consult with our key customers.

ACCESSABILITY AND COMPATIBILITY

04

Multi-Scanning Vendor Compliance.

GLP compliant scanning centers where the customers are US,EU, China

Deciphex plan to provide a comprehensive solution, addressing all of the current shortcomings in current digital pathology workflows

ENGINE

Patents Filed Covering the Potential of Normal Models

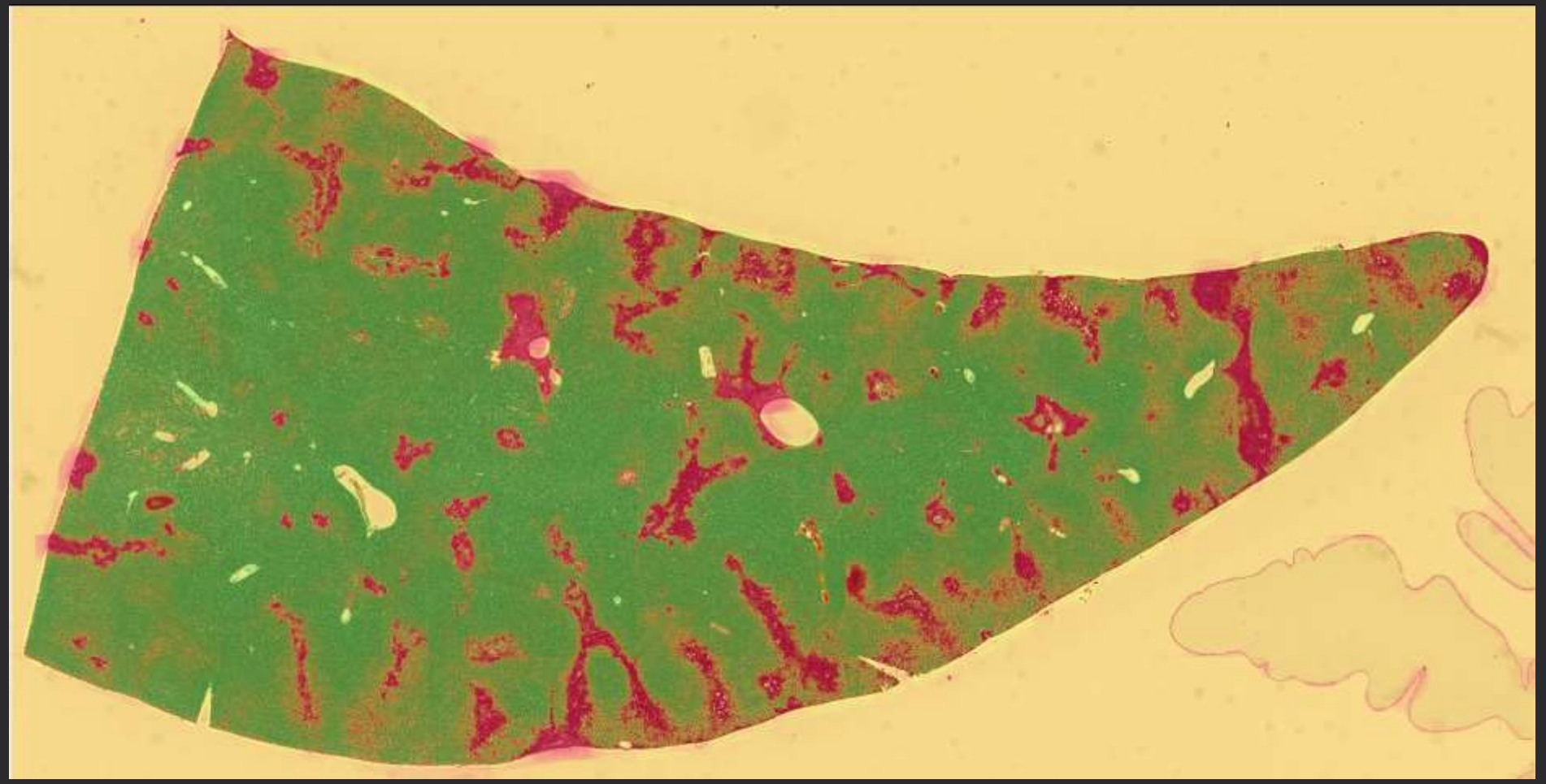
We continue to explore the potential of additional patent filings in 2018

Patent ID #	Named Inventor	Territories filed/granted	Description	Status	Freedom to operate/other
US Application number 62590861	Mark Gregson and Donal O'Shea	US (will expand during PCT & National phase)	**Automated screening of histopathology tissue samples via analysis of a normal model**	Provisional application	FTO study undertaken & is available for review
US Application number 62590866	Mark Gregson and Donal O'Shea	US (will expand during PCT & National phase)	Automated screening of histopathology tissue samples via classifier performance metrics	Provisional application	FTO study undertaken & is available for review

US PATENTS FILED TO COVER KEY METHODS

PATHOLYTIX IN ACTION

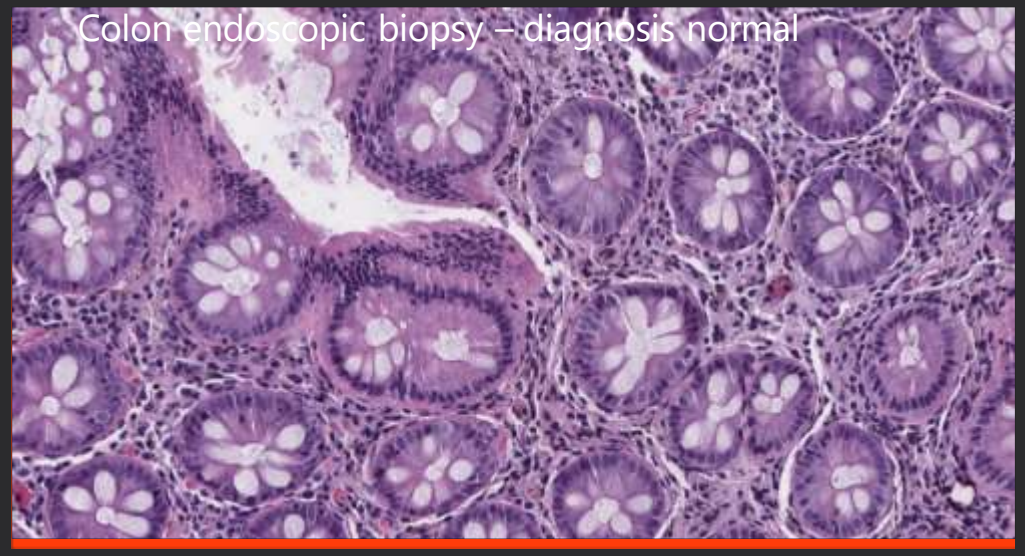
Detection of Hyperplasia in Rat Liver – Veterinary Pathology

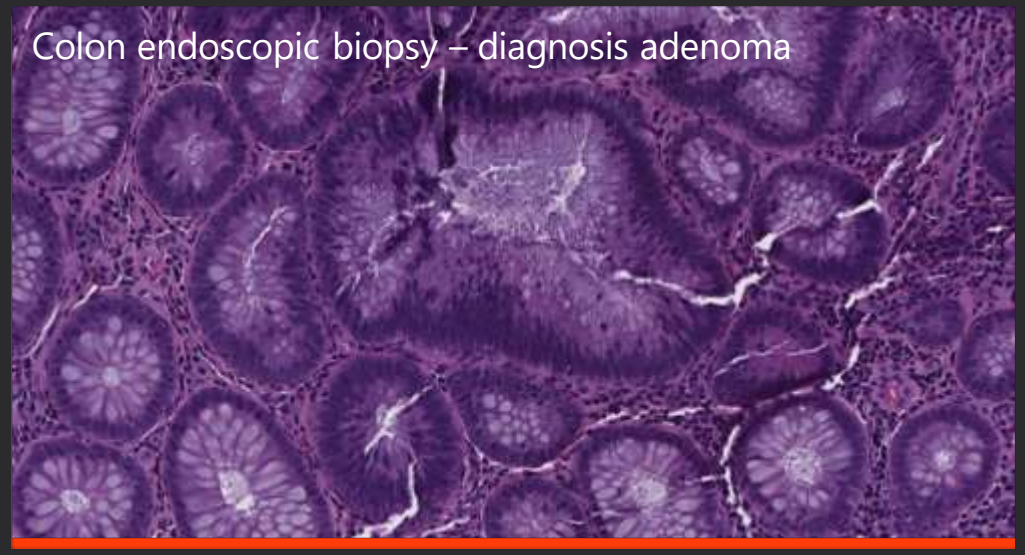


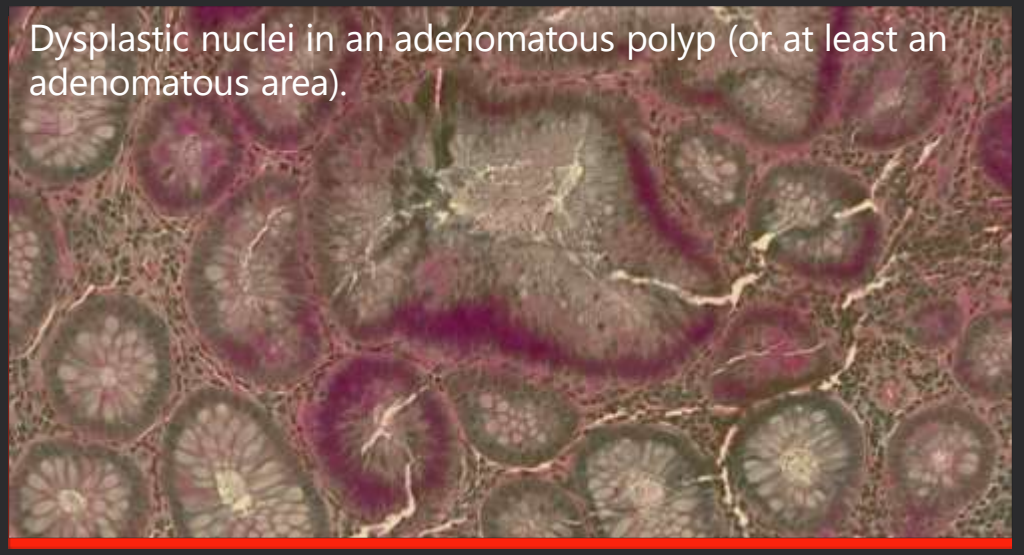
High resolution images produced as fast as scanning, results immediately available to the pathologist

PATHOLYTIX IN ACTION

ABNORMALITY DETECTOR – HUMAN COLON

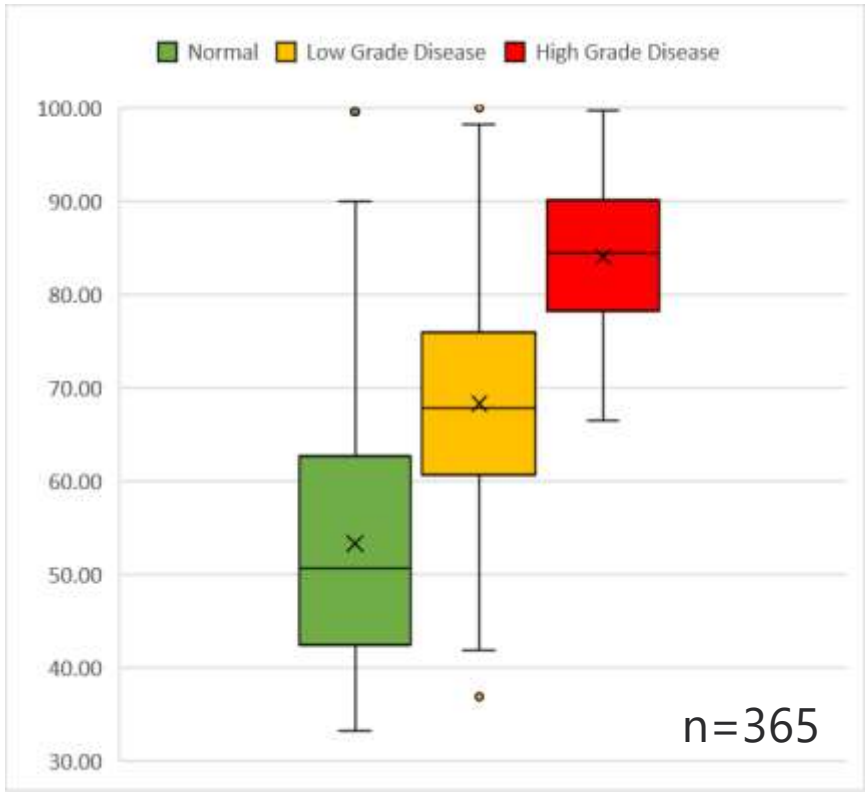


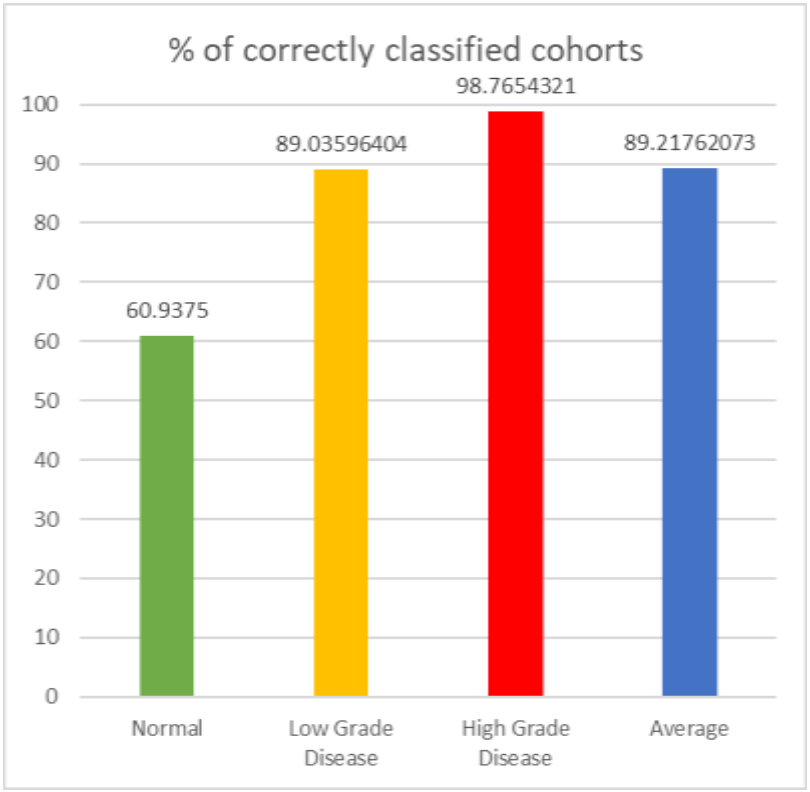


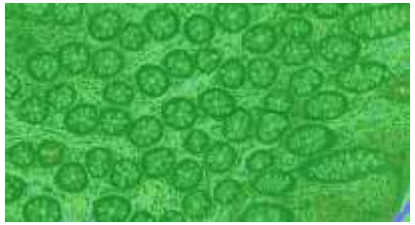


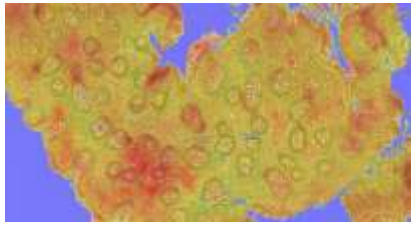
DEEP DIVE ON COLONOSCOPY DATA

Effective Triage of Colonoscopies Based on Extent of Disease Present









COLLABORATIONS

Collaboration Funnel

Several Collaborators Willing to Help us Achieve Our Validation Goals

Preclinical

Innovative Medicines Initiative

National Institutes of Biomedical Innovation, Health and Nutrition
NIBIOHN 国立研究開発法人医薬基盤・健康・栄養研究所

PATHOLOGY EXPERTS Toxicology - Pathology - Preclinical Services

Janssen

charles river

pds

AstraZeneca

Clinical

GI PARTNERS of ILLINOIS, LLC

synevo

NHS Sheffield

MAYO CLINIC

HOLOGIC

Excellent funnel of collaborations in pipeline, with the potential to generate 250,000 pieces of content

EU Grant Success: Fast-Track-To-Innovation

Fast-Track-To-Innovation

- Aimed at SME companies
- Funds multidisciplinary collaboration to develop innovative products
- Budget €2M

Objectives:

- Technology development (AI, workflow and cloud infrastructure)
- Integration with laboratory information management systems (LIMS)
- Validation and Benchmarking studies

GI Partners of Illinois

30,000 Human GI Cases Committed in the Next 3 Years

Consortium of 45 gastroenterologists operating in the Chicago area.

Operating from 9 physical facilities

Generating 12,000 endoscopic biopsies per annum

Biopsies consolidated in a single lab

Negotiating access to entire case cohort

Need to update patient consent form to facilitate use of materials for our needs

GI PARTNERS of ILLINOIS, LLC

TEAM

THE LEADERSHIP TEAM

Donal O'Shea
Chief Executive Officer

VP LEICA BIOSYSTEMS (DANAHER CORP)
GENERAL MANAGER
SERIAL ENTREPRENEUR
3 TRADE SALES (>100M EURO)
2 ACQUISTIONS WITH DANAHER

Mark Gregson
Chief Technology Officer

EXPERIENCED CTO
0.25BN TECHNOLOGY SALES
CAD EXPERT
AI EXPERT
IP PROTECTION EXPERT
CLINICAL WORKFLOW EXPERT

Mairin Rafferty
Chief Operations Officer

EXPERIENCED COO
SUPPORTED 7.5M FUNDRAISING FOR ONCOMARK
EU GRANT EXPERT AND REVIEWER
CLINICAL RESEARCH EXPERT
CANCER BIOLOGIST

STRONG DOMAIN EXPERIENCE AND PROVEN CAPABILITY TO EXECUTE

THE EXTENDED TEAM

Andrea Rizzini
Director Cloud Computing

MSc Computer Sci
Senior Technical Consultant, Mastercard
Senior Developer, Slidepath & Leica Biosystems

William Hughes
Product Development Manager

MSc Computer Sci
Technical Software Development Manager & LIMS integration, Leica Biosystems

Mirko Colleluori
Senior Software Engineer

MSc Computer Sci.
Software engineer, Amazon
Senior Image Analysis Architect, Leica Biosystems

Petra Vanickova
Lead Artificial Intelligence Engineer

MSc Computer Sci.
CTO in startup, Zoodazzle
Project lead & Developer, Leica Biosystems

Martyna Miarka
Data & Clinical Cohorts Manager

BSC Genetics & Cell Biology
Regulatory compliance, Bristol Myers Squibb

STRONG DOMAIN EXPERIENCE AND PROVEN CAPABILITY TO EXECUTE

FINANCIALS

PHASE 1 FUNDRAISING – 500k outstanding

Key Deliverables

Develop and Launch Pharma Product

Further investment in AI model development

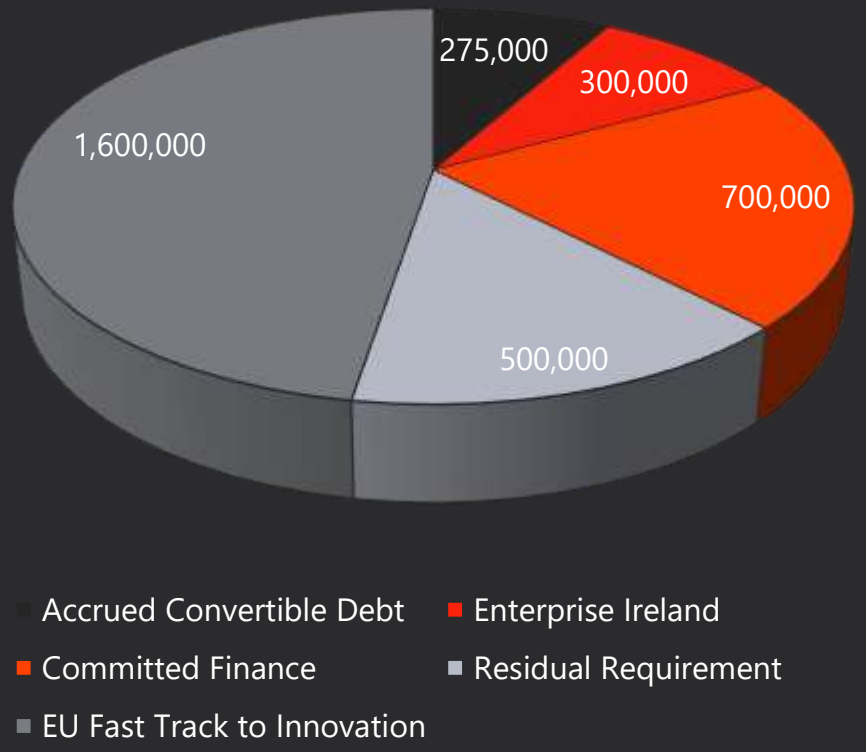
Strengthen and Develop Team

Enable collaboration with GI Partners

Build first 1m EUR in Revenue

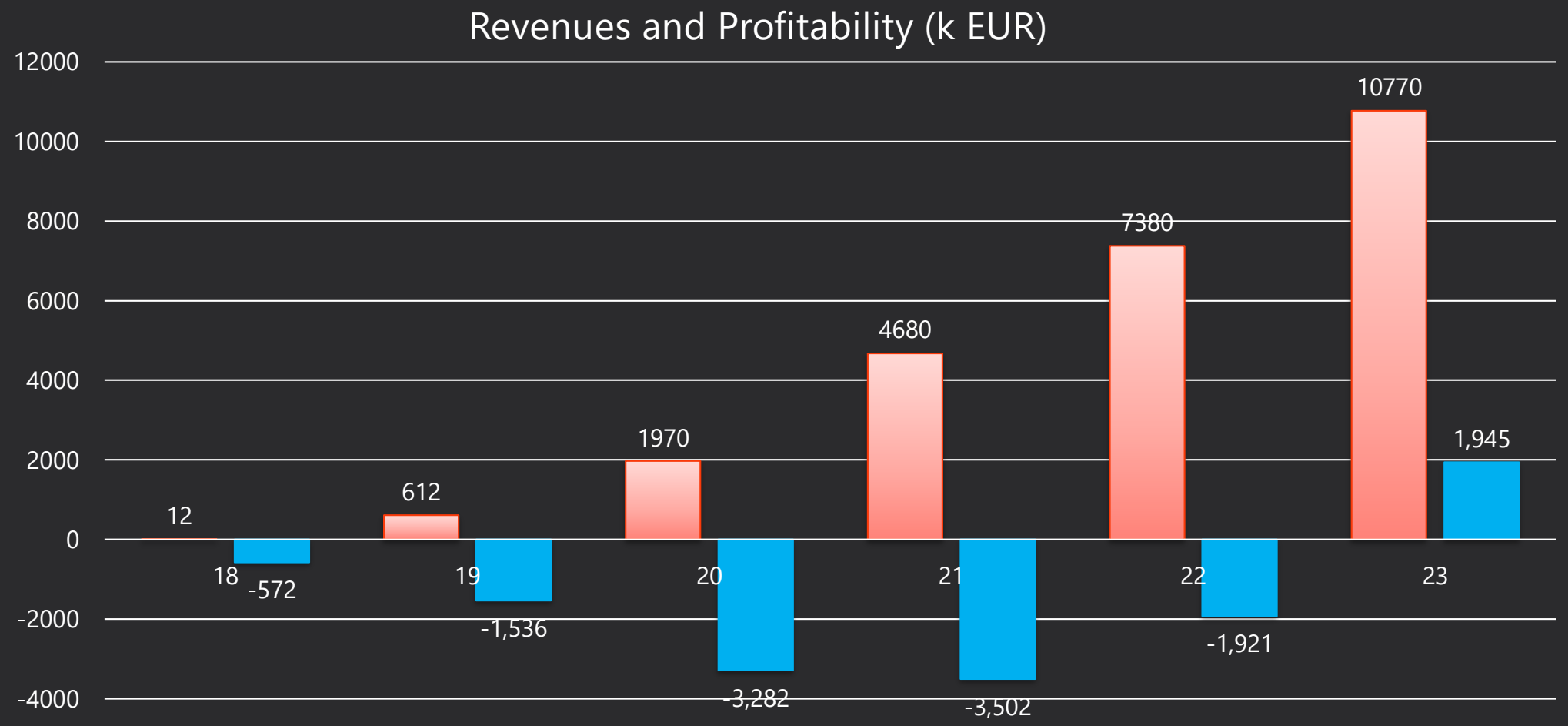
3m EUR Series A Raise in 2020

Total Funding 3.35m



Financial Outlook

10m in Revenues, 2m Profits by 2023



HOW WILL WE DEPLOY CAPITAL

	2018	2019	2020	2021	2022	2023
R&D Team	370	1,252	1,581	1,640	1,667	1,684
R&D Indirect Spend	152	394	665	535	680	823
Marketing & Sales	123	295	1,020	1,250	1,337	1,462
G&A	217	378	713	672	725	816
COGS	2	122	394	936	1,476	2,154
Capital	342	29	47	35	47	59

COMPETITION AND EXIT

DEEP LEARNING/AI NEXT GENERATION

25M USD IN SEED CAPITAL DEPLOYED IN LAST 12 MONTHS

STRONG VALIDATION OF OPPORTUNITY THROUGH PEER INVESTEMENTS

Why are we different?

Screening focus differentiates us from the other commercial players

- Screening Focus
- GI Focus
- Workflow and Decision Support Focus
- Content Focus
- Toxicology Focus
- IVD Focus

WELL DIFFERENTIATED PROPOSITION FROM PEER COMPANIES

M&A Outlook

Potential Future Suitors for Deciphex

Digital Pathology

Players interested In driving further Hardware/system adoption through association with new adoption drivers

Screening Players

Computer aided screening technologies are not new in cytology. Cervical screening routinely apples such tools. Comfortable approach for these players

CROs

Where massive supply demand dynamics apply in veterinary pathology controlling automated pathology provides considerable market advantage

Diagnostics Labs

In a market that is hugely cost driven and consolidation focussed, automated screening tools can reduce cost of diagnosis and provide these players with a winning edge.

STRONG FUNNEL OF LIKELY ACQUIRERS

INVESTOR SUMMARY

DECIPHEX is an exciting investment opportunity for the following key reasons.

01

Significant Market Opportunity

Estimated 1Bn in assessable market. Clear market drivers that will ultimately force adoption.

02

Exciting Technology Space

Deep Learning is proving to deliver real value and productivity in many markets.

03

Experienced Management Team

Over 40 years of combined management experience in this market segment. Proven deal making, both trade sales and acquisitions

04

Strong network of partners

Strongly networked team with world class collaborators in both Human and Veterinary Pathology.

THANK YOU

$500m Global Automation Potential for Endoscopic GI Biopsies

30,000 pathologists globally, 18,000 US, global cost 8-10bn, US 4bn. $250k ave. US salary, 2.5% annual decline in US pathologist numbers.

20% of total pathology workload is gastrointestinal (GI), equating to 6,000 pathologists globally and 2-2.5bn in salary cost. US caseload growing at 3% CAGR, higher globally due to introduction of screening.

15m **endoscopic GI biopsies** each year in the US, 65% normal content. $620m in reimbursement, >$400m in pathologist cost. $1bn global opportunity in reimbursable value/$650m in global professional costs.

We believe we can automate the review of endoscopic GI biopsies. With strong supply demand dynamics, we plan to monetise services as close to the efficiency gained as possible. Reimbursement rates can be positively influenced by using technology that enhances patient safety/reduces error rates.

$500m Automation Potential for Toxicology Biopsies

Annual incremental spend in drug development R&D $150bn, 3% CAGR. 11,000 drugs currently in development with 6000 in preclinical/drug safety assessment.

5500 toxicological pathologists globally, **costing $1.1bn**. Considerable supply demand issues in the market, with recruitment bottlenecks.

10m animals used globally in toxicology evaluation studies, 70% reviewed by pathology, up to 40 organs reviewed per animal, >**100m individual slides reviewed.**

We see our software deliver 50% efficiency gains in this segment. With strong supply demand dynamics, we plan to monetise services as close to the efficiency gained as possible.

charles river

Example customer

Global CRO supporting several Tier1 Pharma companies

2.5m slides reviewed Globally

120 pathologists on Payroll (approx. 80 AP).

$50m cost centre