



Numiera Therapeutics

STALLING THE ENGINES OF CANCER CELLS

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Disease Indication

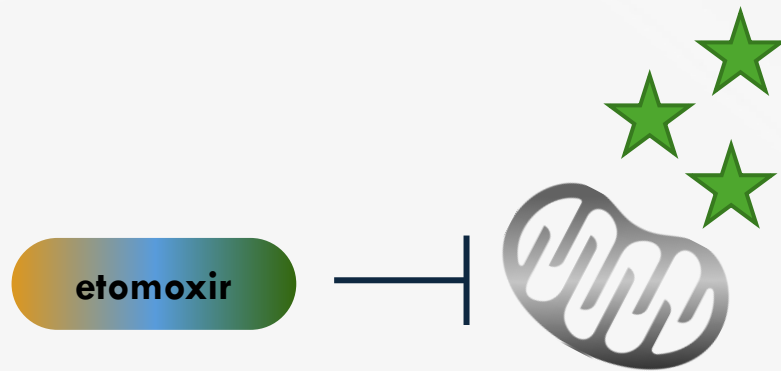
- Glioblastoma is an aggressive and fatal brain tumor
- 34,000 newly-diagnosed patients annually in US + EU
- Only one therapy has benefited GBM patients in 50 years
- *This drug gives patients 2-3 extra months, and has serious side effects*

➤ *Urgent unmet need*

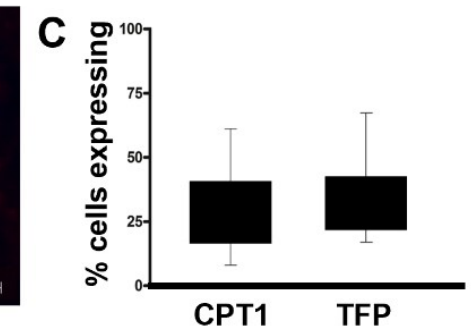
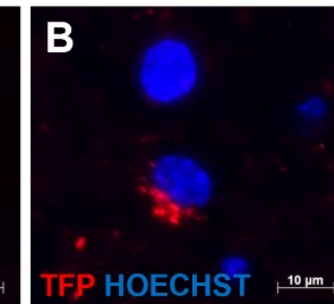
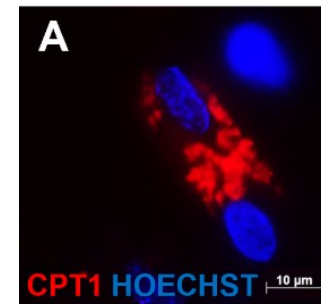




Innovative Solution



First-In-Class
Small-Molecule
CPT-1 Inhibitor



Lin et al. (2017) *Neuro Oncol* 19(1):43-54

The target protein (CPT1) and other FAO enzymes are present in every human GBM sample studied



Intellectual Property



Further Pipeline Development

Additional patent filings for new molecules



Companion Diagnostic

Patent filed in 2024; IVD regulatory path



Combination Product

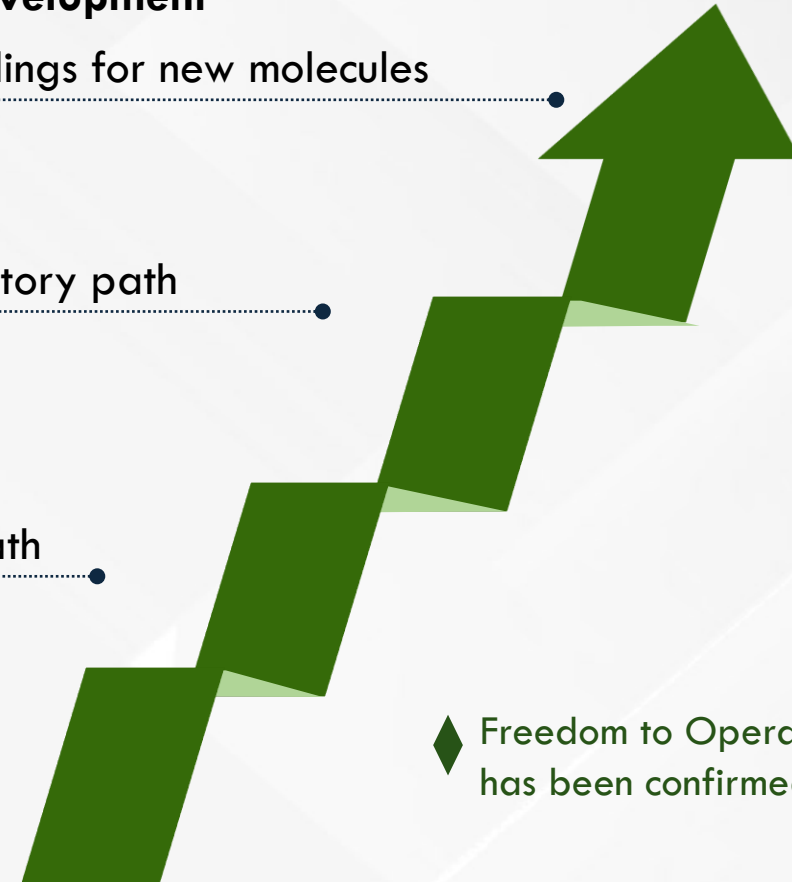
Patent filed in 2024; 505(b)2 regulatory path



Orphan Designation

Seven years of *post-approval* market exclusivity

Freedom to Operate
has been confirmed



Clinical Safety

Etomoxir †		Temodar (Temozolomide) *		Avastin (Bevacizumab) #	
Survival Benefit in Glioblastoma	?	Survival Benefit in Glioblastoma	2.5 months	Survival Benefit in Glioblastoma	2.2 months
Percentage of Patient Population Taking This Drug	?	Percentage of Patient Population Taking This Drug	80%	Percentage of Patient Population Taking This Drug	49%
Serious Side Effects		Serious Side Effects		Serious Side Effects	
High liver enzyme levels	<2%	High liver enzyme levels	12%	High blood pressure	18%
Moderate/Severe		Moderate/Severe		Moderate/Severe	
Cardiac arrhythmia or failure	<2%	Low platelet count	14%	Blood clots, stroke or heart attack	11%
Moderate/Severe		Moderate/Severe		Severe/Can Be Fatal	
		Bone marrow depletion	<10%	Kidney Problems	<7%
		Severe/Can Be Fatal		Severe/Can Be Fatal	
		Induction of other cancers	<2%	Fistula	<2%
		Severe/Can Be Fatal		Severe/Can Be Fatal	
Common Side Effects		Common Side Effects		Common Side Effects	
Increased exercise tolerance		Headache		Headache	
		Nausea		Back Pain	
		Vomiting		Watery Eyes	
		Hair Loss		Inflammation	
		Fatigue		Nosebleed	
Etomoxir †		Temodar (Temozolomide) *		Avastin (Bevacizumab) #	
Lower hepatotoxicity than standard of care Temodar or Avastin. Fewer deaths in treated group (0.9%) than placebo group (3.3%).		Serious adverse effects include liver toxicity, thrombocytopenia, bone marrow depletion and the induction of other cancers.		Serious adverse effects include heart attack, stroke, blood clots, kidney problems, and fistulas which are sometimes fatal.	

† Holubarsch et al. *Clin Sci (Lond)* 2007

* Stupp et al. *New Engl J Med* 2005 and GoodRx.com

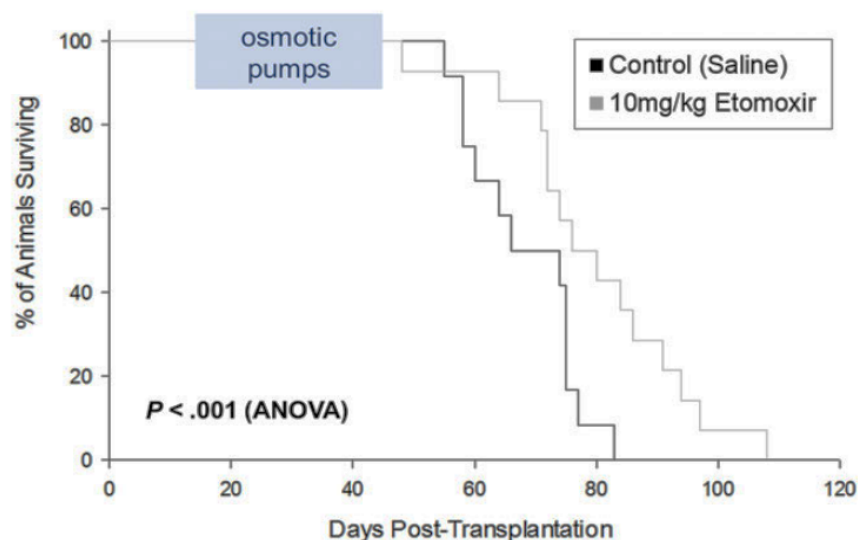
Gramatzki et al. *Ann Oncol* 2018 and Avastin.com

Our Goal:

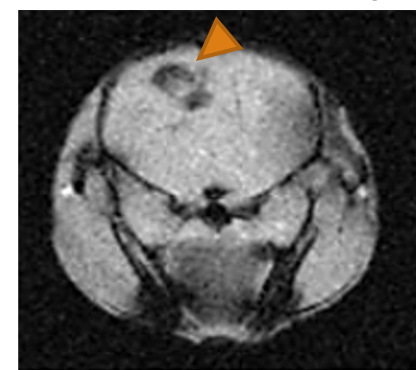
Move our well-characterized orphan lead asset to market approval

Build pipeline of new molecules behind it

Preclinical Efficacy



CONTROL - 75 dpi



TREATED - 75 dpi



10 mg/kg etomoxir from 14 dpi to 42 dpi

Awarded by 
The Society for NeuroOncology

Lin et al. (2017)
Neuro Oncol 19(1):43-54.
Syngeneic mouse model

Independently replicated single agent efficacy in glioblastoma from four other labs

Kant et al. (2020)
Cell Death Dis 11:253.
Implanted patient cells

Shim et al. (2022)
Cancer Cell Int 22:309.
Implanted patient cells

Jiang et al. (2022)
Nature Comms 13:1511.
Implanted U261 cells

Duman et al. (2023)
Cell Death Dis 14:296.
Implanted NCH421K cells

This key target in cancer cell metabolism is also present in breast cancer, prostate cancer, and several other cancers



Market Opportunity



We have received orphan designation on our lead asset: etomoxir

25% of orphan designated products achieve market authorization.

5.3 years is the average time to market authorization from the date of orphan designation.

Phase I clinical data in 226 human subjects indicates our drug is safer than temozolomide.

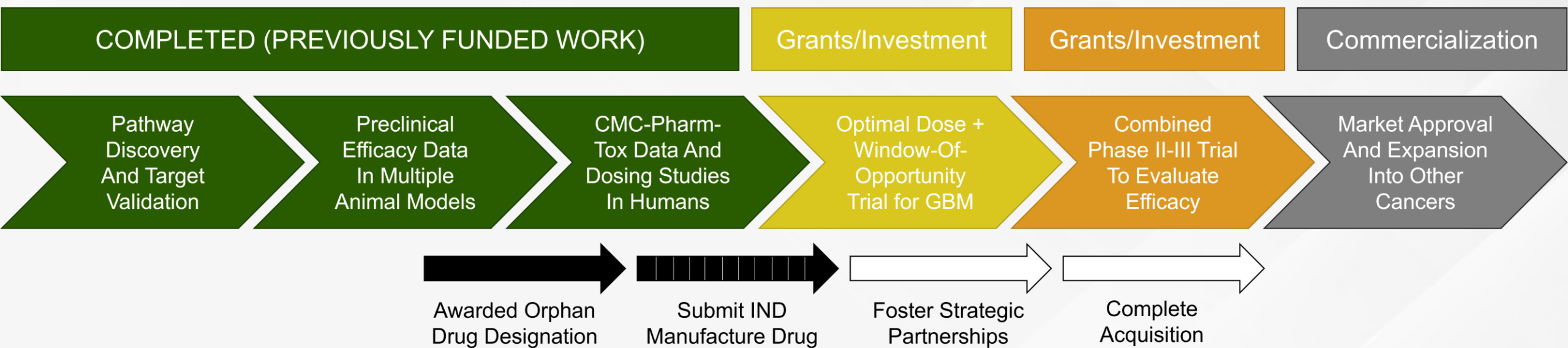
Four additional labs have independently replicated our preclinical efficacy data for this drug.

\$1.2B in annual sales for the US/EU glioblastoma market, if we can beat the current standard of care.

“I do have the advantage of having seen many, many hundreds of potential new therapies. Numiera Therapeutics’ product is in the top tier of my universe.”

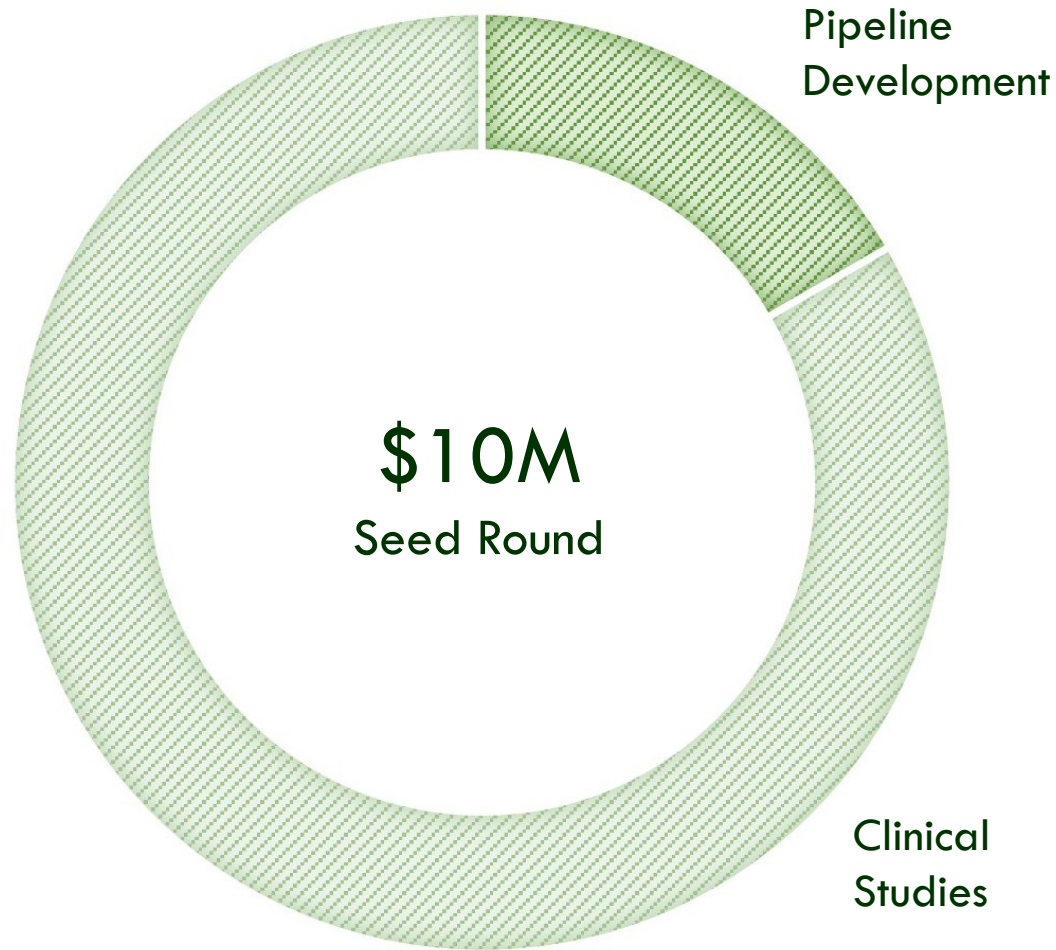
- Tim Cote, First Director of the FDA Office of Orphan Products Development

Commercialization Pathway





Financing Sought



Planned Use of Funds

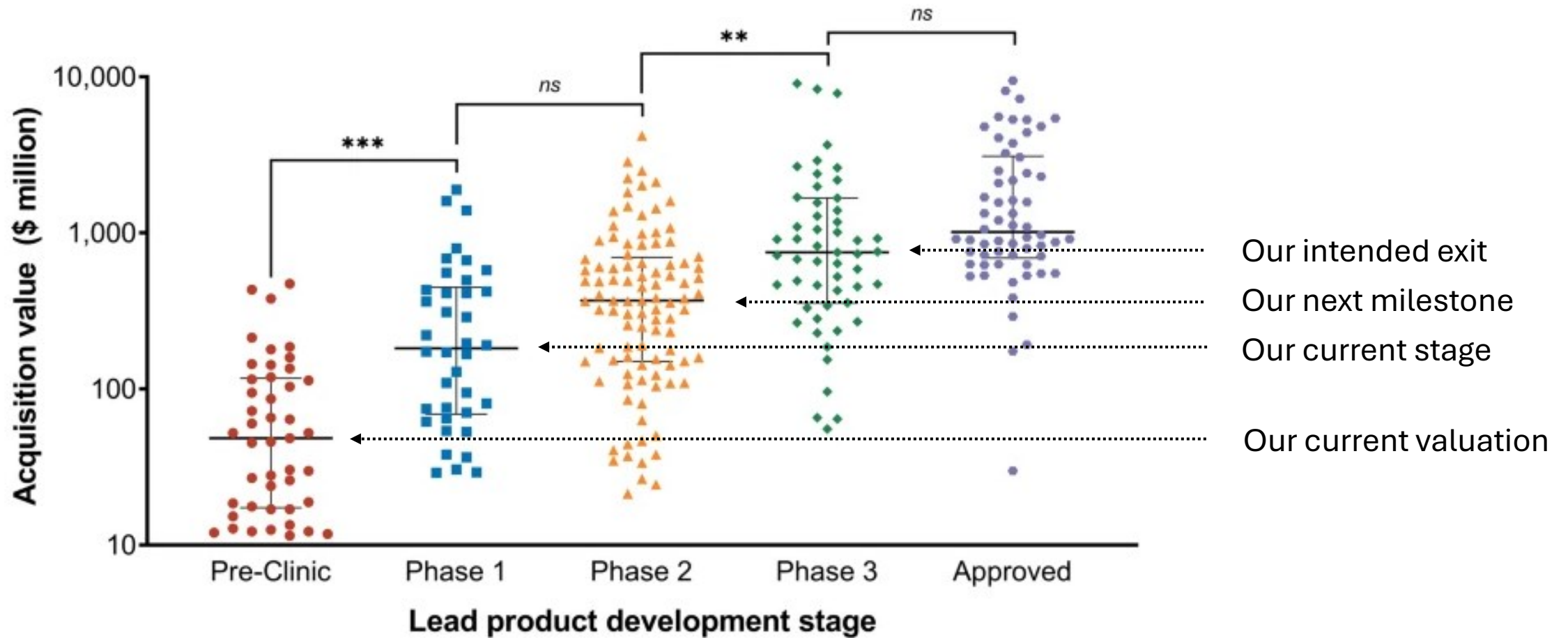
- Submit the already-drafted IND
- Formulate drug into soft-gel capsules
- Identify maximum-tolerated dose for GBM
- Conduct window-of-opportunity surgical trial
- Develop additional intellectual property

Incentives and Non-Dilutives

- Competitively-Awarded Grant Funding
- State Tax Credits Available to Investors



Exit Comps



Leadership Team



Izi Stoll, PhD
CEO/Founder



WESTERN INSTITUTE
FOR
ADVANCED STUDY

Karl Nicholls, CPA
Financial Operations



Gordon Beck, PhD
Corporate Strategy



Dustin Key, MS
Data Management



Vicky Abbas, RN
Clinical Operations



Neuraptive

Patrick Wen, MD
Neuro Oncologist



Key Partners



TECH.
SCIENCE.
ACCELERATED.

SHERIDAN
ROSS attorneys at
innovation
pc





Thank You!



Numiera
Therapeutics

Let's talk more:
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