Zacks Small-Cap Research
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Alpha Cognition, Inc. (ACOGF: OTCQB)

Resolving to Move Ahead

Based on our DCF model and a 15% discount rate, Alpha Cognition is valued at approximately $2.75 per share. Our model applies a 62% probability of ultimate approval and commercialization of Alpha-1062. The model includes contributions from North America, Asia Pacific and other developed markets.

Current Price (6/22/2022)	$0.45
Valuation	**$2.75**

OUTLOOK

Alpha Cognition is developing Alpha-1062, a prodrug of galantamine that is in Ph3 development for mild to moderate AD. Additional pre-clinical work for Alpha-1062 is being conducted in mild TBI. The company is also advancing a preclinical progranulin gene therapy program for ALS.

With few advances in decades, AD represents a material unmet need. While some drugs exist to treat the symptoms of AD, side effects may limit use. To address GI-related side effects and optimize dose, a prodrug of previously approved galantamine has been developed which avoids active drug interaction in the intestine. Exploratory studies have demonstrated an improved GI side effect profile and combined with other findings showing stable cognition, improved mortality and lower burden on caregivers, the drug makes a compelling argument for long-term use in AD patients. The new compound is expected to boost patient compliance which will aid in the realization of galantamine's benefits.

Alpha-1062 should present top line results in 2Q:22 for AD, with an NDA filing in 3Q:22 submitted via the 505(b)(2) regulatory pathway. Other early stage programs will target readouts for mild TBI and progranulin in 2022. Formulation development is also underway for a combination approach for Alpha-1062 and memantine to treat moderate to severe AD.

SUMMARY DATA

52-Week High	**1.80**
52-Week Low	**0.43**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**8,131**
Shares Outstanding (mil)	**67.0**
Market Capitalization ($mil)	**30.3**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0.1**
Insider Ownership (%)	**23.7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2023					$0.0 E
2024					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2021	-$0.28 A	$0.00 A	-$0.09 A	-$0.05 A	-$0.37 A
2022	-$0.04 A	-$0.05 E	-$0.05 E	-$0.04 E	-$0.18 E
2023					-$0.17 E
2024					$0.11 E

WHAT'S NEW

Bioavailability and Bioequivalence Study Results

Alpha Cognition, Inc. (OTCQB: ACOGF) provided topline results from its bioavailability and bioequivalence (BABE) study in a June 22nd press release which was followed by a conference call providing additional detail along with a presentation summarizing key data. Results showed that Alpha-1062 (galantamine benzoate) presented a favorable side effect profile and was within the parameters for bioavailability and bioequivalence required by the FDA to grant approval via the 505(b)(2) regulatory pathway. Next steps are to prepare for the safety and tolerability study that will measure overall adverse events and specific side effects. The trial, designated RESOLVE, will be designed as a three arm study comparing two arms of Alpha-1062 with placebo and enrolling 300 patients. Based on the data that is being developed, a New Drug Application (NDA) is expected to be filed for Alpha-1062 in Alzheimer's Disease (AD) by 2Q:23.

The two objectives of the BABE trial were to measure whether or not the bioequivalence of Alpha-1062 compared with the reference product fell within the limits required for Area Under the Curve (AUC) and maximum plasma concentration (C_{MAX}). During the June 22nd conference call, Chief Medical Officer Cedric O'Gorman, M.D. provided a summary of the data generated from the studies which we include below. The bioequivalence limits given compare Alpha-1062 with galantamine hydrobromide immediate release formulation.

Exhibit I – Summary of BABE Study Data[1]

Pharmacokinetic Parameter	ALPHA-1062 Delayed Release 5mg (n=36)	GALANTAMINE Immediate Release 4mg (n=36)	GALANTAMINE Extended Release 8mg Data on file[3]	% to Reference Drug 80-125%	Sufficient Data for NDA Filing
AUC0-inf (µg × h/mL) Fasted State	306.8	321.5		95%	✓
Cmax (ng/mL) Fasted State	30.7	40.5	26.7	76%	✓
AUC0-inf (µg × h/mL) Fed State	286.7	329.9		87%	✓
Cmax (ng/mL) Fed State	27.6	30.2		91%	✓

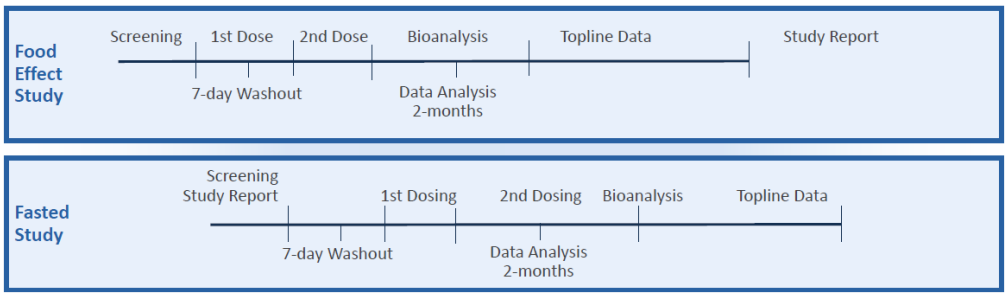
The data provided in the release support continued development of Alpha-1062. The safety profile of the drug was excellent with no serious adverse events (SAEs) in the active arm. The control arm evaluating galantamine hydrobromide IR was associated with two SAEs including diarrhea and vomiting, which were in-line with expectations based on the label for the reference drug. The main objective of Alpha-1062 with its prodrug formulation and enteric coating is to avoid many of the side effects common to approved formulations of galantamine which frequently cause patients to stop taking the drug, thereby failing to obtain its benefits. If Alpha Cognition's formulation of the drug can address these shortcomings, it is likely that the benefits that we elucidate in our initiation will be more broadly available for Alzheimer's patients.

Alpha-1062 Pivotal Bioavailability/Bioequivalence Study Background

Alpha Cognition launched its pivotal bioavailability and bioequivalence studies in 2Q:22, each of which enrolled 36 healthy adult subjects. Both studies were of an open label, balanced, randomized, single dose, two-period, two-way crossover design. The study design called for a single dose of Alpha-1062 delayed release under both fed and fasted conditions. The hurdle for bioequivalence calls for a 90% confidence interval for pharmacokinetic parameters and area under the curve (AUC) and C_{MAX} to fall between 80% and 125% of the standard.

[1] Source: June 2022 Alpha Cognition Corporate Presentation.

Exhibit II – Alpha-1062 Bioavailability/Bioequivalence Study Design[2]



Alpha Cognition Milestones

- Introduction of Alpha-0702 & -0802 – June 2022
- Alpha-1062 pivotal trial results in AD – 2Q:22
- FDA meeting to discuss ongoing development of Alpha-1062 – mid-2022
- Alpha-1062 patient tolerability study start in AD – 3Q:22
- Additional data sets for GEMs – 3Q:22
- Alpha-0602 pre-clinical study (2nd mammal) start – 3Q:22
- IND submission for Alpha-1062 in mild TBI – 4Q:22
- NDA submission for Alpha-1062 in AD – 2Q:23
- Alpha-0602 2nd mammal pre-clinical study top-line results – 2Q:23
- Alpha-1062 patient tolerability study topline results in AD – 2H:23
- Alpha-1062 potential label change – 4Q:23
- Initiation of Alpha-1062 combination (BABE) study – 4Q:23
- Alpha-1062 potential FDA approval for mild to moderate AD – 1Q:24
- Commercial launch of Alpha-1062 in mild to moderate AD – 1Q:24

Exhibit III - Alpha Cognition Clinical Pipeline[3]

Indication	Preclinical	Phase 1	Phase 2	Phase 3 /Pivotal	Status / Upcoming Milestones
ALPHA-1062					
Mild-to-Moderate Alzheimer's Disease (AD)					Positive Pivotal BABE study Top-line Results NDA filing Q2/23
RESOLVE AD Patient Tolerability Study					Initiates Q3/22 Label enabling for dose, safety, tolerability
Moderate-to-Severe Alzheimer's Combination with Memantine					Formulation development ongoing for 505(b)(2) regulatory pathway Pivotal Study Initiation 2H/24
ALPHA-1062 Intranasal					
Mild Traumatic Brain Injury					Pre-IND meeting with FDA Q3/22 Phase 1 studies completed
ALPHA-0602 Progranulin					
ALS and SMA					Preclinical Study Results Q3/22 FDA INTERACT meeting Q4/22
ALPHA-0702 and ALPHA-0802 (GEMs)					
Neurodegenerative diseases					Preclinical Study Results TDP-43, and neuronal survival completed

[2] Source: June 2022 Alpha Cognition Corporate Presentation.
[3] Source: June 2022 Alpha Cognition Corporate Presentation.

Summary

Alpha Cognition has continued to successfully satisfy the requirements needed to submit an NDA for Alpha-1062 using the 505(b)(2) pathway. Now that the BABE study has produced favorable data and provided a bridge between Alpha-1062 and reference products, additional work is ongoing regarding stability studies and the upcoming RESOLVE study which will examine dosing, safety and tolerability. Management has guided towards a 2Q:23 NDA submission for Alpha-1062 and expected approval by 1Q:24, immediately followed by commercialization activities. The BABE results provide confidence that Alpha Cognition's efforts are on the right track. We maintain our $2.75 price target.

PROJECTED FINANCIALS

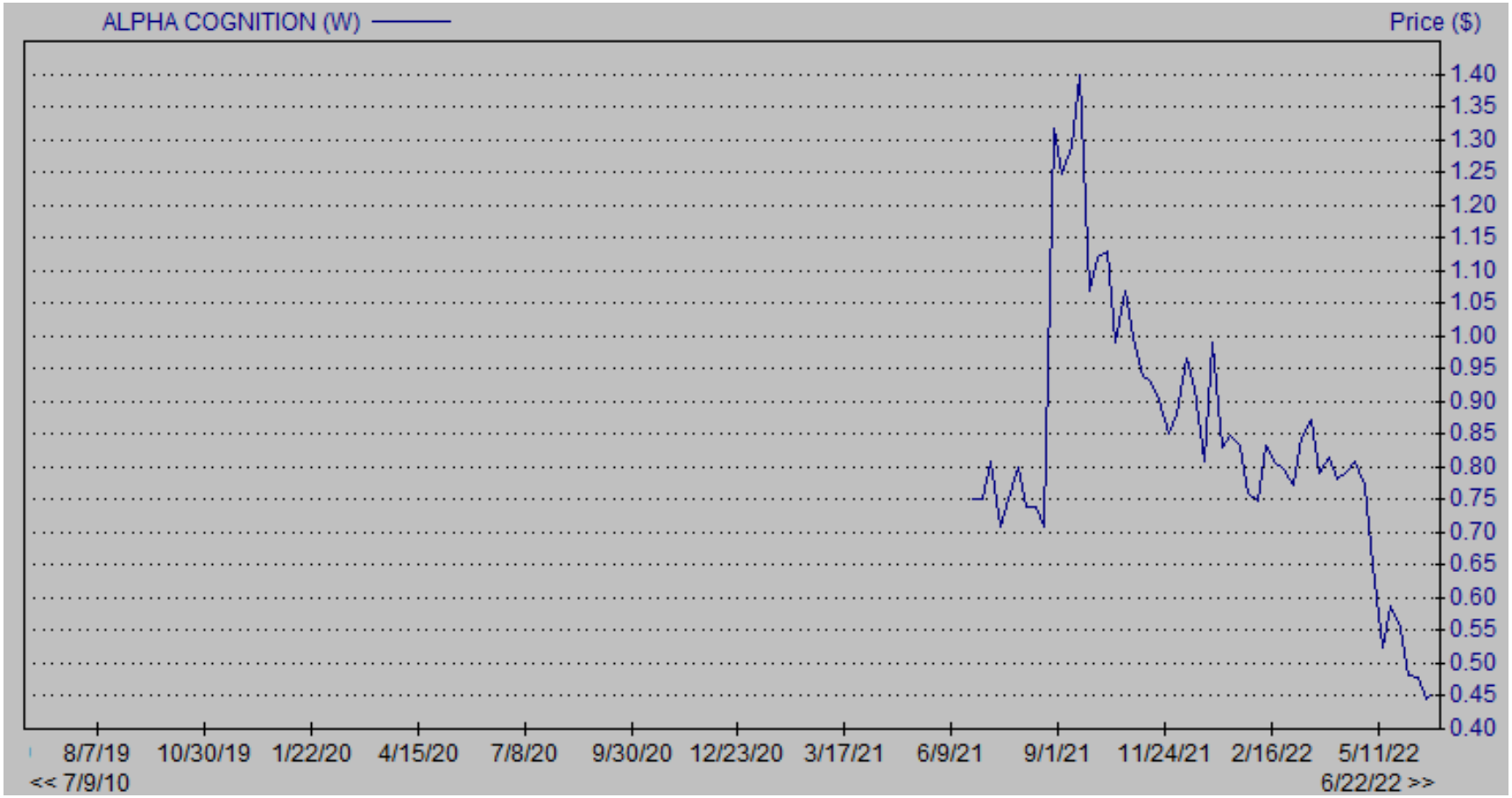
Alpha Cognition Inc. - Income Statement

Alpha Cognition Inc.	2021 A	Q1 E	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($US '000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$45,901**
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$4,590
Gross Margin								90%
Research & Development	$7,973	$1,776	$2,109	$2,195	$2,120	$8,200	$8,800	$8,800
General & Administrative	$4,124	$1,167	$1,050	$1,050	$1,250	$4,517	$4,865	$4,865
Sales & Marketing	$0	$0	$0	$0	$0	$0	$0	$13,770
Income from operations	($12,097)	($2,942)	($3,159)	($3,245)	($3,370)	($12,716)	($13,665)	$13,876
Operating Margin								30%
Other Items	($7,448)	$29	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($19,545)	($2,913)	($3,159)	($3,245)	($3,370)	($12,716)	($13,665)	$13,876
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$3,469
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%
Net Income	**($19,545)**	**($2,913)**	**($3,159)**	**($3,245)**	**($3,370)**	**($12,716)**	**($13,665)**	**$10,407**
Net Margin								
Reported EPS	**($0.37)**	**($0.04)**	**($0.05)**	**($0.05)**	**($0.04)**	**($0.18)**	**($0.17)**	**$0.11**
Basic Shares Outstanding	53,333	67,658	68,000	68,250	75,000	69,727	82,000	95,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Alpha Cognition Inc. – Share Price Chart



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