Zacks Small-Cap Research
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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com
scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Alpha Cognition, Inc. (ACOGF: OTCQB)

Obtaining Capital

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 (2/13/2023)	$0.29
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 presented top line results in 2Q:22 for AD, and is expected to submit an NDA in mid-2023 via the 505(b)(2) regulatory pathway. 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	**1.08**
52-Week Low	**0.15**
One-Year Return (%)	**-64.6**
Beta	**N/A**
Average Daily Volume (sh)	**3,963**
Shares Outstanding (mil)	**68.0**
Market Capitalization ($mil)	**19.7**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0.7**
Insider Ownership (%)	**30.0**
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 A	$0.0 A	$0.0 E	$0.0 E
2023					$0.0 E
2024					$45.9 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	-$0.04 A	-$0.03 A	-$0.04 E	-$0.20 E
2023					-$0.17 E
2024					$0.11 E

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WHAT'S NEW

Financing Update

Alpha Cognition, Inc. (OTCQB: ACOGF) announced a private placement of $5.0 million[1] that is expected to close on February 15, 2023. ACI had been running low on cash in its final stretch to bring Alpha-1062 in front of the FDA with a new drug application (NDA). Proceeds from the raise will be sufficient to bring the lead candidate to the FDA and await its disposition, but will not support development of the progranulin or traumatic brain injury programs.

We expect to see activity related to the NDA submission, including continued progression of the dose proportionality study for Alpha-1062 and ongoing chemistry, manufacturing and controls (CMC) work in support of the Alpha-1062. Other efforts that will be supported by the new funding include FDA interaction with respect to the traumatic brain injury (TBI) IND to identify desired content in the regulatory submission.

As part of the capital raise, Spartan Capital Securities was granted commissions in return for financial advisory services to ACI. Spartan provides services in the investment banking, institutional trading and research realms for middle market and emerging growth companies. Biotech is one of its primary industries. They may provide assistance in ACI's future anticipated efforts to shift its listing to the NASDAQ and raise additional capital.

ACI's Chief Medical Officer, Cedric O'Gorman, recently stepped down. He had been involved in preparing the IND for Alpha-1062 but had completed his responsibilities and moved on to developing programs further down in the pipeline. Chief Scientific Officer Denis Kay remains on board and will shepherd the final stages of the IND development process with the rest of the ACI team.

Based on guidance provided by management, we anticipate a submission of the NDA for Alpha-1062 by summer 2023. Assuming the submission takes place in June or July, and following the customary just-under-a-year review process, a target action date is expected in 2Q:24. If approval is granted, revenues are expected in 2H:24.

The environment for small cap biotech companies has been difficult over the last several quarters. Even late-stage clinical programs that have distinguished themselves and met expected safety and efficacy milestones have faced an uphill battle raising funding to check the last boxes. With the recent capital raise, ACI has distinguished itself from this group with sufficient funding to submit the NDA application.

Exhibit I – Boxed Checked[2]

BioEquivalence Study vs. Immediate Release

PK Parameter	ALPHA-1062 Delayed Release 5mg (n=36)	Gal HBr Immediate Release 4mg (n=36)	% 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	76%	✓
AUC0-inf (µg × h/mL) Fed State	286.7	329.9	87%	✓
Cmax (ng/mL) Fed State	27.6	30.2	91%	✓

Bioequivalence Study vs. Extended Release

PK Parameter	ALPHA-1062 Delayed Release 5mg (n=20)	Gal HBr Extended Release 8mg (n=20)	% to Reference Drug 80-125%	Sufficient Data for NDA Filing
AUC0-24 (µg × h/mL) Steady State	527.5	492.1	107%	✓
Cmax (ng/mL) Steady State	41.7	32.8	127%	✓

[1] Also reported at CAD$6.8 million.
[2] Source: January 2023 Alpha Cognition Corporate Presentation

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 – 2Q:22
- European patent defense in motor neuron disease – June 2022
- Additional data sets for GEMs – 3Q:22
- FDA meeting for TBI – 2Q:23
- NDA submission for Alpha-1062 in AD – mid-2023
- IND submission for Alpha-1062 in mild TBI – 2023
- Alpha-1062 potential FDA approval for mild to moderate AD – 1Q:24
- Commercial launch of Alpha-1062 in mild to moderate AD – 3Q:24
- Initiation of Alpha-1062 combination (BABE) study – 2025
- Alpha-1062 + memantine pivotal trial – 2H:25

Exhibit II – Alpha Cognition 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 Top-line Results NDA filing June/July 2023
RESOLVE AD Patient Tolerability Study					Additive, but not required for approval Label enabling for dose, safety, tolerability
Moderate-to-Severe Alzheimer's Combination with Memantine					Formulation development ongoing $3.5B market value Pivotal Study Initiation 1H/25
ALPHA-1062 Intranasal					
Mild Traumatic Brain Injury					Pre-IND meeting with FDA Q2/23 Phase 1 studies completed
ALPHA-0602 Progranulin					
ALS and SMA					Positive pre-clinical results
ALPHA-0702 and ALPHA-0802 (GEMs)					
Neurodegenerative diseases					Preclinical Study Results: mitigate TDP-43 toxicity, pro-neuronal survival, and anti-neuroinflammation completed

Summary

Alpha Cognition secured a small capital raise that is expected to close on February 15th. The funds are sufficient to complete the last steps required to submit the NDA, including an ongoing dose proportionality study, CMC work and NDA compilation. The funds will also support initial interaction with the FDA for later submission of an IND to pursue and indication in TBI. We maintain our $2.75 price target.

[3] Source: January 2023 Alpha Cognition Corporate Presentation

PROJECTED FINANCIALS

Alpha Cognition Inc. - Income Statement

Alpha Cognition Inc.	2021 A	Q1 E	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($US '000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$45,901**
YOY Growth								
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$4,590
Gross Margin								90%
Research & Development	$7,973	$1,776	$2,973	$1,620	$950	$7,319	$8,800	$8,800
General & Administrative	$4,124	$1,167	$1,445	$1,238	$985	$4,834	$4,865	$4,865
Sales & Marketing	$0	$0	$0	$0	$0	$0	$0	$13,770
Income from operations	($12,097)	($2,942)	($4,418)	($2,857)	($1,935)	($12,153)	($13,665)	$13,876
Operating Margin								30%
Other Items	($7,448)	$29	$1,414	$782	$0	$0	$0	$0
Pre-Tax Income	($19,545)	($2,913)	($3,004)	($2,075)	($1,935)	($12,153)	($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)**	**($3,004)**	**($2,075)**	**($1,935)**	**($12,153)**	**($13,665)**	**$10,407**
Net Margin								
Reported EPS	**($0.37)**	**($0.04)**	**($0.04)**	**($0.03)**	**($0.03)**	**($0.17)**	**($0.17)**	**$0.11**
YOY Growth								
Basic Shares Outstanding	53,333	67,658	68,023	68,023	75,000	69,676	82,000	95,000

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

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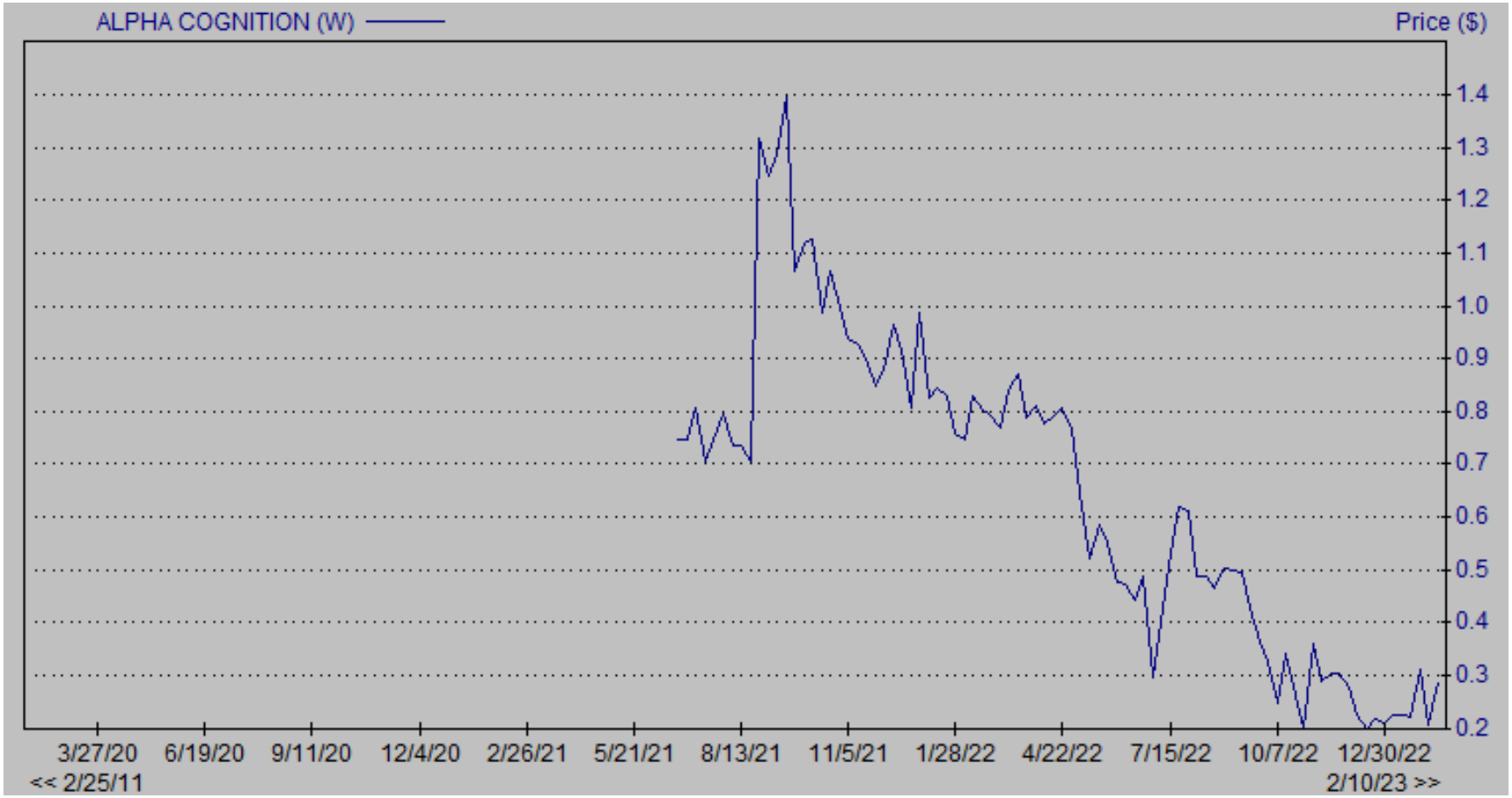
HISTORICAL STOCK PRICE

Alpha Cognition Inc. – Share Price Chart



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