



Numiera Therapeutics

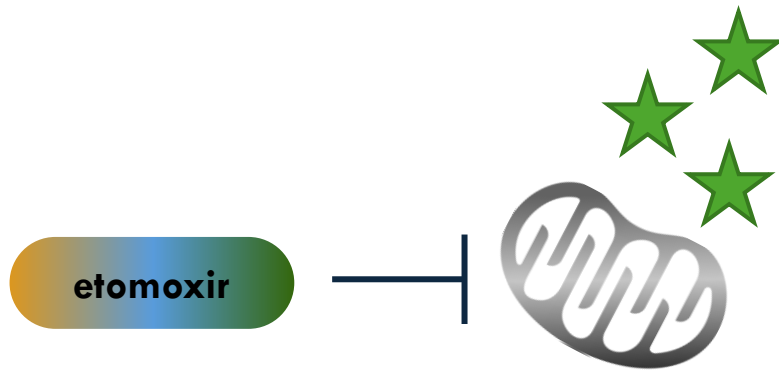
STALLING THE ENGINES OF CANCER CELLS

Disease Indication

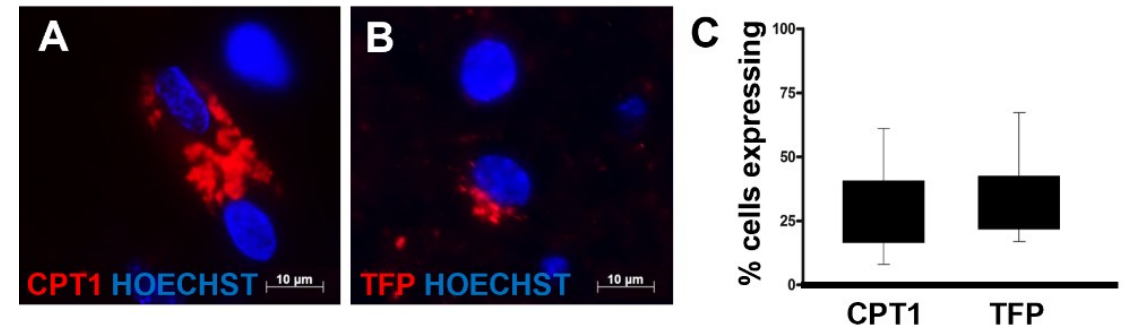
- Glioblastoma is an aggressive brain tumor, with median survival of 15 months
 - 250,000 newly-diagnosed patients each year worldwide
 - Only one new therapy has significantly benefited GBM patients in the past 50 years and been integrated into standard-of-care.
 - *This drug – temozolomide – only gives patients a few extra months and has serious side effects.*
 - *Many patients also take the approved drug bevacizumab, which has no significant survival benefit but reduces brain swelling.*
- ***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 enzymes involved in mitochondrial fatty acid oxidation - are present in every human GBM sample studied, and these are enriched in the cancer stem cells which drive the growth of the tumor.

Intellectual Property



Further Pipeline Development

Additional patent filings for new molecules



Companion Diagnostic

Patent filed in 2024; IVD regulatory path



Combination Product

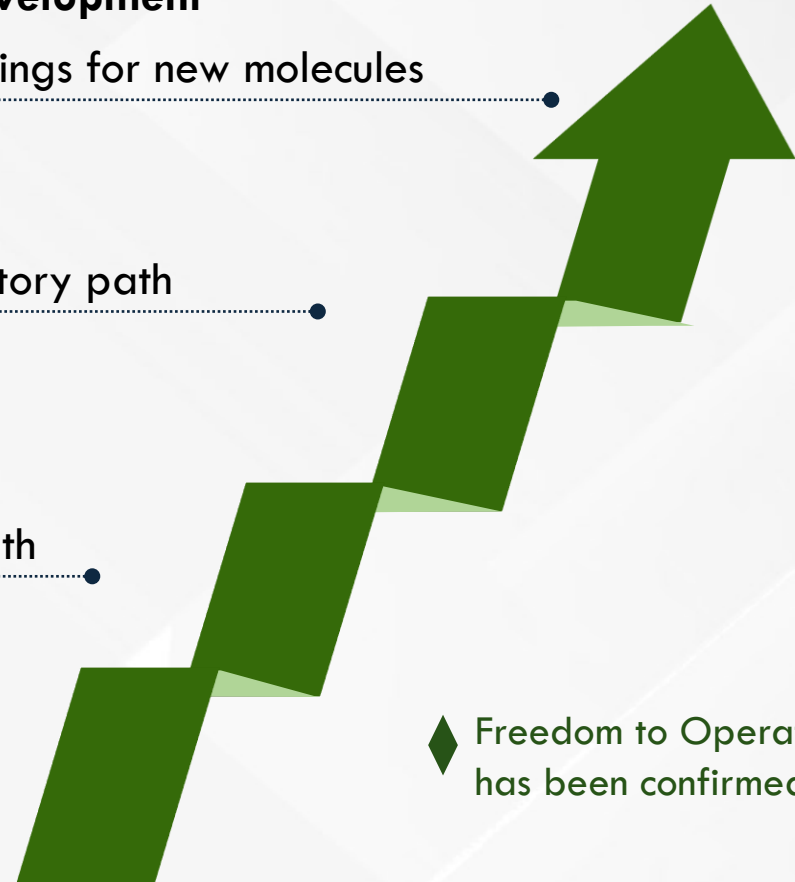
Patent filed in 2024; 505(b)2 regulatory path



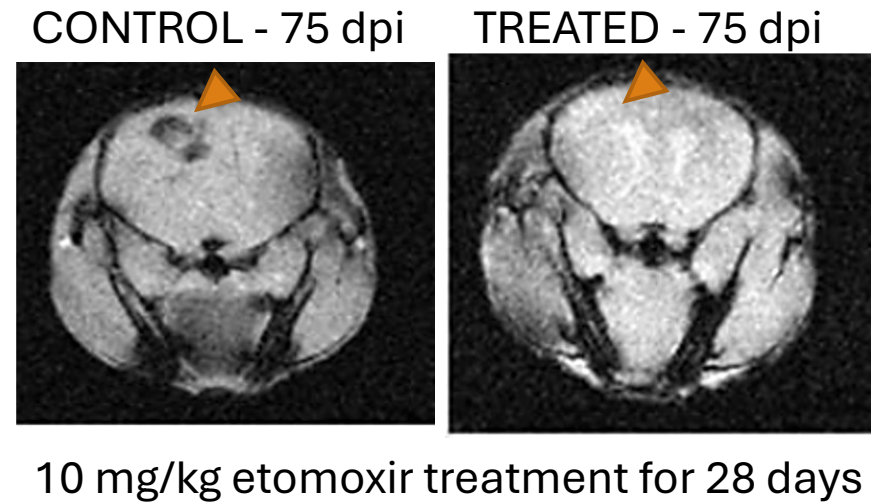
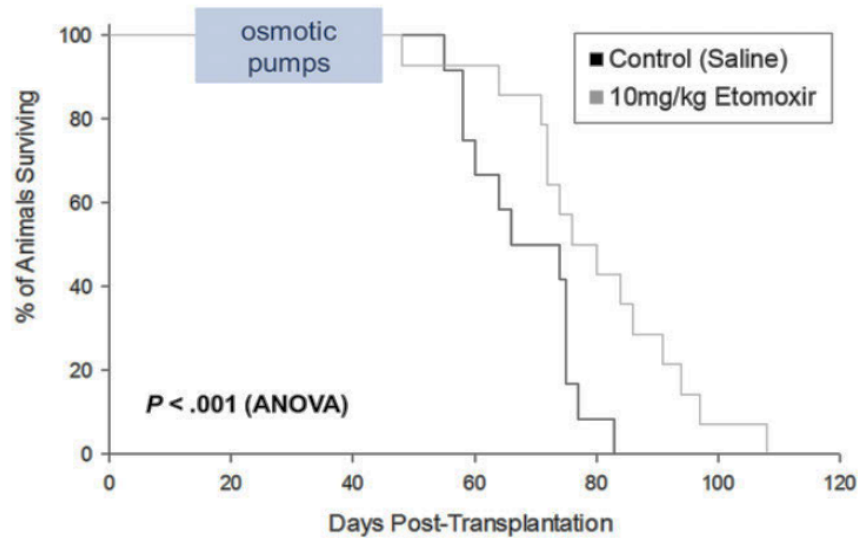
Orphan Designation


Seven years of *post-approval* market exclusivity

Freedom to Operate
has been confirmed



Preclinical Efficacy

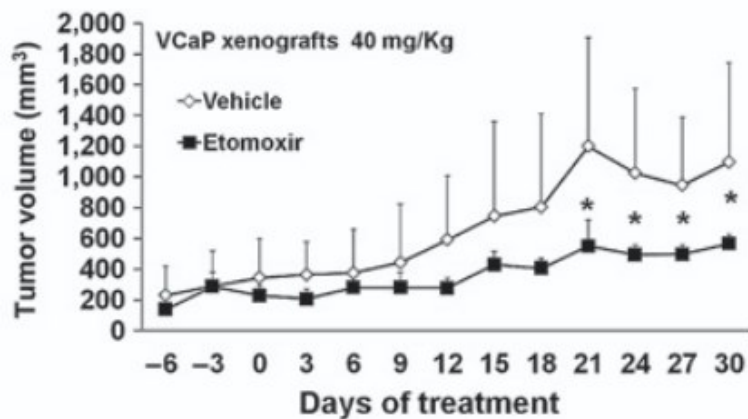


Our team was the first to publish this target and was awarded by  ¹

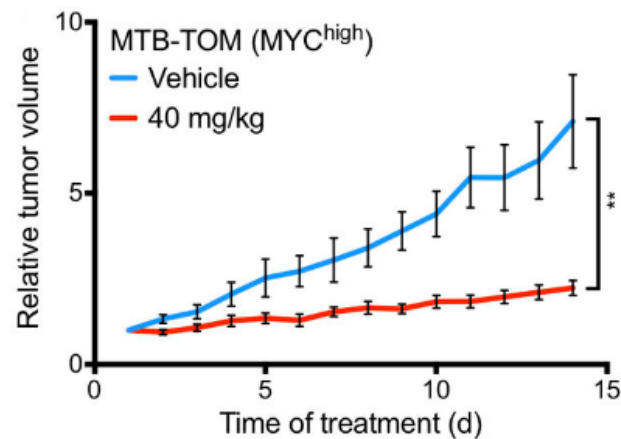
The Society for NeuroOncology

There is now independently-replicated single-agent efficacy in glioblastoma from four other labs ^{2,3,4,5}

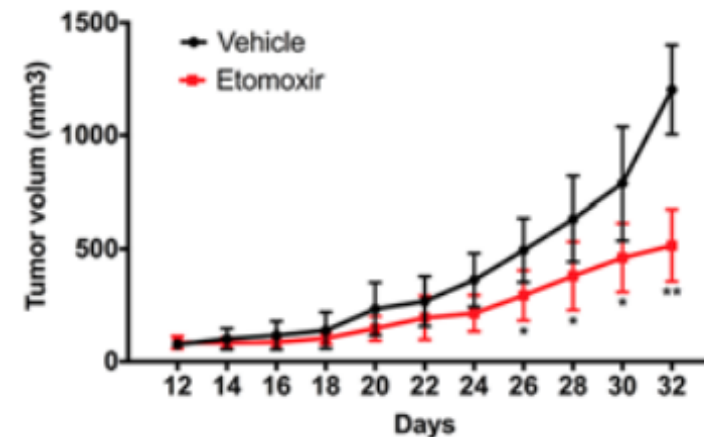
Additional Indications



Prostate Cancer:
Schlaepfer et al. (2019)
Mol Cancer 13(10); 2361–71



Breast Cancer:
Camarda et al. (2016)
Nat Med 22(4): 427-32



Bladder Cancer:
Cheng et al. (2019)
Clin Sci 133: 1745-58

This molecular target is present in multiple aggressive cancers, and etomoxir significantly slows tumor growth.

Clinical Safety

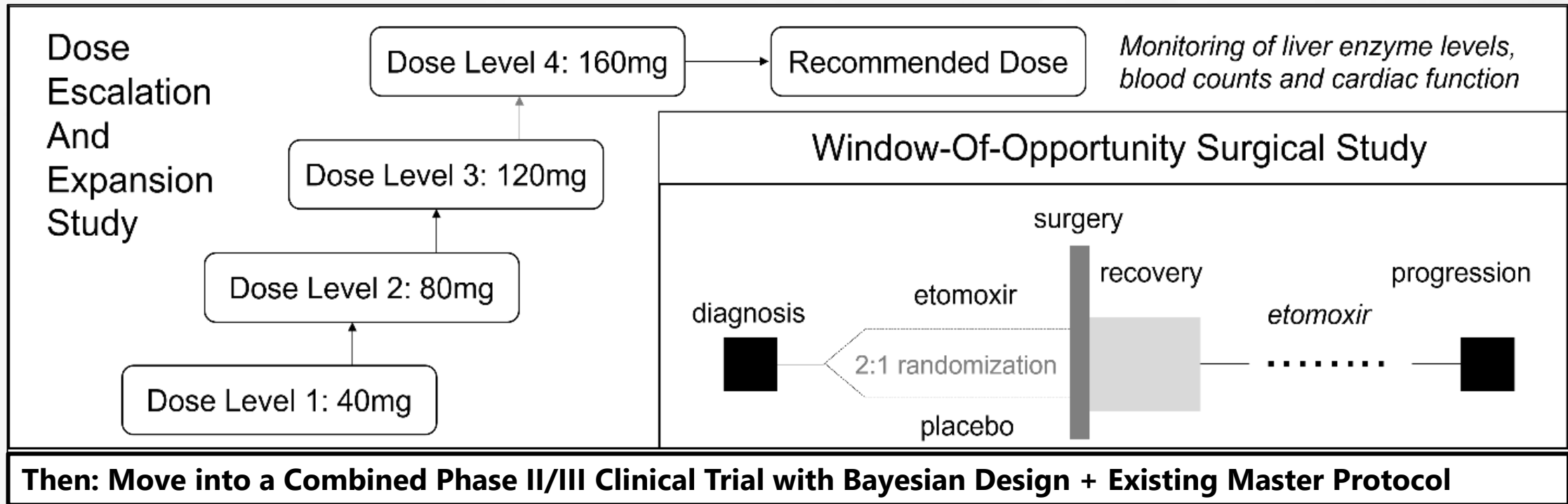
Etomoxir †		Temodar (Temozolomide) *		Avastin (Bevacizumab) #	
Survival Benefit in Glioblastoma	?	Survival Benefit in Glioblastoma	2.5 months	Survival Benefit in Glioblastoma	2.2 months
Percentage of Patient Population Taking This Drug	?	Percentage of Patient Population Taking This Drug	80%	Percentage of Patient Population Taking This Drug	49%
Serious Side Effects		Serious Side Effects		Serious Side Effects	
High liver enzyme levels Moderate/Severe	<2%	High liver enzyme levels Moderate/Severe	12%	High blood pressure Moderate/Severe	18%
Cardiac arrhythmia or failure Moderate/Severe	<2%	Low platelet count Moderate/Severe	14%	Blood clots, stroke or heart attack Severe/Can Be Fatal	11%
		Bone marrow depletion Severe/Can Be Fatal	<10%	Kidney Problems Severe/Can Be Fatal	<7%
		Induction of other cancers Severe/Can Be Fatal	<2%	Fistula Severe/Can Be Fatal	<2%
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. <i>Clin Sci (Lond)</i> 2007 226 human subjects treated w/ etomoxir		* Stupp et al. <i>New Engl J Med</i> 2005 and GoodRx.com		# Gramatzki et al. <i>Ann Oncol</i> 2018 and Avastin.com	

Our Goal:

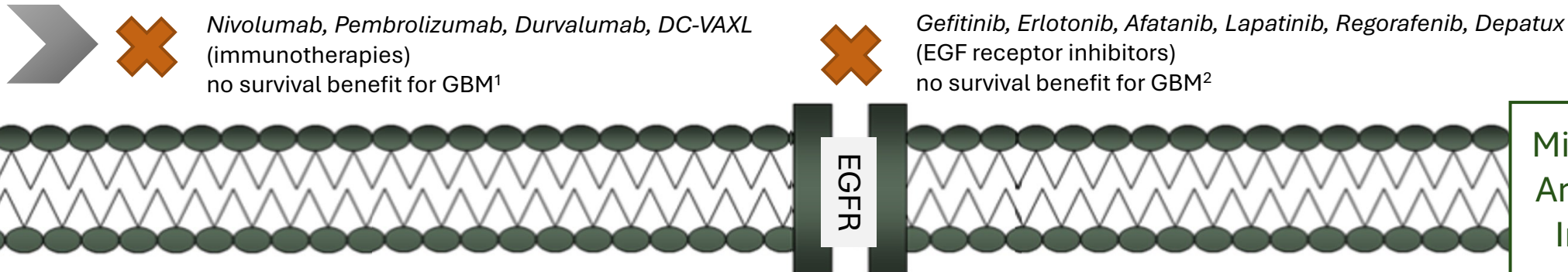
Move our well-characterized orphan lead asset to market approval

Build out pipeline to expand into additional oncology indications

Trial Design



Competitive Landscape



Mitochondrial Targets
Are **Game-Changers**
In Neuro Oncology

● ✗ *Buparlisib, Paxalisib*
(PI3 kinase inhibitors)
no survival benefit for GBM³

✗ *Selexinor, Eltanexor*
(XPO1 nuclear export inhibitors)
no survival benefit for GBM⁴

⚡ ✗ *temozolomide, VAL-083*
(DNA damaging agents)
survival benefit of only
2-3 months for GBM⁵

➕ *Vorasidenib*
(IDH inhibitor, [Agios](#))
16+ months survival benefit for
IDH-mutant low-grade glioma

➕ *Dordaviprone*
(ClpP activator, [Chimerix](#))
10+ months survival benefit for
H3K27M-mutant diffuse glioma

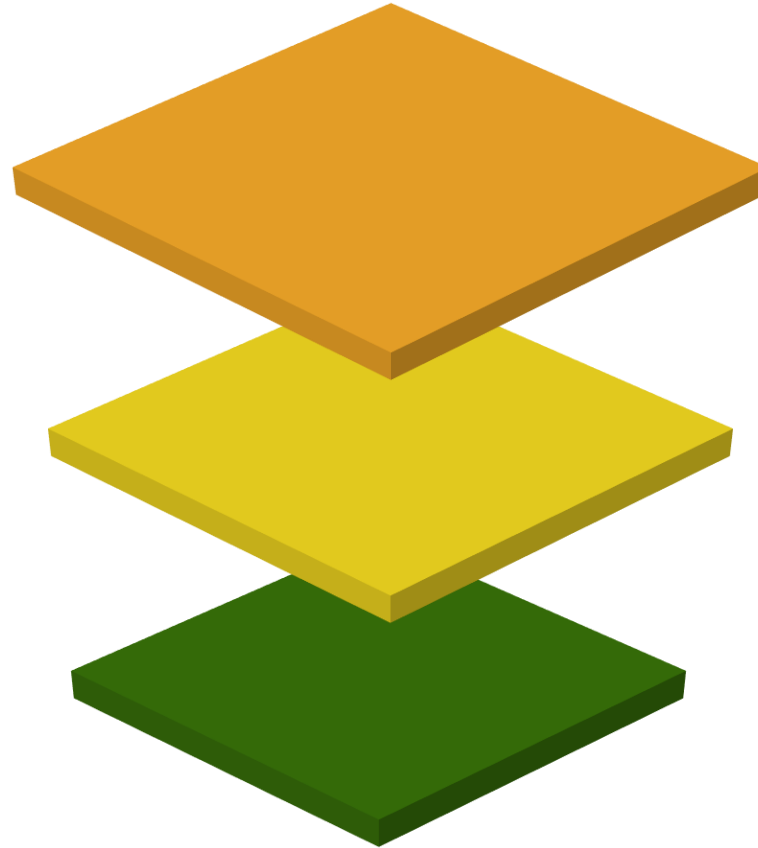
? *Etomoxir*
(CPT1 inhibitor, [Numiera](#))
Awarded orphan drug designation for
all malignant gliomas, including GBM

Market Opportunity

Treatment-resistant cancers with this mitochondrial target comprise a **\$50B+ TAM**

US/EU glioma **SAM of \$4B+** by expected market approval date

US/EU glioblastoma **SOM of \$2B+** by expected market approval date



Combination Product Oncology Market:
Androgen Insensitive Prostate Cancer
Triple-Negative Breast Cancer
Bladder Cancer

FDA awarded a broader designation for our lead asset than we requested, acknowledging its clinical potential

Quick ramp to market saturation with successful clinical results

Company Highlights



We have received orphan designation on our lead asset: etomoxir

25% of orphan designated products with Phase I safety data 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 standard of care.

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

Mitochondrial targets actually benefit neuro oncology patients, with billion-dollar successes.

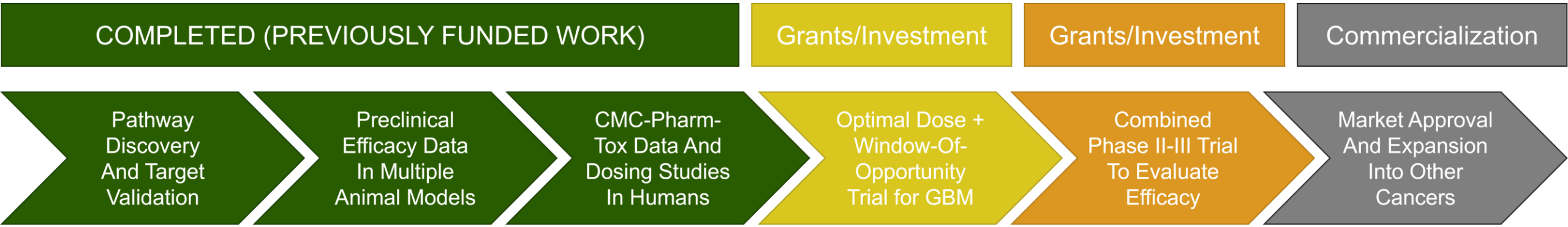
Additional cancer indications represent a \$50B market, with further pipeline development.

“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.”

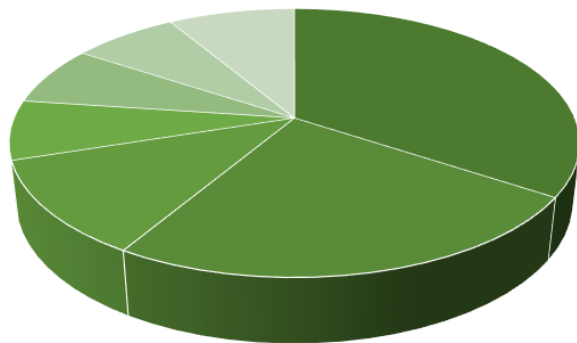
- Tim Cote, First Director of the FDA Office of Orphan Products Development

Commercialization Pathway

\$10M Seed Round

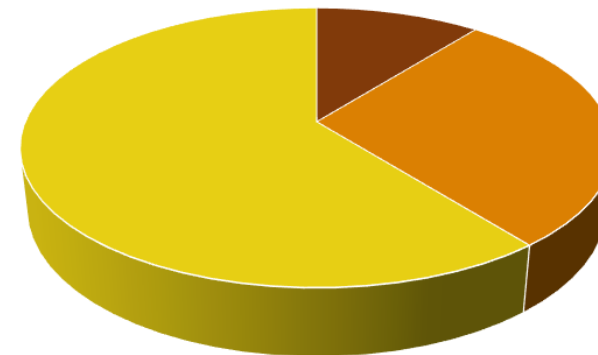


Proposed Use of Funds



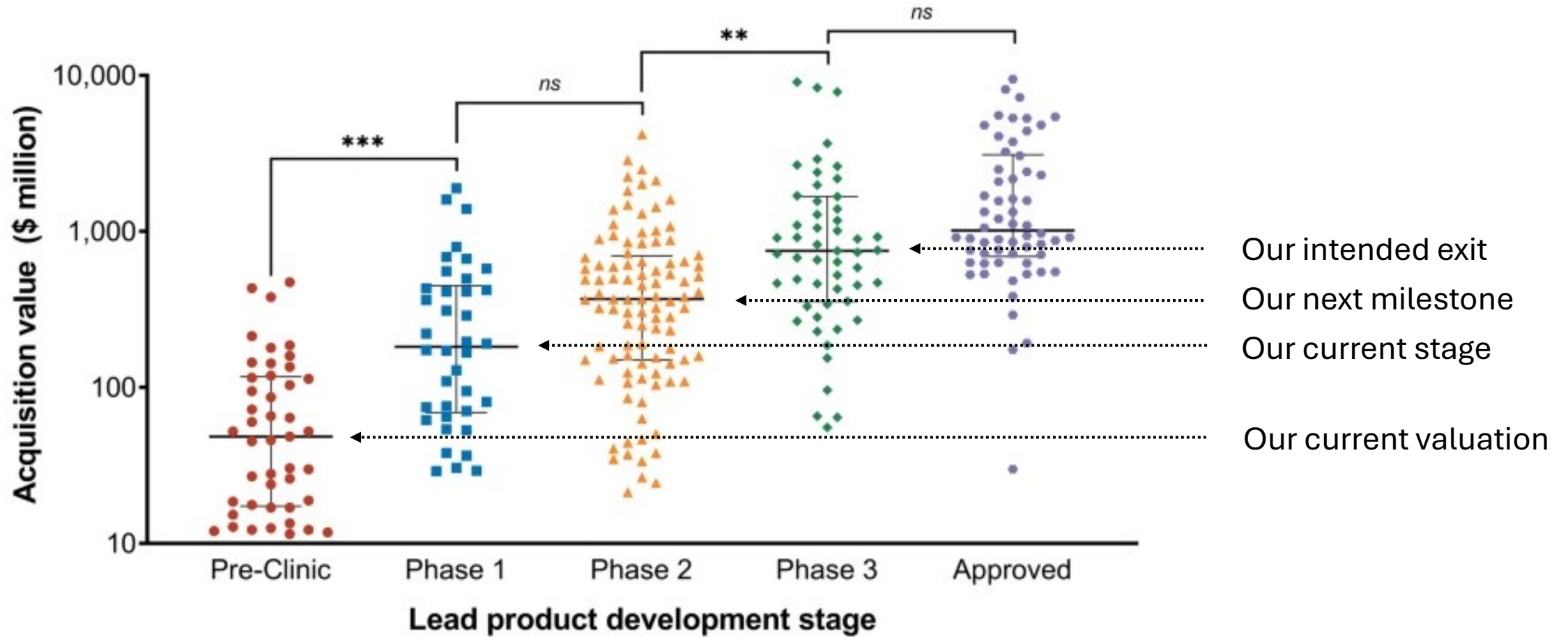
- Clinical Site
- Regulatory Support
- Pipeline Development
- Data Management
- Legal/Accounting
- Team Salaries
- Drug Manufacture

Fundraising Progress



- Written Commitments
- Soft Commitments
- Funds Sought

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



Patrick Wen, MD
Neuro Oncologist



Key Partners





Thank You!



Numiera Therapeutics

Let's talk more:
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