



**DNB Nordic Healthcare Conference**

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# ACT<sup>®</sup> for targeted delivery of therapies

Enabling precision medicine with a platform for targeted  
ultrasound mediated drug delivery

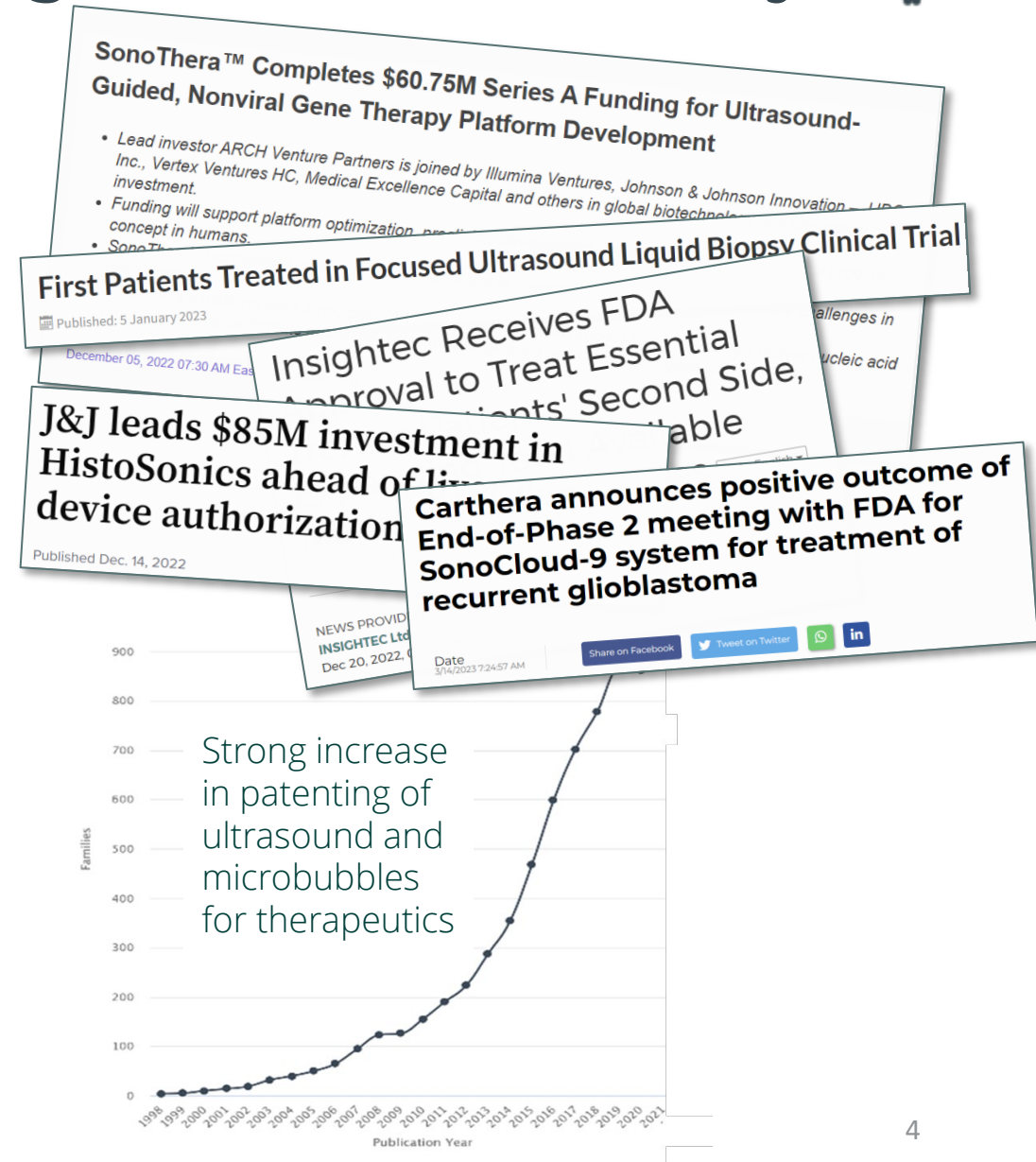




# Targeted ultrasound – an emerging treatment modality






- Enhancing targeted delivery represents a significant unmet need at critical junction for future therapies
- Ultrasound is gaining momentum as a new promising treatment and drug delivery modality, with pharma VCs and other key players entering the stage
- Targeted ultrasound is noninvasive and can potentially be used for a range of treatment applications
- The Acoustic Cluster Therapy (ACT®) platform technology is specifically designed to enhance the clinical benefit of targeted ultrasound



# 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

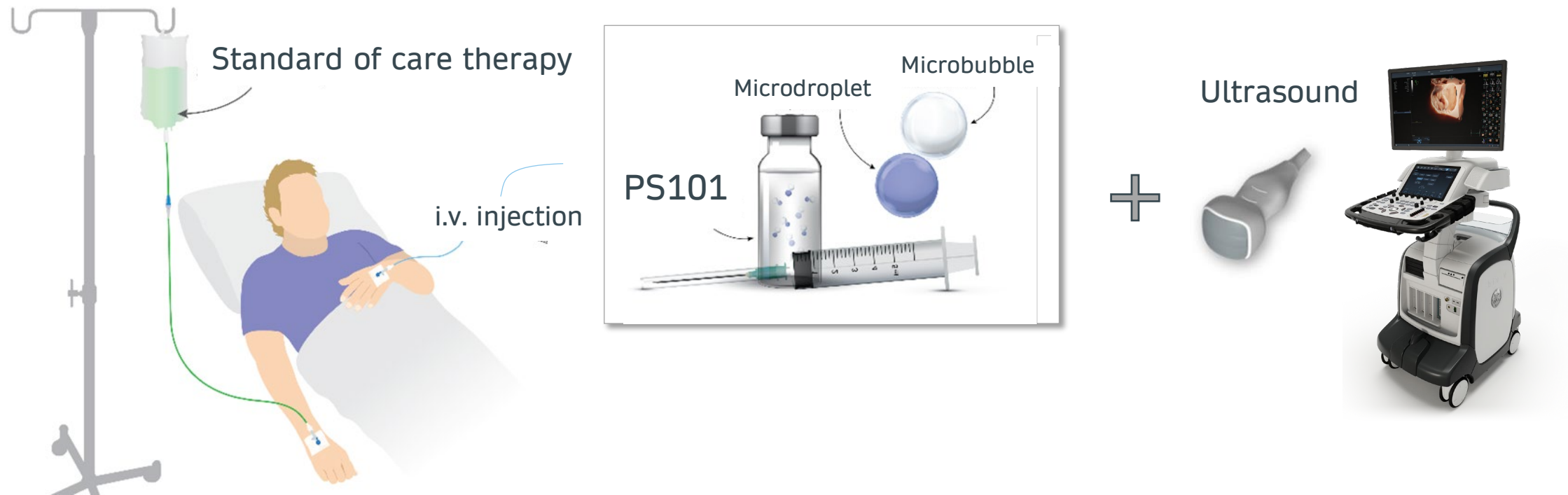
-  Pancreatic cancer – the dense stroma and poor vascularity limits the passage of current and future precision medicine therapies
-  Brain cancer – many therapies have failed development due to the blood-brain-barrier, resulting in limited survival improvement the last 20 years
-  Liver metastasis – 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**

# The versatile ACT platform concept



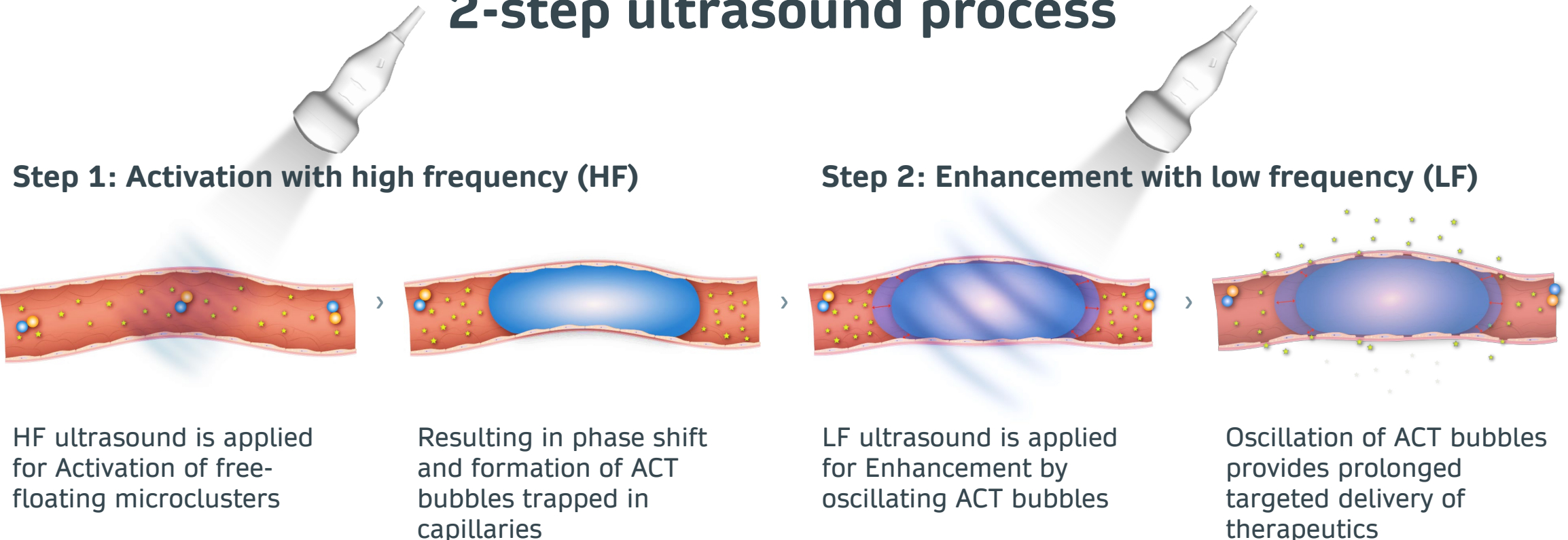
- Spin-out from the ultrasound leader GE Healthcare
- A precision health platform with a broad set of potential uses
- ACT treatment is given concomitant with standard of care therapy



# 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

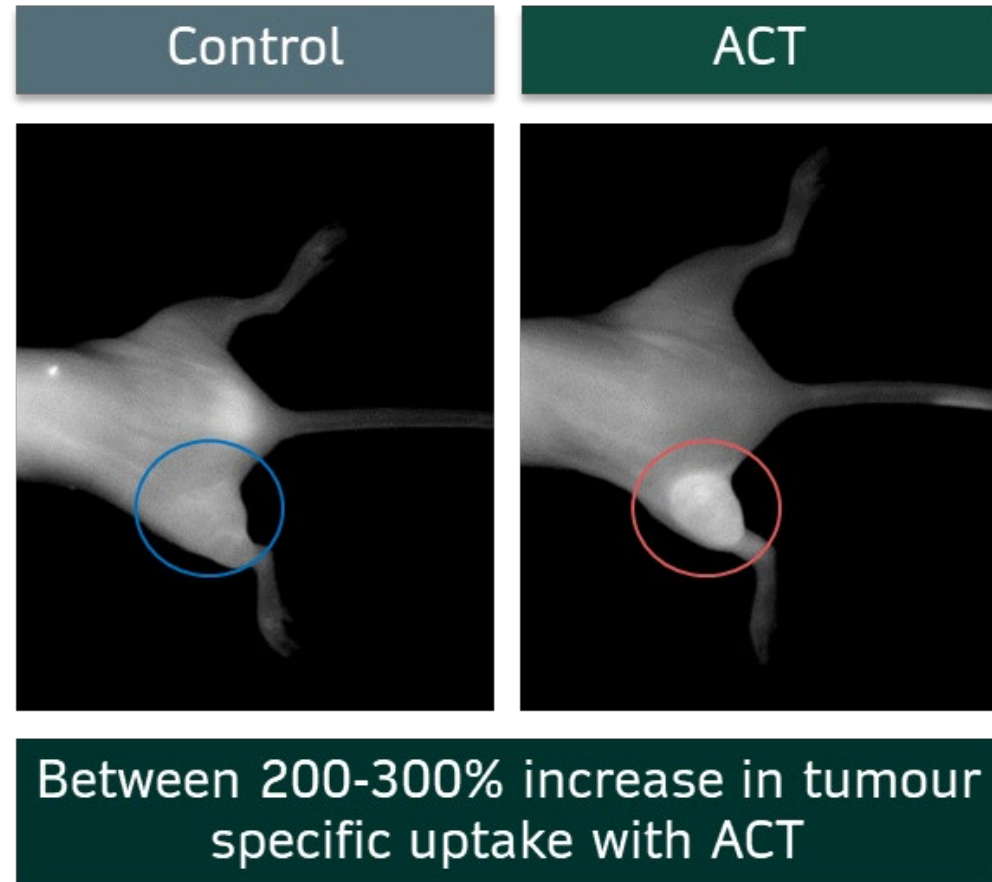
Oscillation of ACT bubbles provides prolonged targeted delivery of therapeutics

# Significantly enhanced uptake into tumour



**Ultrasound targeted  
activation of ACT  
induce uptake of co-  
administered drug**

Model drug\* uptake in tumour





# Strong preclinical evidence across models *and* drugs

## Proof-of-concept model



### Brain

Demonstrated **targeted, temporary, and safe** blood-brain-barrier 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**

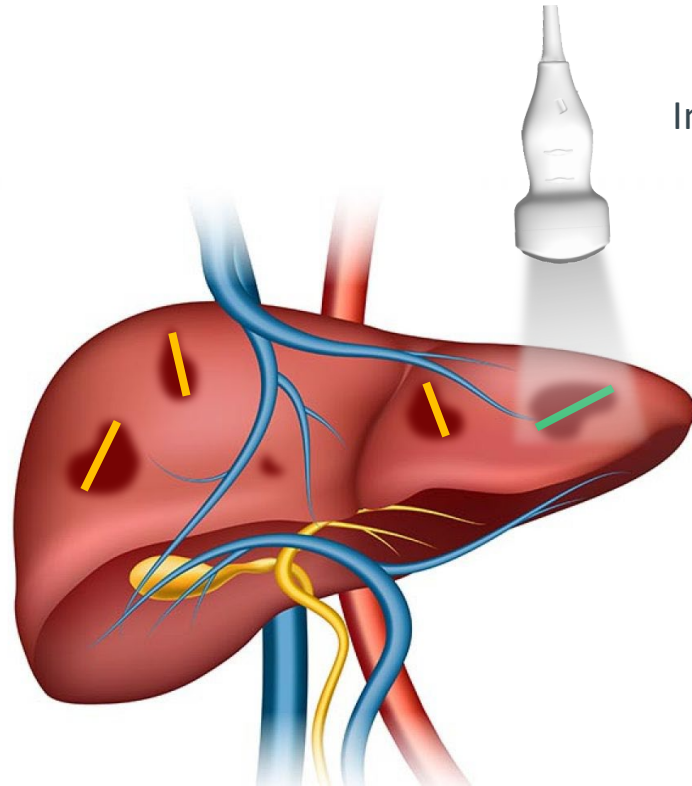
Prof de Lange Davies, NTNU, Norway

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



# ACTIVATE Phase I study

## - Innovative assessment of anticancer activity



Insonation

Sum of diameters and volume of selected liver metastases

	Control	Insonated
Baseline		
Week 8 follow up		



Comparing % change between baseline and Week 8 for insonated vs. control lesions



# ACTIVATE Phase I study

## 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	20 µl/kg	5	FOLFOX
2		5	FOLFOX
3		6	FOLFIRI
4	40 µl/kg	4	FOLFOX
5		5	FOLFIRI
6		3	FOLFIRI
7		7	FOLFIRI
8		4	FOLFIRI

FOLFOX = folinic acid + 5-FU + oxaliplatin  
 FOLFIRI = folinic acid + 5-FU + irinotecan

### ACT treatment well tolerated

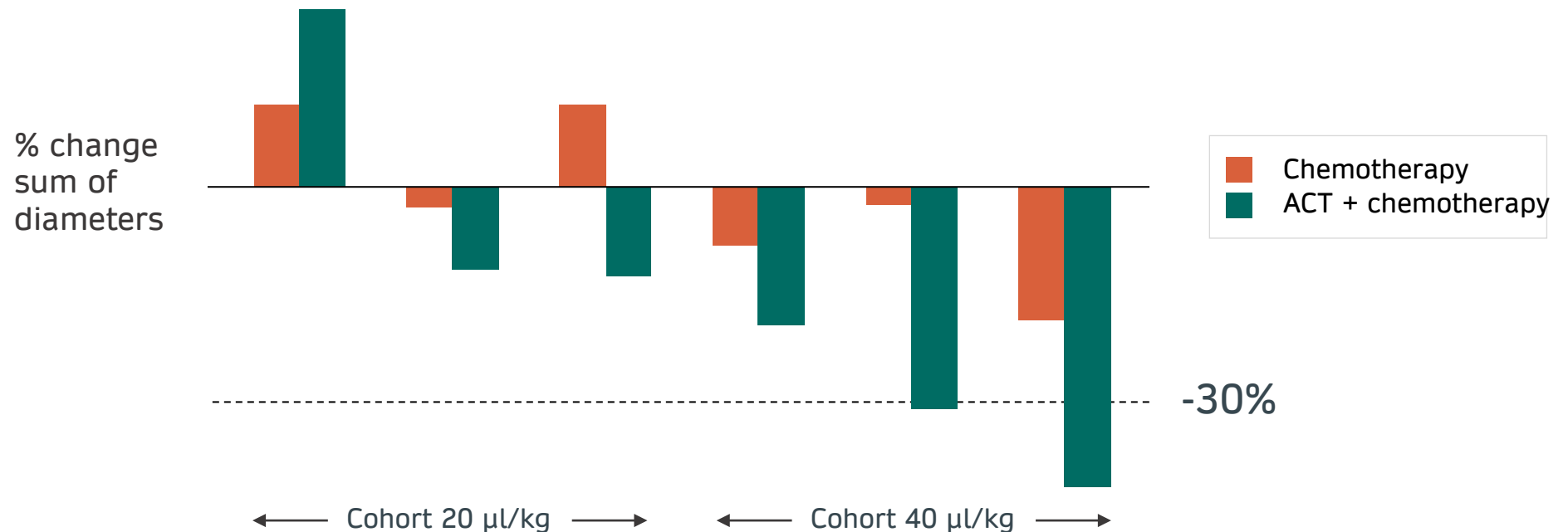
	20µl/kg (n=3)	40µl/kg (n=5)
	No of AE (% patients)	No of AEs (% patients)
<b>All AEs, any grade</b>	33 (100%)	32 (100%)
PS101 related (All/gr≥3)	0/0	0/0
<b>Serious adverse events</b>	<b>0</b>	<b>2</b>
PS101 related	NA	0
Chemotherapy related	NA	2

# ACTIVATE Phase I study

## Encouraging initial anticancer activity



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



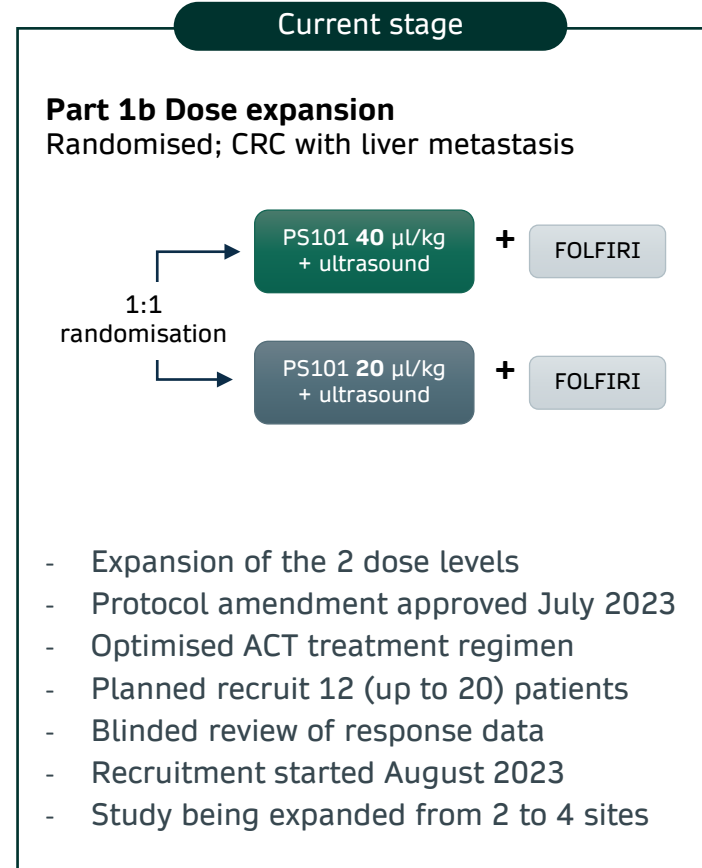
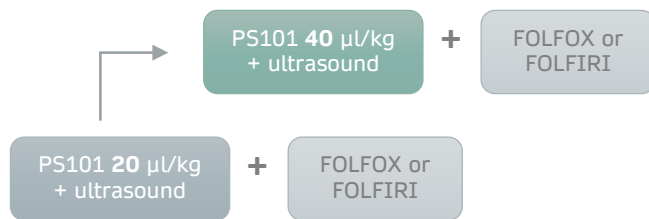
# ACTIVATE study – dose expansion part started



Generate more clinical data and establish recommended dose for Phase 2

Completed

**Part 1a Dose escalation**  
3+3 design; Solid tumours with liver metastasis

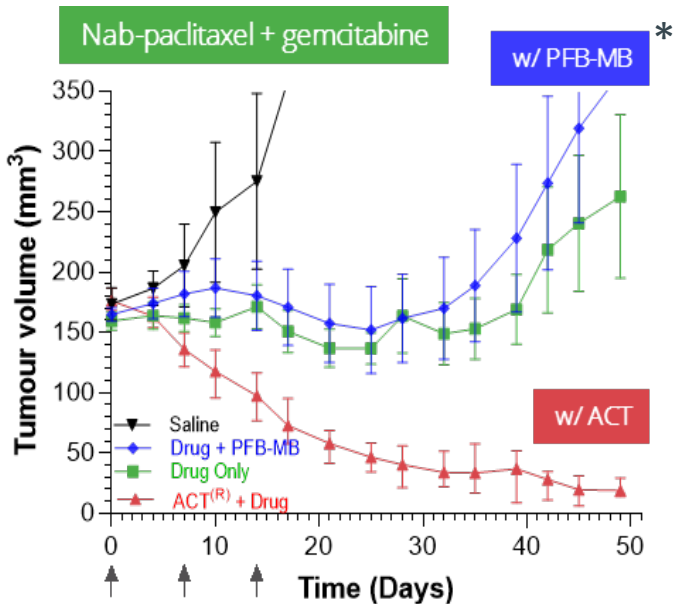




# ACT for pancreatic cancer – strong preclinical data and prominent KOL support



Prof Daniel Von Hoff's clinical trial work has led to the approval of 3 of the 4 drug combinations for treatment of pancreatic cancer patients. The ACT study by his group was done in a **pancreatic cancer model** in mice with **patient derived material**, that largely **retain the stromal content of the originating tumour**.



**Dr. Daniel Von Hoff, Distinguished Prof & national lead expert in pancreatic cancer**

*“Pancreatic cancer is notoriously resistant to treatment. The results are some of the most encouraging ones we have seen, and we look forward to being involved in the further development of this promising technology”*

**Dr. Haiyong Han, Prof. TGen's Molecular Medicine Division & study senior author**

*“...ACT treatment resulted in a significant increase in tumour growth inhibition and a **7.2 times higher probability of having a complete remission** of the tumour...”*

**Advisory board established with US and EU KOLs in pancreatic cancer**

\* The ultrasound procedure with a standard diagnostic microbubble

# Next study: Pancreatic cancer

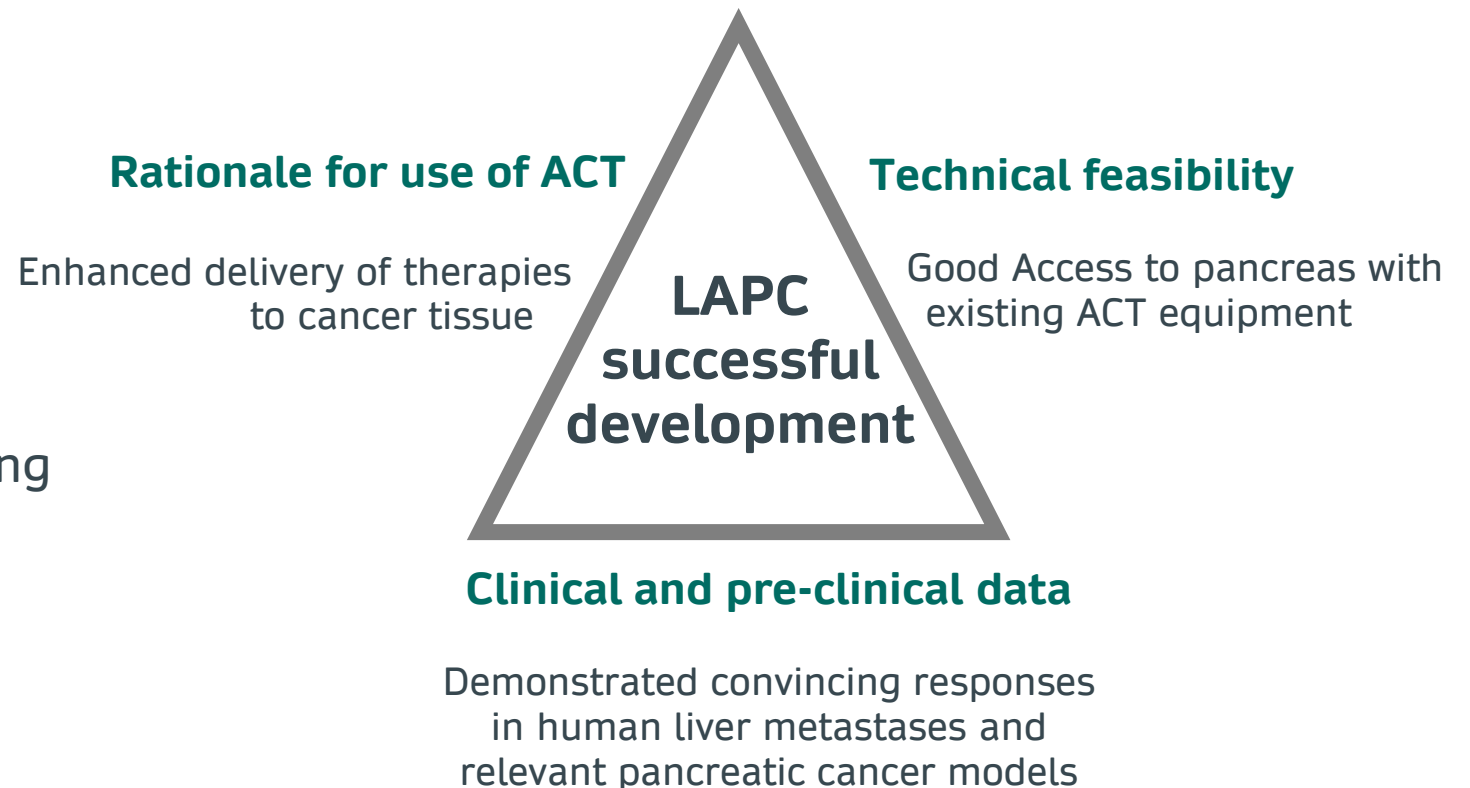


## High unmet medical need

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

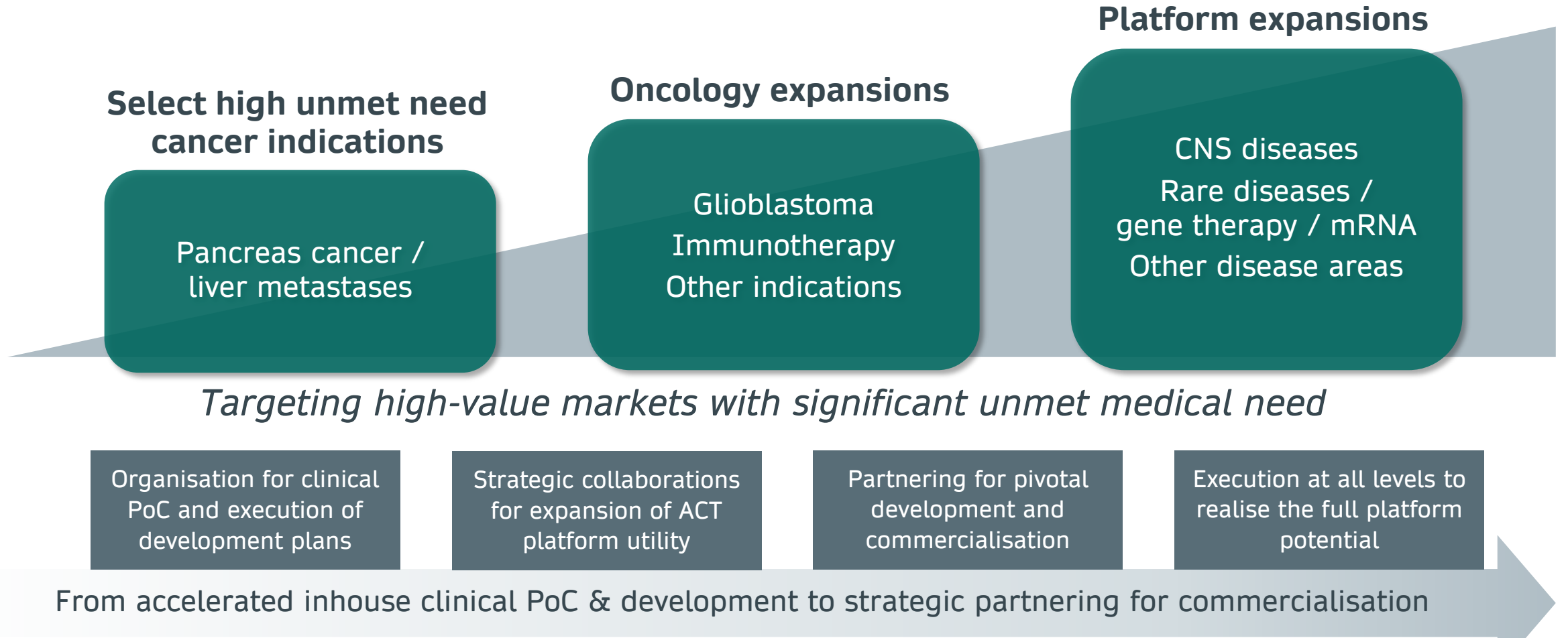
Support from advisory forum consisting of top US and EU experts in the field



# Building the value of the ACT platform



Transforming the concept of precision therapeutics



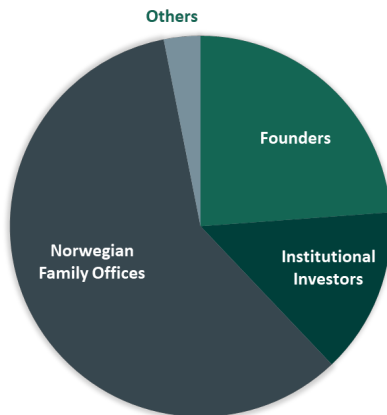




Spin-out of GE  
Healthcare – listed on  
Euronext Growth, July  
2020:



Solid Shareholder  
base:



Collaboration  
partners:



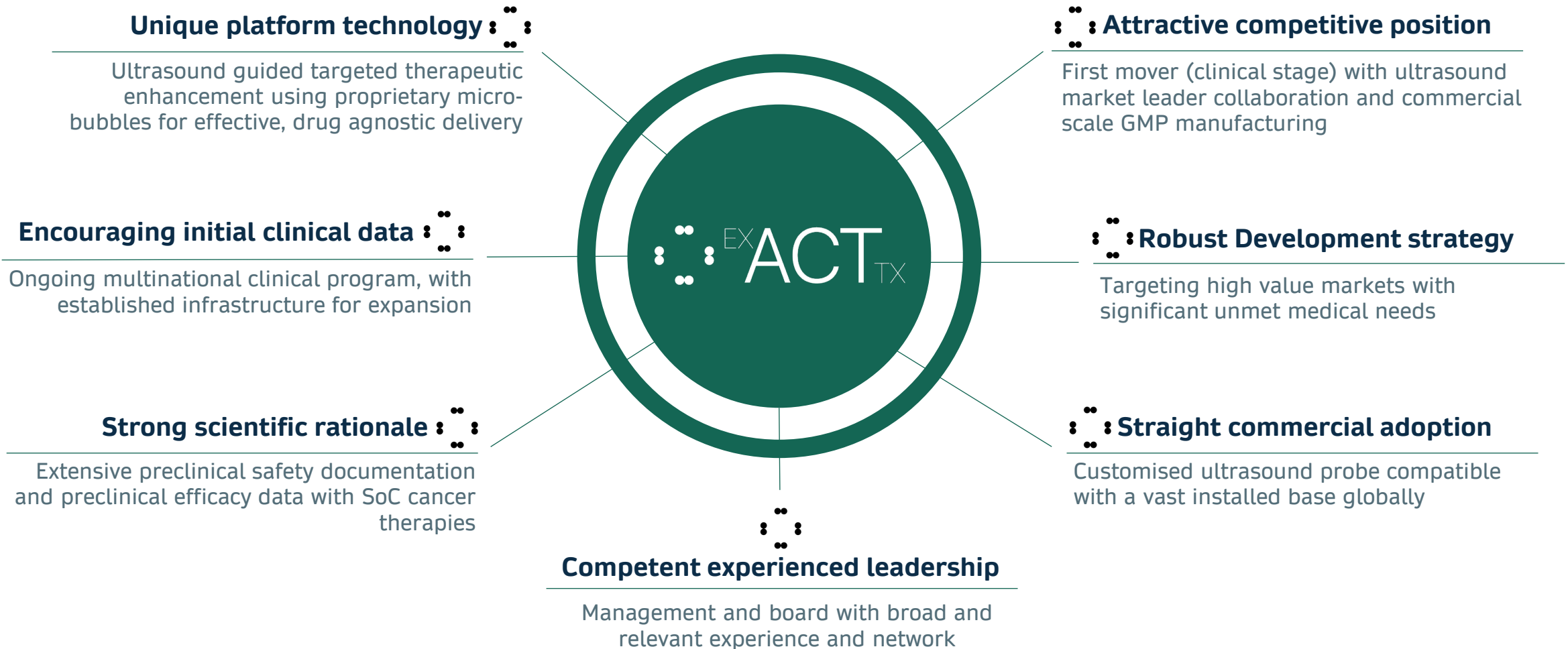
Significant grants  
awarded by:



Selected international  
and national research  
partners:



# EXACT Therapeutics – highlights



# Upcoming catalysts 2024



- Well funded to reach key clinical and preclinical catalysts
  - Read-out of ACTIVATE dose expansion
  - Pre-IND meeting with the FDA for ENACT
  - ACT<sup>®</sup> platform expansion – glioblastoma
  - ACT<sup>®</sup> platform expansion – CNS (BBB)
  - ACT<sup>®</sup> platform expansion – Immuno-oncology





# Q&A