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December 6, 2022
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Alpha Cognition, Inc. (ACOGF: OTCQB)

Seeking 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 (12/5/2022)	$0.28
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 2Q:23 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	**1.08**
52-Week Low	**0.20**
One-Year Return (%)	**-61.6**
Beta	**N/A**
Average Daily Volume (sh)	**4,427**
Shares Outstanding (mil)	**68.0**
Market Capitalization ($mil)	**19.0**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0.8**
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

Third Quarter 2022 Operational & Financial Results

Alpha Cognition, Inc. (OTCQB: ACOGF) released 3Q:22 operational and financial results on November 28, 2022 in a press release and concurrently filed its interim report with SEDAR.

Highlights for 2022 include:

- Preclinical histology data for Alpha-1062 in TBI - February 2022
- Preclinical data for Alpha-0602 announced – March 2022
- Addition of new CFO Don Kalkofen – April 2022
- Introduction of two new GEMs candidates: Alpha-0702 & Alpha-0802 – June 2022
- Pharmacokinetic equivalence study results for Alpha-1062 – June 2022
- Bioequivalence study results for Alpha-1062 – August 2022
- Announcement and withdrawal of marketed public offering – November 2022

For the third quarter of 2022 versus the same prior year period, both ending September 30.

- No revenues were generated in either period;
- Research and development expenses totaled $1.6 million, down 24% from $2.1 million on a reduction in product costs for the development of Alpha-1062 and Alpha-0602.
- General and administrative expenses increased 26% to $1.2 million from $1.0 million on higher management fees and salaries due to the hiring of new personnel, greater accruals for bonuses which were partially offset by lower investor communication costs;
- Total operating expenses fell 8% to $2.9 million from $3.1 million;
- Net other items were $0.8 million due to contributions by a gain in foreign exchange, interest income and a gain on revaluation of derivative liability;
- Net loss was ($2.8) million vs. ($4.3) million or ($0.03) and ($0.09) per share, respectively.

As of September 30, 2022, cash and equivalents totaled $3.7 million. This amount compares to an $11.3 million balance at the end of December 2021. In terms of debt, Alpha Cognition carries a promissory note issued in March 2015 to Neurodyn Life Sciences for the acquisition of Alpha-1062 held on the balance sheet at $1.2 million. Cash used in operations for 3Q:22 was ($1.6) million compared with cash used of ($3.1) million in 3Q:21. Financing cash flows totaled ($2,000) related to interest paid on promissory notes.

Capital Needs

Since our previous update in September, Alpha Cognition has continued its work on the Alpha-1062 program to prepare it for an anticipated New Drug Application (NDA) submission next year. To support further research and development activities including an upcoming study to allow for patients to receive a higher dosage more quickly, designated RESOLVE, additional capital will be needed. On November 17th, ACI announced that it would be offering a marketed public offering

Alpha-1062 Extended-Release Bioequivalence Study Topline Results

Results from the second bioequivalence study were shared with investors on August 22, 2022. The data demonstrated pharmacokinetic equivalence between 5 mg of Alpha-1062 delayed release tablets and 8 mg galantamine hydrobromide extended release (ER) capsules. These results combined with the data released in June show that both approved formulations of galantamine hydrobromide fall within the parameters required for bioequivalence.

The study was a two-treatment, two-period crossover study that enrolled 40 healthy subjects evenly split between the Alpha-1062 5 mg b.i.d. arm and the 8mg q.d. ER capsule arm. Alpha-1062 achieved area-under-the-curve (AUC) and peak (C_{MAX}) exposures of ~107% and ~127% respectively compared to results produced by galantamine hydrobromide ER. The C_{MAX} results fell between the galantamine immediate release (IR) and ER results. The data will support the anticipated submission of the new drug application (NDA) targeted for 2Q:23.

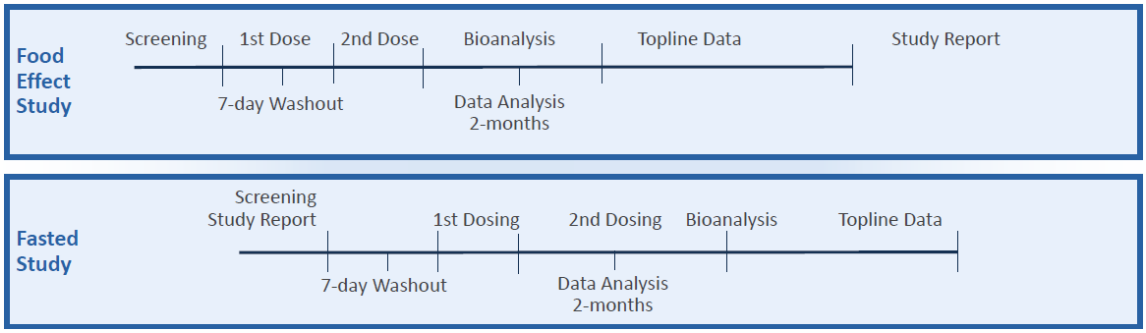
Exhibit I – BABE Study vs. Extended Release[1]

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%	✓

Bioavailability and Bioequivalence Study Results

Alpha Cognition launched its pivotal bioavailability and bioequivalence studies in 2Q:22 which enrolled 32 healthy adult subjects. The study design calls for a single dose of Alpha-1062 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.

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



ACI 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 AUC and 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 in the following exhibit. The bioequivalence limits given compare Alpha-1062 with galantamine hydrobromide immediate release formulation.

[1] Source: Alpha Cognition Second Quarter 2022 SEDAR Filing, Management Discussion & Analysis.
[2] Source: Alpha Cognition June 2022 Corporate Presentation

Exhibit III – Summary of BABE Study Data[3]

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%	✓

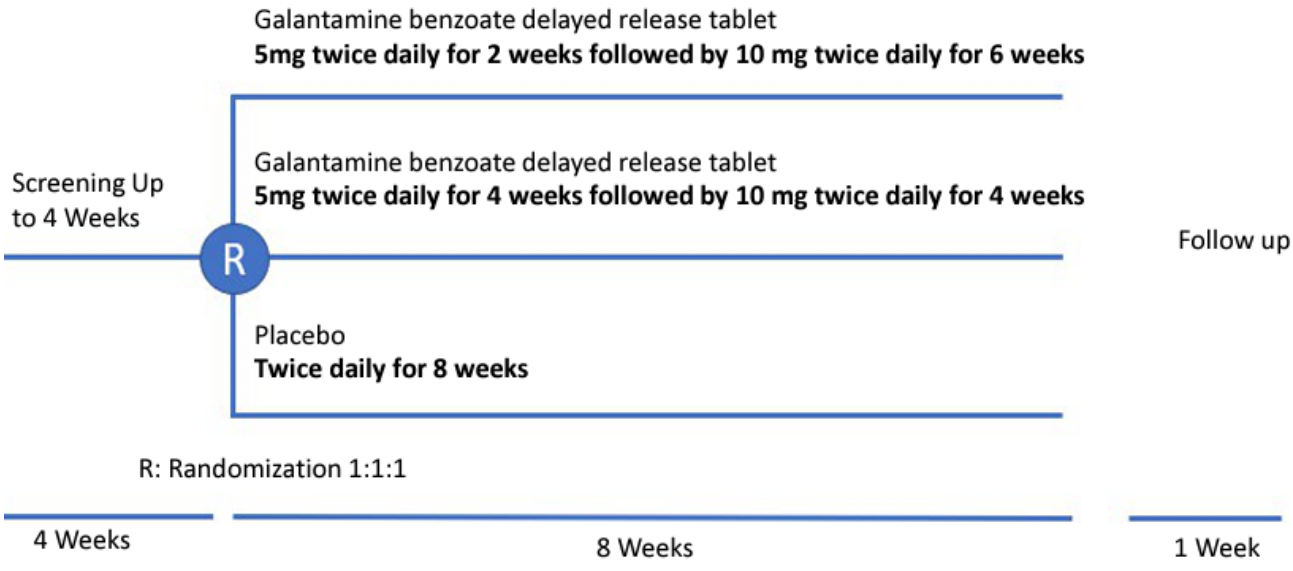
The data provided in the release support continued development of Alpha-1062. The safety profile of the drug was excellent with no serious adverse events (SAEs) in the active arm. The control arm evaluating galantamine hydrobromide IR was associated with two SAEs including diarrhea and vomiting, which 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.

RESOLVE Study

ACI met with the FDA during the second quarter 2022 to discuss Alpha-1062, specifically the RESOLVE trial, and related labeling and manufacturing. Based on the FDA's response, the company expects to file its NDA for Alpha-1062 in 2Q:23. The submission will include additional stability data. Preparation for the RESOLVE trial is underway with processes in place, engagement of data management support, site identification, evaluation and qualification. Institutional Review Board (IRB) approval has been granted and the final study protocol has been submitted via the Investigational New Drug (IND) application. The trial is expected to begin within a quarter of securing capital.

RESOLVE is a safety and tolerability trial designed to evaluate adverse events in comparison with a placebo that will evaluate 300 subjects. It will measure rates of overall adverse events and specific adverse events particular to galantamine including diarrhea, nausea, vomiting, insomnia and dizziness. The study will also assess the impact of standard and accelerated titration schedules on tolerability.

Exhibit IV – Study Design for RESOLVE[4]



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

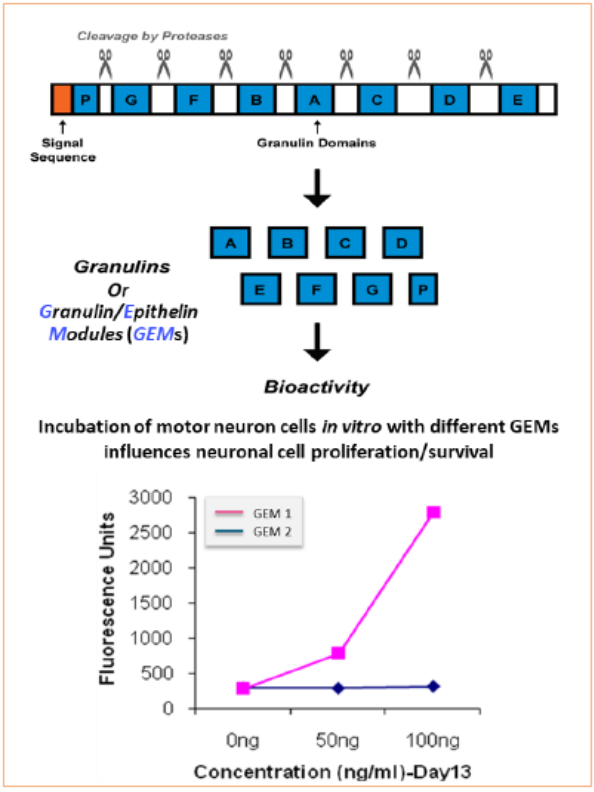
GEMs Program

In a June 13th press release, Alpha Cognition updated investors on the status of preclinical work developing Granulin Epithelin Motifs or GEMs for use in a variety of neurodegenerative diseases including amyotrophic lateral sclerosis (ALS), frontotemporal disorder (FTD) and spinal muscular atrophy (SMA). GEMs are important in regulating cell growth, survival, repair and inflammation. The new candidates are designated Alpha-0702 and Alpha-0802 and have demonstrated favorable results in preclinical work and are in preparation for additional neuroinflammation and toxicity to confirm activity. Conclusions from the work conducted on Alpha-0702, -0802 and -0602 are:

- Alpha-0702 and Alpha-0802 maintained prolonged cell survival and neuronal morphology, with a potency equivalent to, or approaching full length progranulin;
- Alpha-0702 and Alpha-0802 reduced both mutant and wild type TDP-43 toxicity, with a potency equivalent to, or approaching full length progranulin;
- Alpha-0602, Alpha-0702 and Alpha-0802 enhanced Cathepsin D maturation suggestive of improved lysosomal function. These effects were seen in induced pluripotent stem cells, derived from patients harboring toxic TDP-43 mutations that were terminally differentiated into motor neurons.

Many others in the space including Eli Lilly (LLY) through its Prevail Therapeutics acquisition, Passage Bio (PASG), Pfizer (PFE) and Alector (ALEC) are working on GEMs for a broad variety of neurodegenerative diseases making this a hotly contested space. Alpha Cognition has submitted composition of matter and method of use patents to patent authorities around the globe that, if approved, could provide protection into the 2040s for a broad variety of neurodegenerative diseases.

Exhibit V – Components of Progranulin / GEMs[5]



[5] Source: Alpha Cognition June 2022 Corporate Presentation

Alpha-1062 Mild Traumatic Brain Injury (mTBI) Program

Alpha-1062 is being investigated in mild traumatic brain injury and is at a preclinical stage of development. According to the Management of Concussion and Mild Traumatic Brain Injury 2020 data, three million individuals are affected by this condition in the United States annually. In contrast to the oral form administered for AD, Alpha-1062 for mTBI will be administered using a nasal spray. A mammal model is being employed to determine neurobehavioral and cognitive improvement of drug treatment, as compared to injured without treatment and uninjured cohorts in a three-arm study. In December, results of the neurobehavioral and cognitive improvement were released and demonstrated a statistically significant improvement in treated animals over their untreated counterparts. Furthermore, results for treated injured animals obtained results equal with uninjured animals in four of five neurobehavioral primary endpoints. Additional histology work was discussed in a press release and analyst call and will be presented at an upcoming conference. Results showed a dramatic benefit from Alpha-1062 where sufficient brain tissue was saved in treated animals compared with vehicle. All IND-necessary studies have been completed and next steps are to meet with the FDA. If the IND is cleared by the FDA, the mTBI program could advance immediately to a Phase II study.

Summarized findings from the histological pre-clinical study of Alpha-1062 vs. vehicle in mTBI announced in February 2022 demonstrated:

- Statistically significant reduction in lesion size measured at 35 days after injury;
- Preserved hippocampal structure;
- Statistically significant reduction in neuronal cell loss. The number of neurons in the Alpha-1062 treated animals were equivalent to those in the uninjured cohort of animals at the end of treatment;
- Statistically significant enhanced neurogenesis as evidenced by an increase in the number of neuron precursor cells and new neurons in the dentate gyrus, which plays a critical role in learning, information processing and mood regulation.

Exhibit VI - Alpha Cognition Clinical Pipeline[6]

Indication	Preclinical	Phase 1	Phase 2	Phase 3 /Pivotal	Status / Upcoming Milestones
ALPHA-1062					
Mild-to-Moderate Alzheimer's Disease (AD)					Achieved positive pivotal BABE study top-line results NDA filing Q2/23
RESOLVE AD Patient Tolerability Study					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 Q4/22 Phase 1 studies completed
ALPHA-0602 Progranulin					
ALS and SMA					Achieved positive preclinical study results Q3/22
ALPHA-0702 and ALPHA-0802 (GEMs)					
Neurodegenerative diseases					Preclinical Study Results TDP-43, and neuronal survival completed

[6] September 2022 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 – 1Q:23
- IND submission for Alpha-1062 in mild TBI – 1Q:23
- NDA submission for Alpha-1062 in AD – 2Q:23
- Alpha-1062 patient tolerability study (RESOLVE) start in AD – 1H:23
- Alpha-0602 2nd mammal pre-clinical study top-line results – 2Q:23
- Alpha-0602 pre-clinical study (2nd mammal) start – 2023
- Alpha-1062 patient tolerability study topline results in AD – 2H:23
- Alpha-0707 / -0802 topline data – 3Q: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 – 2Q:24
- Alpha-1062 + memantine pivotal trial – 2H:24

Summary

Alpha Cognition reported third quarter 2022 results following withdrawal of a marketed public offering. Raising sufficient capital to advance the RESOLVE study and successfully submit an NDA are key priorities for the company. During the third quarter the company continues its work on the BABE studies and continued preparations were made for the RESOLVE trial. Assuming that the AD results meet expectations, and sufficient capital is raised we should see an NDA submission in 2Q:23. ACI's priorities, which will be guided by the availability of capital, are first to file the NDA in 2Q:23 and conduct the RESOLVE study, second to advance the TBI program including the mammal study or partnership, and third to move the progranulin program forward.

Alpha Cognition's lead candidate Alpha-1062 is in a late stage of development and secondary candidates are in preparation to be submitted to the FDA for IND clearance. Alpha-1062's prodrug formulation and anticipated improved side effect profile compared to galantamine supports widespread use in AD patients if approved. We maintain our $2.75 price target.

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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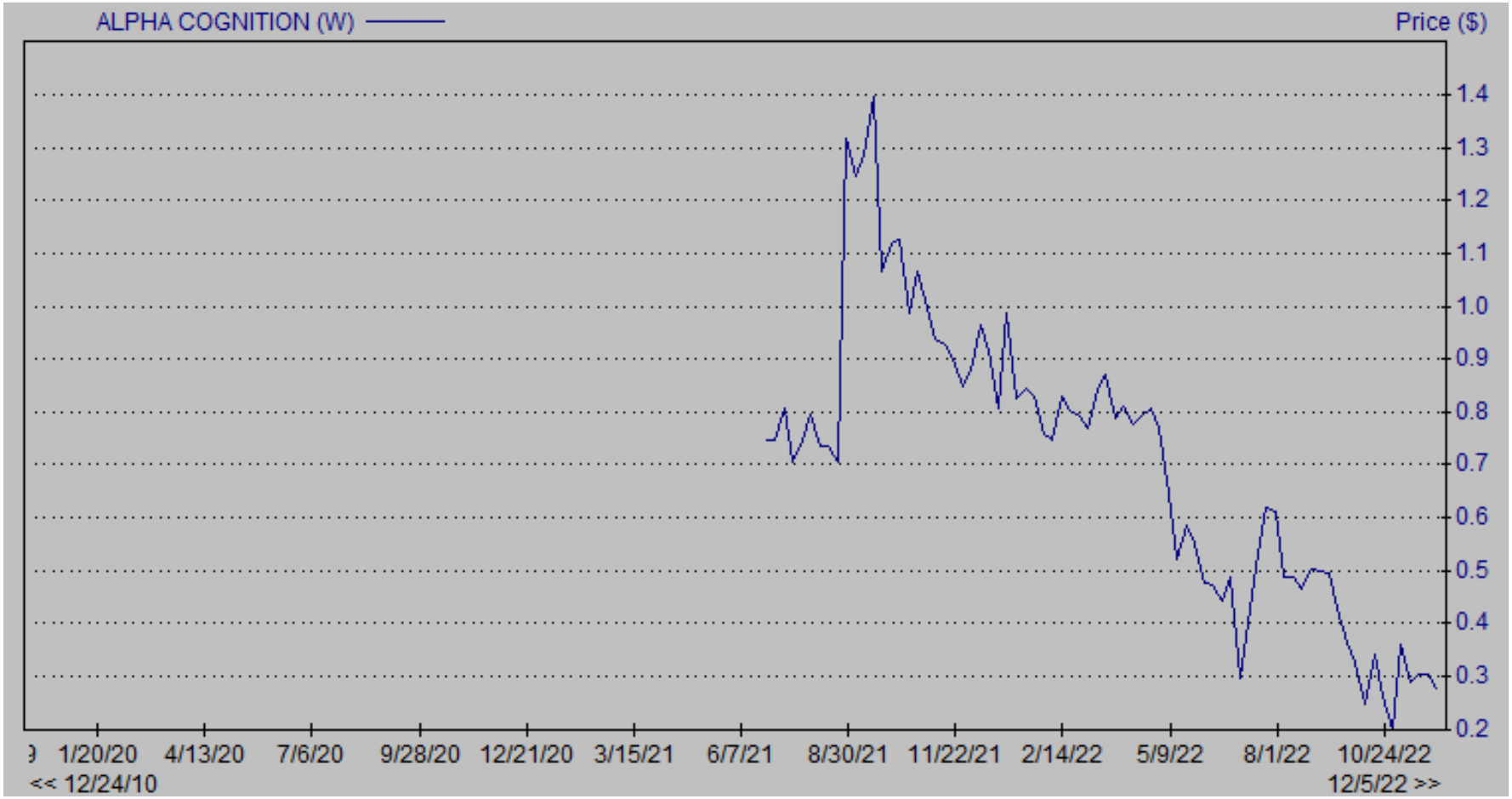
HISTORICAL STOCK PRICE

Alpha Cognition Inc. – Share Price Chart



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