



First half 2023 presentation

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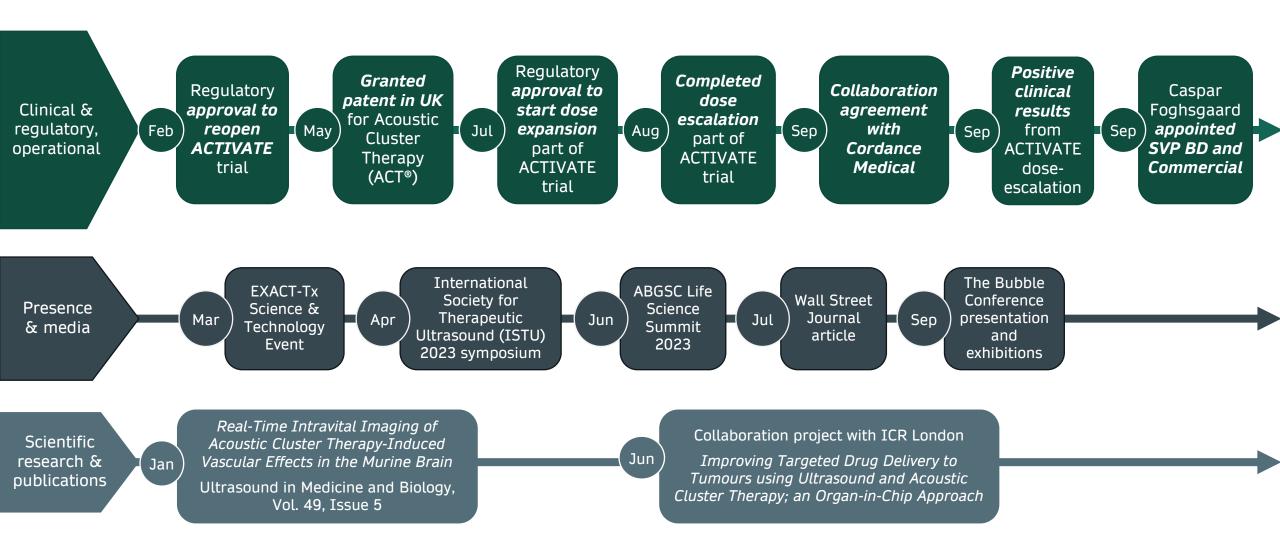
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# 2023 highlights





# **EXACT Therapeutics**



### Unique platform technology: "

Ultrasound guided targeted therapeutic enhancement using proprietary microbubbles for effective, drug agnostic delivery

# Encouraging initial clinical data: ...:

Ongoing multinational clinical program, with established infrastructure for expansion

### Strong scientific rationale: ::

Extensive preclinical safety documentation and preclinical efficacy data with SoC cancer therapies



Management and board with broad and relevant experience and network

# : Attractive competitive position

First mover (clinical stage) with ultrasound market leader collaboration and commercial scale GMP manufacturing

# Robust Development strategy

Targeting high value markets with significant unmet medical needs

## : Straight commercial adoption

Customised ultrasound probe compatible with a vast installed base globally

Source: Company information

Note: SoC - Standard of Care, GMP - Good Manufacturing Practice



# Building value



# Strong preclinical evidence across models and drugs



### **Proof-of-concept** model



**Brain** 

Demonstrated targeted, temporary, and safe blood-brainbarrier disruption

Prof de Lange Davies, **NTNU**, Norway

### Mice cancer models, combining different cancer drugs with ACT



### **Pancreas**

5x increase in complete disappearance of cancer using ACT with standard of care therapeutics

Prof's Von Hoff & Han. TGen, Arizona, US



### **Breast**

ACT + therapy caused the cancer to completely disappear in >60 % of animals vs. 0 % with therapy only

Prof Jeff Bamber, ICR, UK



### Colon

4x increase in complete disappearance of cancer using ACT with standard of care

Prof Jeff Bamber, ICR, UK



### **Prostate**

ACT + therapy caused the cancer to completely disappear in >70%. of animals vs. 0% with therapy only

Prof de Lange Davies, **NTNU**, Norway

**Six** different cancer drugs included – ACT strongly enhanced efficacy of **all** 

# Defeating biological barriers that hamper drug delivery :

A significant unmet need at a critical junction in the development of precision medicine

- ACT is designed to provide targeted delivery of drugs to tissues throughout the body, with initial focus on
  - Solid tumours, altering the tumour microenvironment to overcome tumour-associated biological barriers
  - Central nervous system (CNS), by providing safe passage over the protective blood-brain-barrier (BBB)
- Focus on enhancing standard of care therapies across several tumour types



Pancreatic cancer – the dense stroma and poor vascularity limits the passage of current and future precision medicine therapies



Brain cancer – many therapies have failed development due to the blood-brain-barrier, resulting in limited survival improvement the last 20 years



Liver metastasis – clinical tumour response provides two opportunities: 1. treatment of liver metastasis from right-sided CRC, and 2. reducing immunosuppression of liver metastasis to enhance systemic CPI effects

Strong rationale for the application of ACT treatment in pancreas cancer, brain cancer, and liver metastases

# **Building the value of the ACT platform**



Transforming the concept of precision therapeutics

Select high unmet need cancer indications

Pancreas cancer / liver metastases

**Oncology expansions** 

Glioblastoma Immunotherapy Other indications **Platform expansions** 

CNS diseases
Rare diseases /
gene therapy / mRNA
Other disease areas

Targeting high-value markets with significant unmet medical need

Organisation for clinical PoC and execution of development plans

Strategic collaborations for expansion of ACT platform utility

Partnering for pivotal development and commercialisation

Execution at all levels to realise the full platform potential

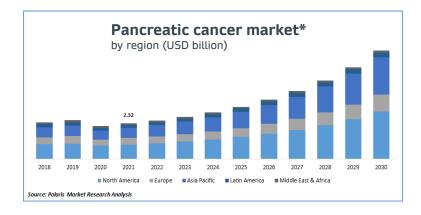
From accelerated inhouse clinical PoC & development to strategic partnering for commercialisation

# Strong rationale and fit with high unmet need indications:

## Large and growing market opportunities

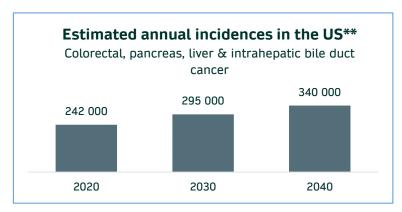
### Pancreatic cancer on the rise globally

- Overall projections show growth in Pancreatic cancer incidences
- Pancreatic cancer to be the second top cause of cancer related deaths in 2030
- Market size expected to grow with CAGR of 13.8% until 2030\*



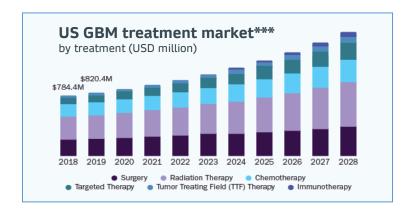
### Improved treatment of liver metastases

- GI tract cancers overall are increasing in the US and affecting younger people
- Expected to be 3 of the top 4 causes of cancer deaths in the US in 2040\*\*
- A large number of patients expected to die from uncontrolled tumour growth in the liver



#### GBM is the deadliest brain tumour

- In 2020, the incidence of brain and CNS cancers was 308,102 globally
- GBM is the most common brain cancer, accounting for ~16% of all primary brain cancers, and with a growing prevalence
- GBM heterogeneity expected to drive a personalized treatment approach



# EXACT Therapeutics - a broad ACT-enabled pipeline

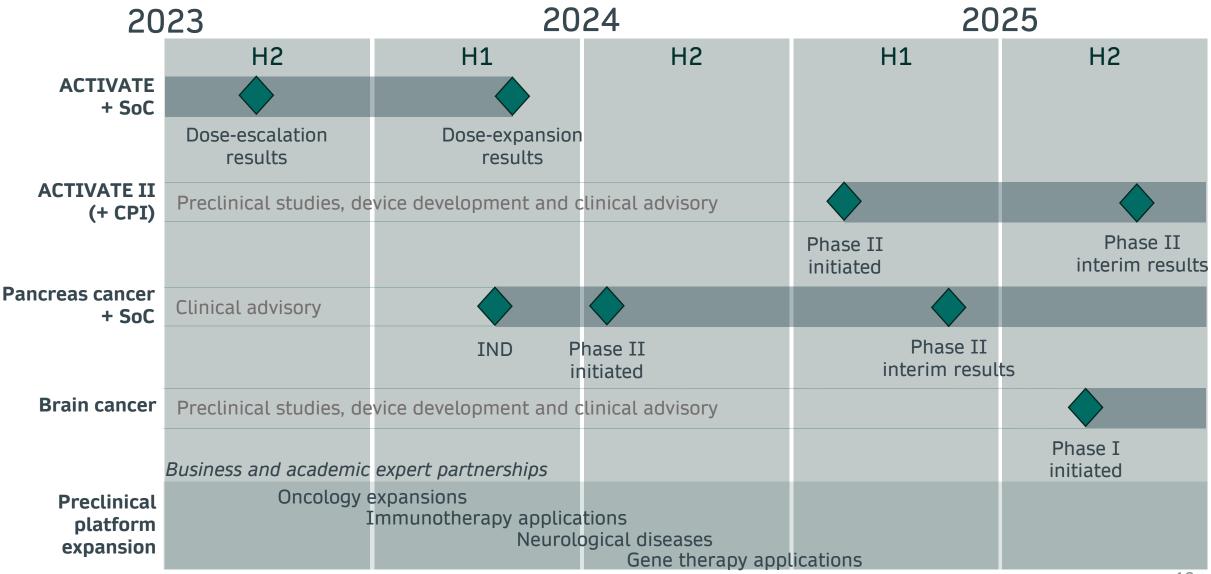
Building on ACT core strengths: defeating barriers in solid tumours & providing safe BBB passage

Area / disease		Preclinical	Phase I	Phase II/III
Oncology	Liver metastases			
	Pancreatic			
	Glioblastoma			
	Immunotherapy			
Other	CNS diseases			
	Gene therapy			

# **Outlook and inflection events**

### **Indicative timeline**





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# Clinical

First results and future development



# **Dose escalation part - patients and safety**



- 8 patients enrolled, 6 evaluable for dose limiting toxicities
- No adverse events considered by the investigator related to PS101 or the ultrasound

## **Enrolled patients**

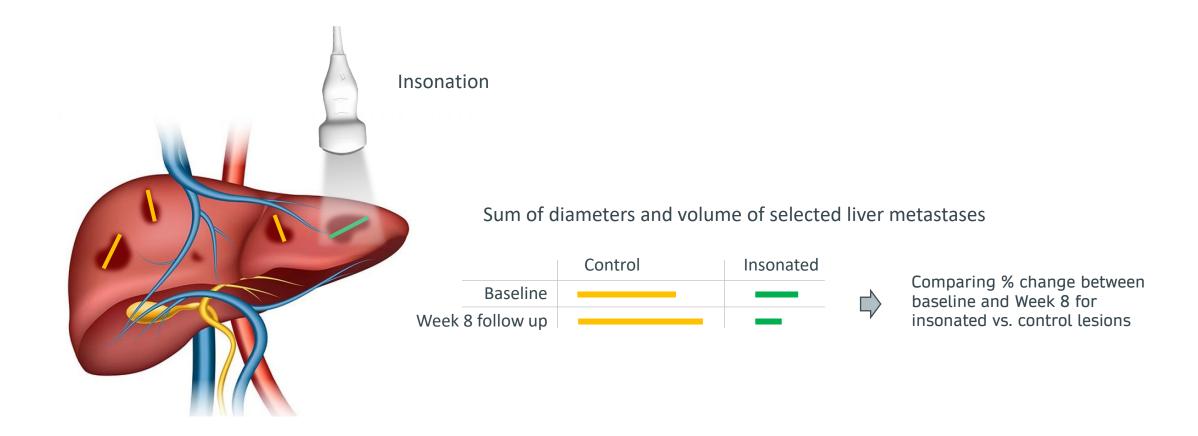
Patient	Dose	Prior lines of therapy	Study chemotherapy
1		5	FOLFOX
2	20 μl/kg	5	FOLFOX
3		6	FOLFIRI
4		4	FOLFOX
5	40 μl/kg	5	FOLFIRI
6		3	FOLFIRI
7		7	FOLFIRI
8		4	FOLFIRI

# ACT treatment well tolerated

	20μl/kg (n=3)	40µl/kg (n=5)	
	No of AE (% patients)	No of AEs (% patients)	
All AEs, any grade	33 (100%)	32 (100%)	
PS101 related (All/gr≥3)	0/0	0/0	
Serious adverse events	0	2	
PS101 related	NA	0	
Chemotherapy related	NA	2	

# Innovative assessment of anticancer activity



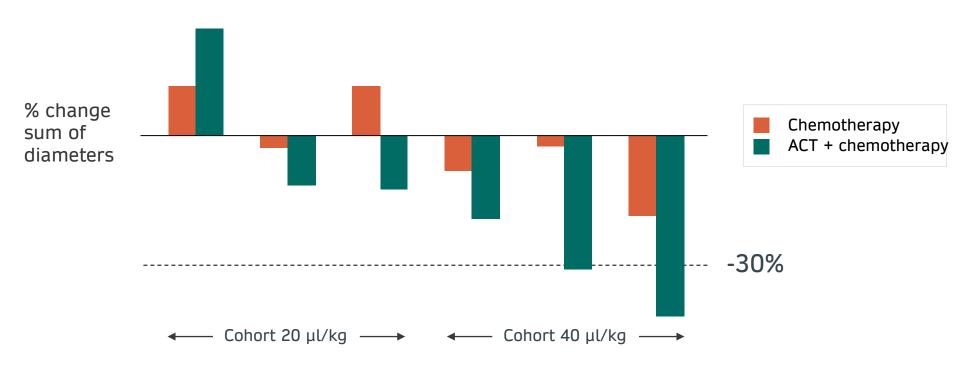


# **Encouraging initial anticancer activity**



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- Assessment of insonated and control liver lesions at baseline and week 8
- Assessment by central reviewer, blinded to which lesion was insonated

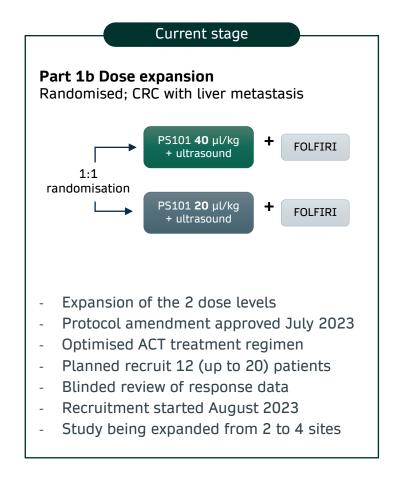


# **ACTIVATE** study – dose expansion part started



Generate more clinical data and establish recommended dose for Phase 2

# Part 1a Dose escalation 3+3 design; Solid tumours with liver metastasis PS101 40 μl/kg + FOLFOX or FOLFIRI PS101 20 μl/kg + FOLFOX or FOLFIRI



# **Next study: Pancreatic cancer**

# :::

# High unmet medical need

Phase 2 study in **first line treatment of locally advanced pancreatic cancer** in combination with Standard of Care chemotherapies

- Initiation 2H 2024
- Interim review 1H 2025
- Initial estimation: 40 60 patients

Support from advisory forum consisting of top US and EU experts in the field

Rationale for use of ACT

Enhanced delivery of therapies to cancer tissue

Successful development

Clinical and pre-clinical data

Technical feasibility

Good Access to pancreas with existing ACT equipment

existing ACT equipment

Clinical and pre-clinical data

Demonstrated convincing responses in human liver metastases and relevant pancreatic cancer models



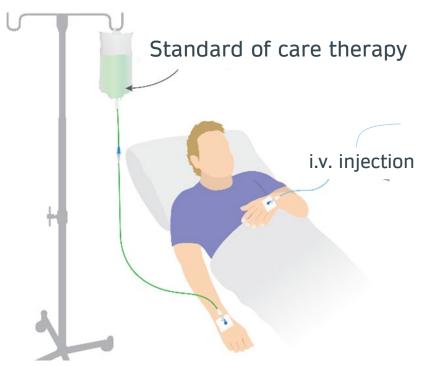
# The ACT Technology

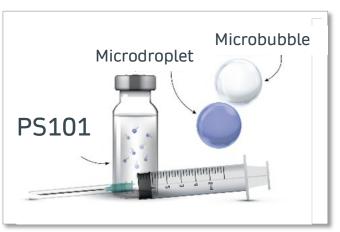


# The versatile ACT platform concept



- A precision health platform with a broad set of potential uses
- ACT treatment is given concomitant with standard of care therapy



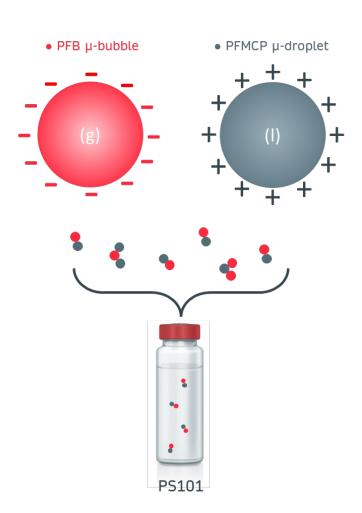




# PS101 – a highly engineered ultrasound-activated prodrug



- Commercial scale GMP supply of PS101 established
- PS101 consists of small clusters of gas bubbles and oil droplets
- The clusters are free-flowing after injection into the blood, which means they can reach any tissue in the body
- Can be co-administered with drugs without any need for drug reformulation
- Ultrasound exposure converts the oil to gas, transforming the clusters to larger ACT bubbles that are temporarily trapped in capillaries
- The ACT bubbles can then be manipulated with targeted ultrasound to induce drug delivery
- The gas in the ACT bubbles dissolve into blood over time and are released from the capillaries within 5-15 minutes



# A simple and non-invasive treatment process

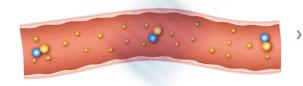


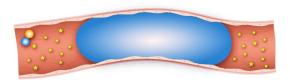
# ACT achieves therapeutic benefit through a

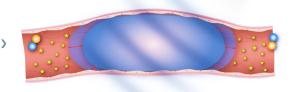
2-step ultrasound process

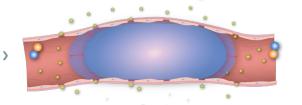












HF ultrasound is applied for Activation of free-floating microclusters

Resulting in phase shift and formation of ACT bubbles trapped in capillaries LF ultrasound is applied for Enhancement by oscillating ACT bubbles

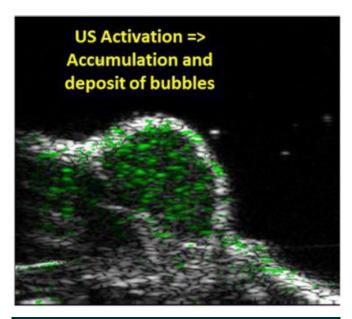
Oscillation of ACT bubbles provides prolonged targeted delivery of therapeutics

# Significantly enhanced uptake of model drug into tumour



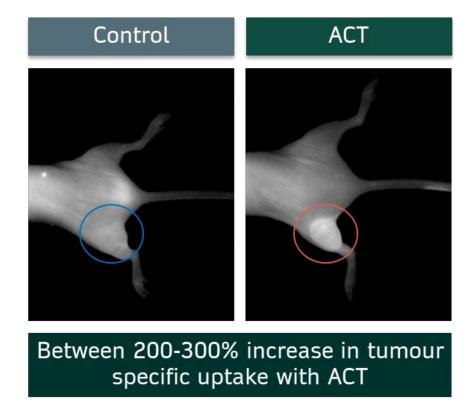
# Oscillation of activated bubbles induce uptake of co-administered drug

Activated deposited ACT bubbles in tumour



Ultrasound imaging showing ACT bubbles (green) in tumour

Model drug\* uptake in tumour





# Company overview



# A global leadership team with extensive industry experience



### **Board of Directors**



#### **Anders Wold, Chairman**

- 40 yrs from start-up to industrial success in Ultrasound & Med Tech
- Former President & CEO, GEHC CCS & Ultrasound
- BSc & MBA



#### Dr Masha Strømme, Vice Chair

- Early stage investor Lifesciences
- Former Investment banker (Morgan Stanley & Altium Cap) w/ Life science/ Healthcare focus
- D.Phil, Rhodes Scholar



#### Sir William (Bill) Castell, Board member

- Former CEO of GE Healthcare; Vice Chair GE; CEO of Amersham plc; Director BP plc; Chairman of the Wellcome Trust
- LVO FMed Sci.



#### **Ann-Tove Kongsnes, Board Member**

- Investment professional & Head of International Affairs at Investinor
- MBA

### Management team



#### Dr Per Walday, CEO

- 30+ years developing pharmaceuticals from preclinical to commercialization, including drug-device combinations
- Former CEO, PCI Biotech; Global Head, Proj. Mgmt new pharma GEHC
- PhD



- Former CFO Questback. Experience from various CFO/FM roles including PatientSky, KPMG Boston, Kistefos, AC Nielsen
- MFin



#### Dr Amir Snapir, CMO

- Extensive experience in global clinical development of novel therapeutics and combination products, from early clinical translation to regulatory approval and marketing authorization
- MD PhD



#### Dr Svein Kvåle, COO & Co-founder

- 25+ years' experience from pharma R&D; Nycomed Imaging/Amersham Health/GE Healthcare
- Inventor in diagnostics cancer therapeutics
- PhD

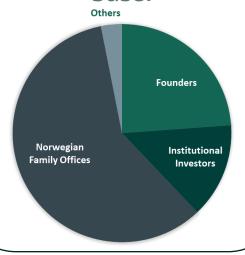




Listed on Euronext Growth, July 2020:



Solid Shareholder base:



Collaboration partners:





Significant grants awarded by:



Selected international and national research partners:









# Financials



# Financials - Overview



NOK Millions	H1 2023	H1 2022	FY 2022
Revenue	0.0	0.0	0.5
Total operating expenses	22.3	26.3	41.2
Operating result	-22.3	-26.3	-40.8
Net financial items	-0.5	-0.6	1.0
Total comprehensive income	-22.8	-26.9	-40.1
Earnings per share	-0.8	-0.9	-1.3
Number of employees	11	8	10
Cash and cash equivalents, end of period	39.1	78.8	69.4
Net change in cash, cash deposits and equivalents	-30.3	-24.9	-34,3
Equity %	85 %	83 %	79 %

### **Cash and liquidity**

- mNOK 39.1 in cash by end of H1 2023
- Cash runway through the dose expansion part of the study

### Net result

- Operating loss of mNOK 22.3 for H1 2023
- Change compared to last year due to organizational build-up and increased FTEs, increased clinical / pre-clinical activities, finalized probe development project



# Q&A



# **EXACT Therapeutics – highlights**



## Unique platform technology:

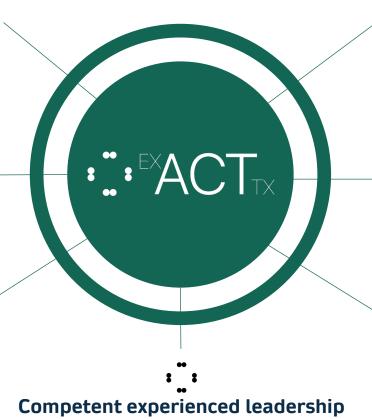
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### \* Straight commercial adoption

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