ALPHA SEVEN Therapeutics, Inc

Company Overview – Q2 2024

http://alphaseventbi.com

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THERAPEUTICS

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ALPHA SEVEN Therapeutics Overview

ALPHA-1062IN: Potential first treatment for Cognitive Impairment with Mild Traumatic Brain Injury (mTBI; Concussion)

- Licensed worldwide rights to develop and commercialize ALPHA-1062IN in TBI and related disorders, and Acute Pancreatitis from Alpha Cognition, Inc.
- **US Cognitive Impairment market is estimated at $13B+** with **no currently approved product**
- ALPHA-1062IN pre-clinical data has demonstrated positive cognitive effects and protects brain from damage; no toxicity observed
- Patents extending to 2043

Company offers significant milestone events for value creation

- Formulation and Stability work completion – Q3 2024
- Department of Defense (DOD) bomb blast **study completion** – Q4 2024
- Toxicity study completion – Q4 2024
- **Anticipated IND acceptance** – Q1 2025
- PH2 clinical **study initiation** – 1H 2025
- Initiation of pre-clinical acute pancreatitis study – 1H 2025
- Completion of pre-clinical acute pancreatitis study – 2H 2025
- Potential path to **Fast Track** designation – 2H 2025

Our Vision

To develop transformative therapies for people with brain injury

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What Is A Mild Traumatic Brain Injury (mTBI) And Cognitive Impairment?

- An mTBI occurs when a **head injury** disrupts brain function

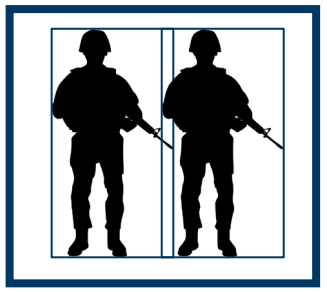
CAUSES

FALLS

VEHICLE RELATED CONCUSSIONS

VIOLENCE

SPORTS INJURIES



COMBAT INJURY

- mTBI can cause a wide range of functional challenges:
  - **Cognitive Impairment:** short-term memory loss, trouble concentrating, difficulty multi-tasking, lack of focus, slowed brain processing
  - **Mood/behavioral issues:** panic attacks, depression, irrational anger, increased sadness, irritability
  - **Physical functioning:** headache, dizziness, nausea, light/noise sensitivity, blurry/double vision, fatigue, trouble falling asleep, excessive sleeping

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Cognitive Impairment With mTBI Represents Significant $13B+* Market Opportunity

+5.0M Citizens who live with a permanent brain injury-related disability

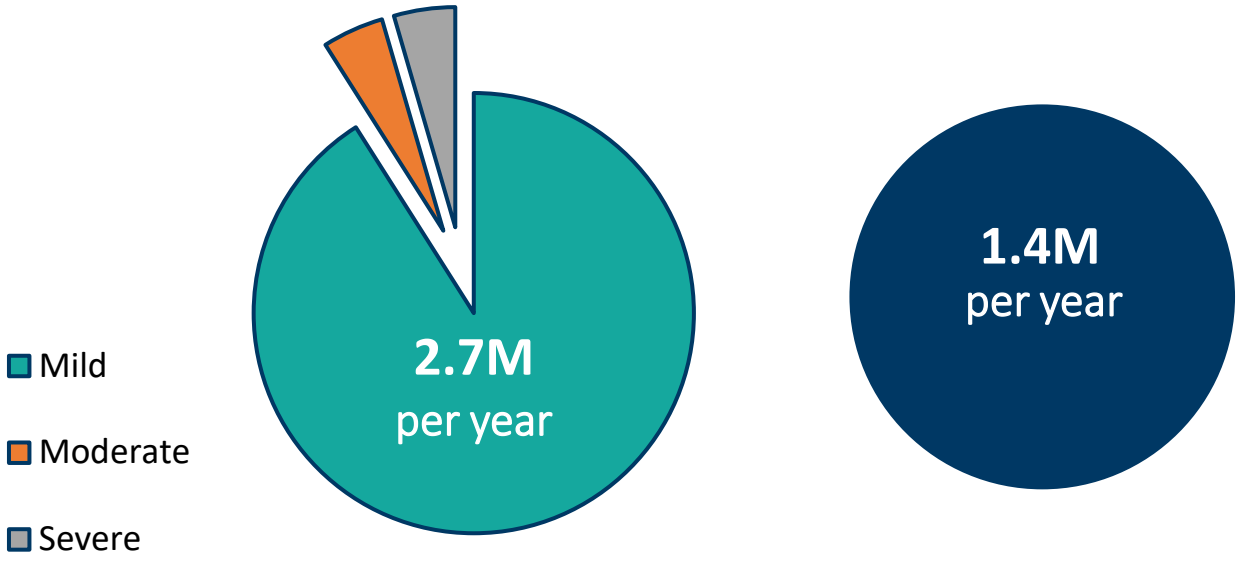
3.0M US TBI diagnosed events in 2019

2.8M Annual TBI-related ER visits[4]*, hospitalizations, and deaths

+400K Active military personnel diagnosed 2000-2019

Total Available Market

Addressable Market



3 Million TBIs/year
78% adult
91% are mild (mTBI)[1]

50% have persistent cognitive dysfunction[2]

Source: 1. DRG Executive Insights, Traumatic Brain Injury, June 2020
2. McInnes K, Friesen CL, MacKenzie DE, Westwood DA, Boe SG. Mild Traumatic Brain Injury (mTBI) and chronic cognitive impairment: A scoping review. PLoS ONE. 2017; 12: e0174847. 4. US *$13B = 1.2M cases per yr X $12.5K per treatment US

ALPHA-1062IN Scientific Rationale To Treat Cognitive Impairment With mTBI

Mechanism: Alpha7-Nicotinic modulation and ACHE inhibition

- Alpha-7 modulation affects improves brain receptor transmission, which exerts anti-inflammation effect and stimulates the cholinergic pathway
- Increases acetylcholine (ACH) neurotransmission, which affects memory, thinking, and attention
- Exerts downstream effect on other receptors (GABA, 5ht2, dopamine) responsible for attention, processing, memory, and reaction time.

Pre-clinical and clinical experience with ALPHA-1062IN

- Pre-clinical data demonstrated pronounced effect on cognition and brain healing
- Positive Phase 1 studies completed
- Secondary efficacy findings of improved attention and focus
- Adverse events have been mild and resolved over time
- No toxicity seen

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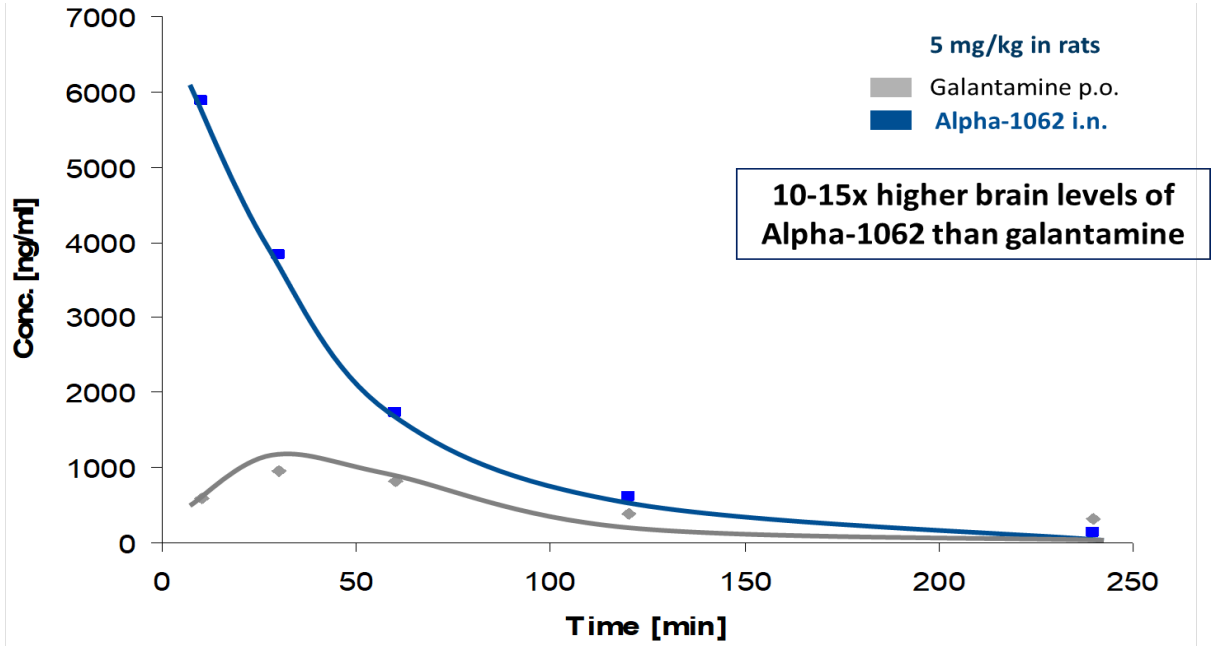
Alpha-1062IN Formulation Delivers An Optimal Level Of Medication

- Intranasal Formulation of Alpha-1062IN developed to deliver higher levels of active drug that can work in the brain
- Allows rapid transport across blood-brain barrier within 15 minutes
- ALPHA-1062IN safe and well-tolerated



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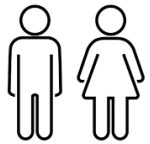
Alpha-1062IN Has Demonstrated Safety In Multiple Non-Clinical And Human Trials

Pre-clinical Studies (animal studies)

• Four toxicity studies completed	Safety confirmed
• Cardiovascular safety study	Safety confirmed



Clinical Studies (human studies)

• Single dose ascending study (SAD)	No safety issues observed
• Multiple dose ascending study (MAD)	No safety issues observed
• EEG Assessment Study	No safety issues observed
• 3 bioequivalence studies[1]	No safety issues observed
• 1 dose proportionality study[1]	No safety issues observed

1. Different formulation with same active drug moeity tested in these studies

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Development Program Of ALPHA-1062IN

Pre-Clinical Work Completed and Ongoing

- ✓ 2022: Brain histology study completed
- ✓ 2022: Preclinical TBI cognitive and motor sensory study
- ✓ 2011: Pharmacology studies completed
- ✓ 2010: Pharmacokinetics completed
- • 2024: Toxicology study – 90 day study

Clinical, Manufacturing, and Regulatory Work Completed and Ongoing

- ✓ 2014: Ph1 SAD completed
- ✓ 2016: Ph1 MAD completed
- • 2024: Next generation formulation work
- • 2025: IND submission to FDA
- • 2025: IND approval from FDA
- • 2025: PH2 Clinical Trial Initiation

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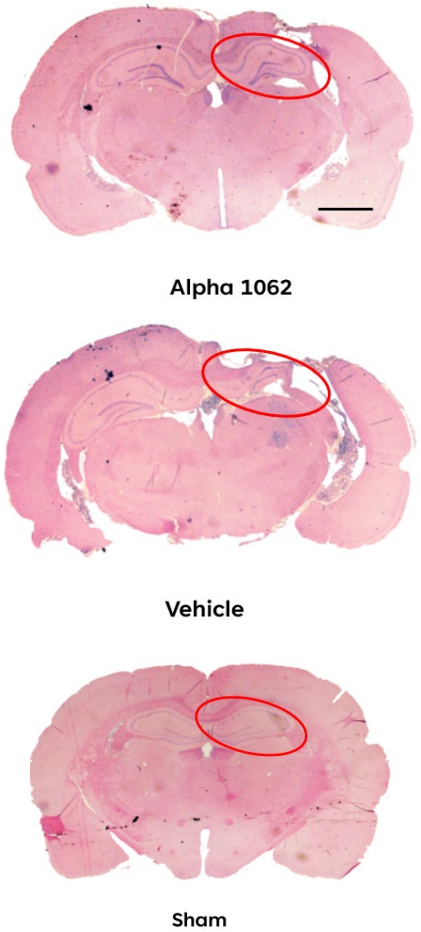
ALPHA-1062IN Acutely Preserves Function & Persistently Improves Recovery After TBI

PRECLINICAL RESULTS			
		VEHICLE	SHAM (UNINJURED)
Cognitive Functional Tests	Morris Water Maze	SUPERIOR*	EQUIVALENT TO
	Novel Object Recognition	SUPERIOR*	EQUIVALENT TO
Motor and Sensory Functional Recovery	nMSS[1]	SUPERIOR*	–
	Foot-fault	SUPERIOR*	EQUIVALENT TO
	Adhesive Removal	SUPERIOR*	EQUIVALENT TO

Equivalent to uninjured animals in 4/5 primary endpoints

No toxicity or safety issues observed



Brain Neuroprotection and Neurogenesis occurred

*P=0.05

1. Modified Neurological Severity Score

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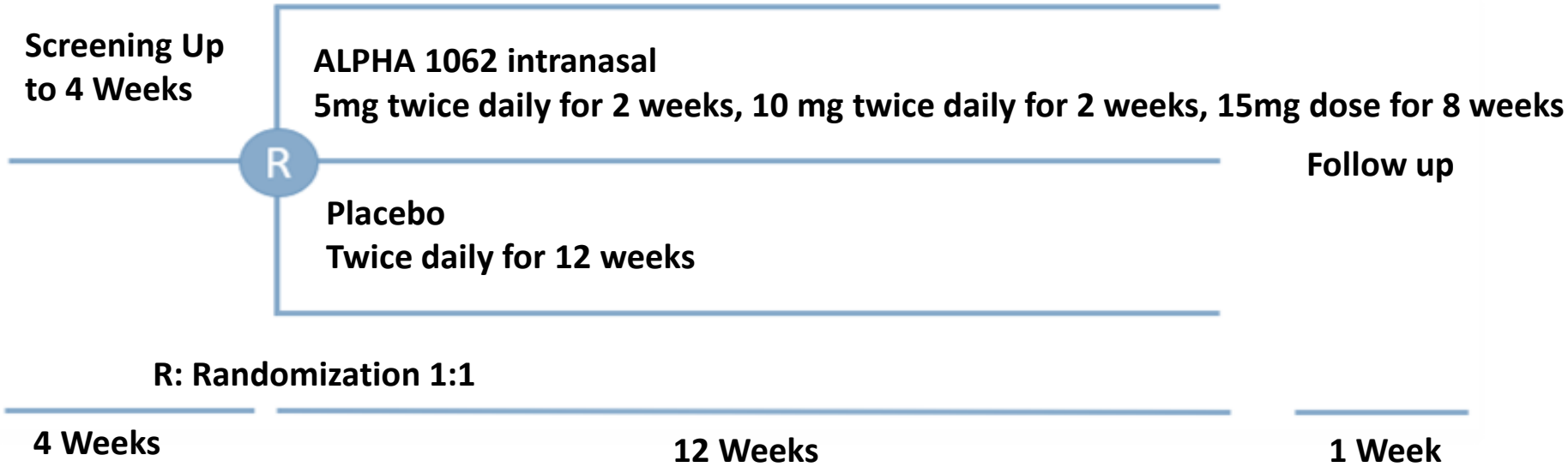
PH2 Study Design: Cognitive Impairment With mTBI

12 week, multi-center, double blind placebo controlled study (N=100)

- **Change in Cognitive Battery cumulative scores - primary endpoint[1]**
- **Change in PHQ9, GAD7, PSQI, HRQOL, Headache diary[2] - secondary endpoints**

Study Design: Two Arm Study (N=100)



1. NIH Cognition Battery will be used as primary endpoint tool 2. PHQ9=Patient Health Questionnaire 9 for depression; GAD7=general anxiety disorder 7; PSQI=Pittsburgh sleep quality Index; HRQOL=Health Related Quality of Life; Daily Diary=Measures headache

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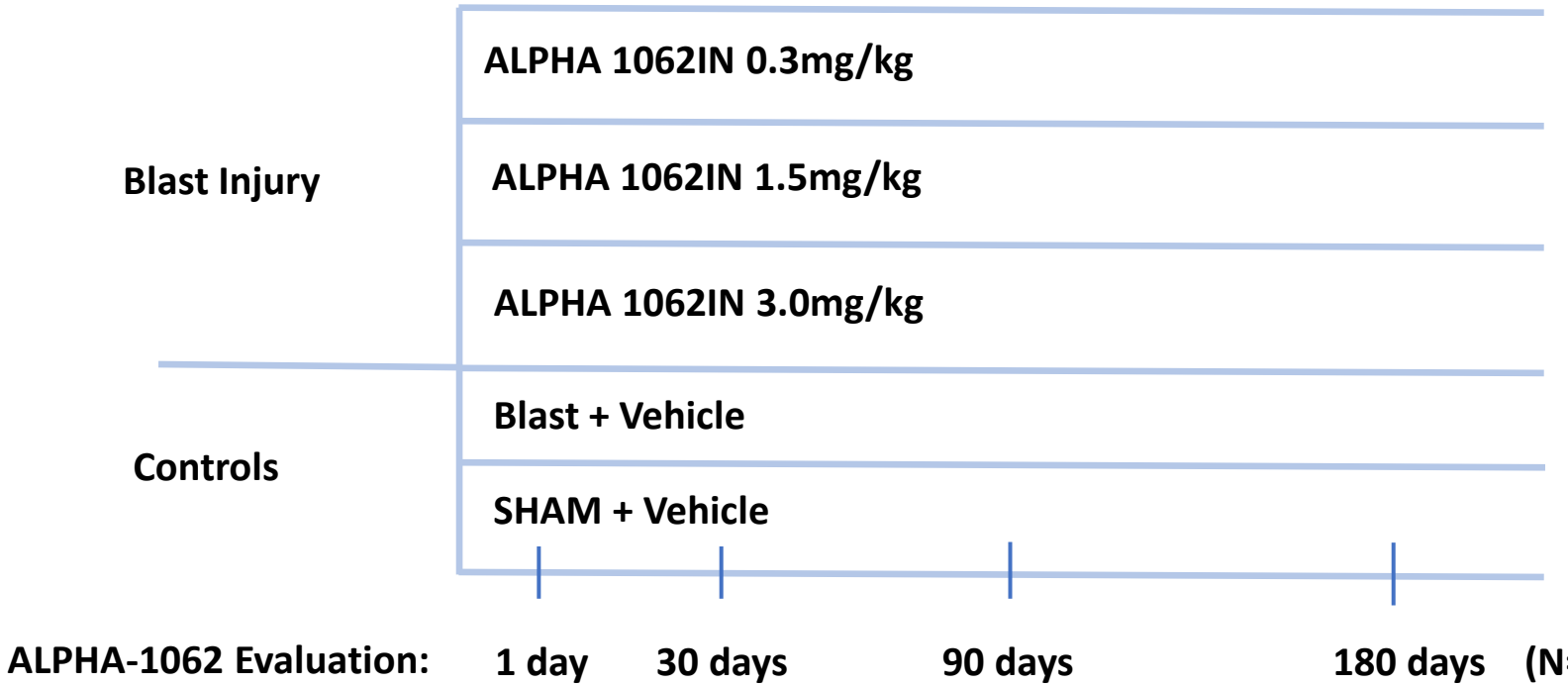
Pre-clinical Blast mTBI Study Design With Department of Defense

Determine ALPHA-1062IN reduction of: 1.) behavioral/functional deficits & 2.) brain-wide burden of neuropathologically (cell death, neuroinflammation, Tauopathy); following single or repetitive (3x) blast mTBI, as compared to vehicle-administered blast mTBI and uninjured control mice.

Study Design: Single and multiple blast mTBI and sham procedures in mice



- At 1 & 30 days of ALPHA-1062 administration, all 3 drug doses will be evaluated.
- The optimal dose from these timepoints will be used for the 90 and 180 day administration timepoints.

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ALPHA-1062IN Opportunity

Large, Underserved Market

1.4M with Cognitive Impairment following TBI annually

Large $13B Market

No approved product for condition

Any approved product **will have a premium price**

Symptom Focus Improves Opportunity

Focus on Cognitive Impairment targets symptoms where ALPHA-1062IN has demonstrated effect

Cognition Impairment a top 3 symptom that people with TBI/concussion suffer

ALPHA-1062IN has demonstrated effect on executive function

Excellent Rationale For Efficacy

Modulates A7 Receptor which is implicated in memory and processing speed

Decreases damage to the blood brain barrier

Reduces inflammation via targeted receptors in brain

Increases brain function and repair

Upcoming Milestones

FDA Meeting for alignment of clinical development plan

DOD pre-clinical study completion

Toxicity study

Obtain IND acceptance

Obtain Fast Track Designation

Initiation of PH2 clinical study

Use Of Proceeds

Use of Proceeds	Description	Budget	Percent of Budget
Manufacturing and Formulation Work	Drug supply, stability work, Formulation for Tox study	$1.05M	35%
Regulatory, Legal, Banking	Type A meeting, Regulatory consultation, IP filing	$780K	26%
R&D	90 day toxicity study, pre-clinical Acute Pancreatitis study	$920K	30%
G&A	Accounting, consulting, salaries	$285K	09%
Total		**$3.0M**	

Seed Round is structured to complete formulation and manufacturing work, toxicity study, pre-clinical acute Pancreatitis, and to file additional intellectual property that can be filed for ALPHA-1062IN. Post toxicity study, IND would be prepared to file with FDA.

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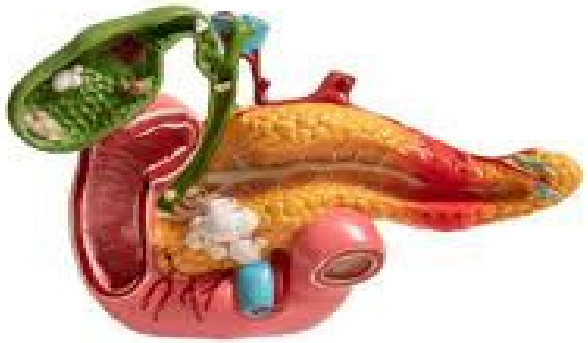
A Second Indication for Acute Pancreatitis
What Is Acute Pancreatitis?



- Acute Pancreatitis is characterized by severe abdominal pain accompanied by elevated pancreatic enzymes owing to inflammation in the pancreas.
- Alcohol, gallstones, hypertriglyceridemia (HTG) are predominant etiological factors. Drugs (steroids, GLP1s, valproate), hypercalcemia, and viral infection constitute other causes of acute pancreatitis
- Symptoms are severe abdominal pain, nausea, and vomiting
- Mortality is estimated at 5% in overall AP and 25% in severe acute pancreatitis
- 2.8M cases reported a year
- 275,000 hospital stays due to AP per year
- Analgesics are currently used to treat acute pancreatitis

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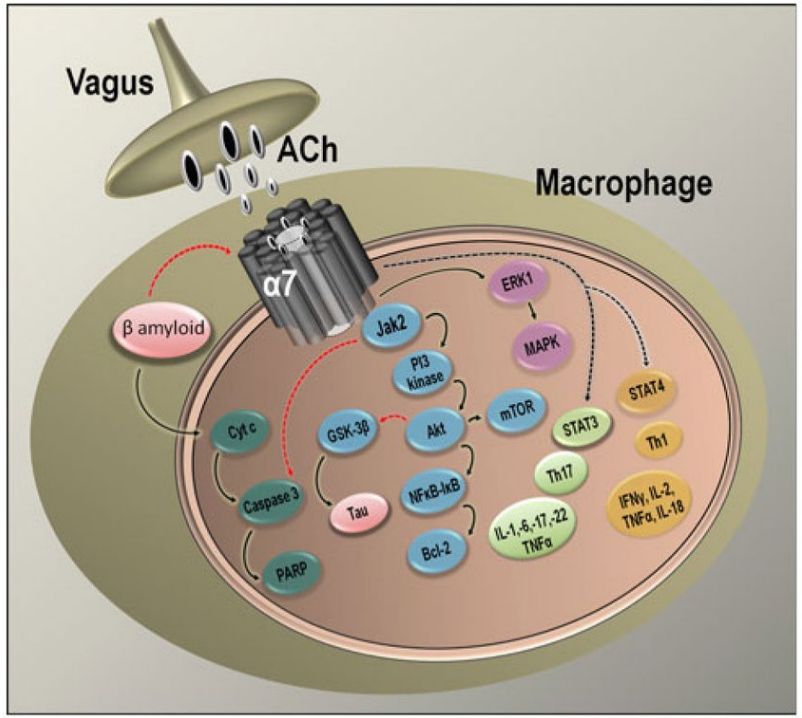
Rationale for ALPHA-1062 Efficacy in Acute Pancreatitis

- Activation of gastrointestinal tract-brain cholinergic anti-inflammatory pathway
- Inhibits infiltration of pancreatic neutrophils
- Decreases plasma amylase and lipase levels
- Direct effect on immunomodulatory cells located in the spleen
- Exhibition of both AChEI and nicotinic receptor potentiating activities



Reference for chart: Alpha7 niconitic receptors as novel therapeutic targets for inflammation-based diseases; Cellular and Molecular Life Sciences, Oct 2010; Bencherif

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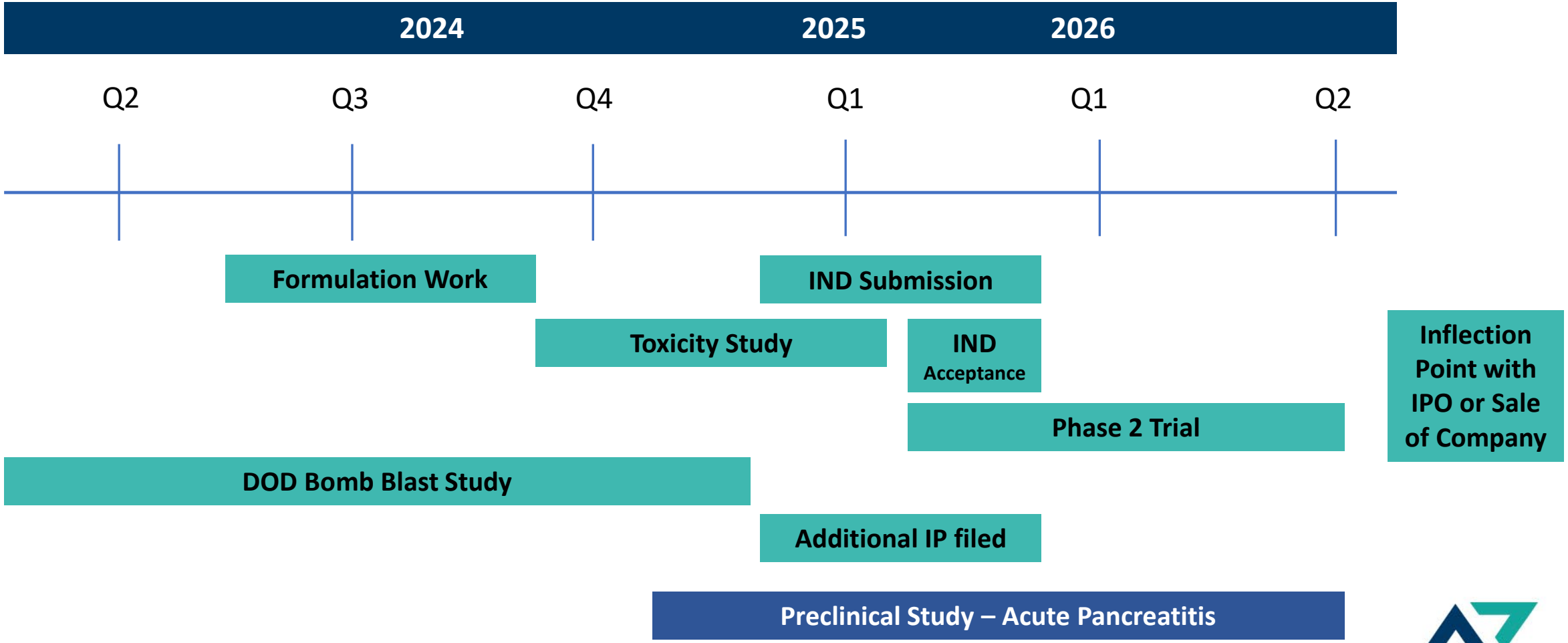
Company Timing To Inflection Points



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Capitalization Table

EQUITY HOLDERS	PERCENT OF COMPANY	$3M SEED ROUND (pre $) $10M Val
Alpha Cognition, Inc	85%	64.1%
Management and BOD; Strategic Consultants	15%	13.3%
Seed	0%	22.6%
	100%	100%

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Operational And Clinical Team And Advisors Have Significant Experience In Neurology Drug Development

Management

Michael McFadden
CEO

Denis Kay, PhD
Scientific Consultant

Lauren D'Angelo
CBO

BOD

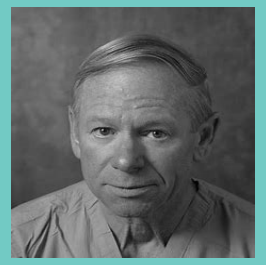
Tony Strickland
CEO, Nexus Triage

Michael McFadden
CEO

Scientific Advisors

Elaine Peskind, MD

Mental Illness Research, VA Puget Sound Health Care System



Robert Cantu, MA, MD, FACS, FACSM

Cantu Concussion Center

Charles Bernick, MD, MPH

Cleveland Clinic, Lou Ruvo Center for Brain Health

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Relationship Between Alpha Cognition (ACI) And Alpha Seven (A7)

Worldwide license provided to A7

- IP Protection with ability to file new IP
- R&D and marketing rights to A7
- Includes TBI and related conditions, Acute Pancreatitis and related conditions

ACI-A7 Relationship

- Data Sharing Agreement
- Supply Agreement through R&D completion
- Patent Synergy and leverage points
- Pre-clinical and clinical support

Preclinical and Clinical Data

- A7 has ability to leverage preclinical data and ongoing trials
- A7 will have clinical data that it can reference with FDA
- Intellectual history of molecule will be leveraged

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Investor Relations

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Backup

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