

Alpha Cognition, Inc.

(ACOGF: OTCQB)

Results Are a Real Gem

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 (6/13/2022)

\$0.47

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 pro-drug 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)	7,180

Shares Outstanding (mil)	67.0
Market Capitalization (\$mil)	31.5
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
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Risk Level	Above Average
Type of Stock	Small-Growth
Industry	Med-Biomed/Gene

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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

First Quarter 2022 Operational & Financial Results

Alpha Cognition, Inc. (OTCQB: ACOGF) released 1Q:22 operational and financial results on May 31, 2022 and concurrently filed its annual 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

For the first quarter of 2022 versus the first quarter of 2021, both ending March 31st.

- No revenues were generated in either period;
- Research and development expenses totaled \$1.8 million, up 9.5% from \$1.6 million on higher product development expenses and recognition of subcontractor costs related to Alpha-1062 and Alpha-0602, partially offset by lower consulting fees and share based compensation;
- General and administrative expenses rose 40% to \$1.2 million from \$834,000 on higher management fees and salaries, recognition of investor relations and marketing costs, greater professional fees and more share based compensation partially offset by lower accretion expenses;
- Total operating expenses rose 20% to \$2.9 million from \$2.5 million;
- Net other items were \$29,000 dominated by gain on revaluation of derivative liability related to warrants partially offset by foreign exchange loss;
- Net loss was (\$2.9) million vs. (\$2.5) million¹ or (\$0.04) and (\$0.28) per share, respectively.

As of March 31, 2021, cash and equivalents totaled \$9.1 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 \$1.1 million. Cash used in operations for 1Q:22 was (\$2.4) million compared with cash used of (\$1.1) million in 1Q:21. Financing cash flows totaled \$35,000, related to exercise of options, partially offset by interest paid on promissory notes.

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

¹ Note that comparison of prior year results ignores the impact of other items which included (\$8.3) million loss on derivative liability and (\$1.4) million in listing expense.

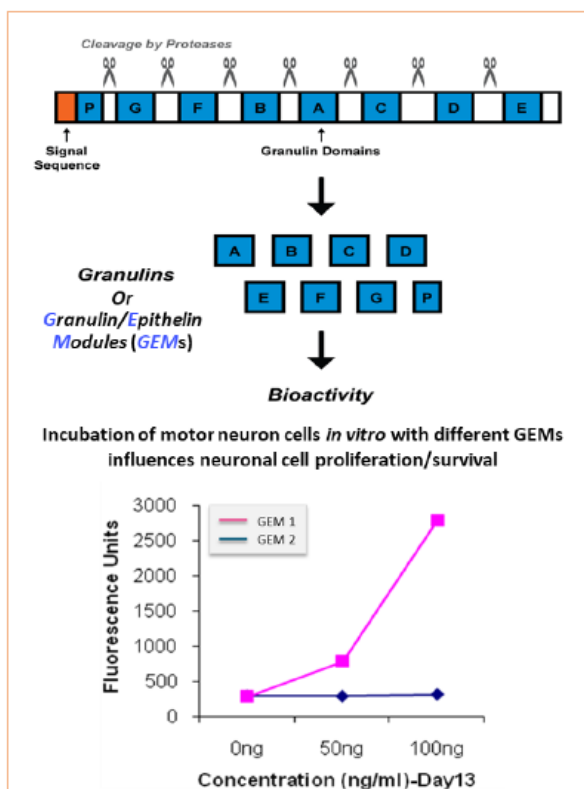
GEMs Program

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). 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. Additional data on the program is expected to be available in 3Q:22.

Exhibit I – Components of Progranulin / GEMs²



Lab Visit with Dr. Denis Kay

Dr. Denis Kay is Alpha Cognition's Chief Scientific Officer and we met with him at his University of Prince Edward Island laboratory. Dr. Kay co-founded Alpha Cognition's original company Neurodyn Life Sciences in August 2006. He has been working with progranulin since 2005 and filed the first patents for the protein in 2007. Further progranulin patents were filed in 2008 specifically for ALS and additional work continues to identify components of the progranulin protein known as granulin/epithelin modules (GEMs).

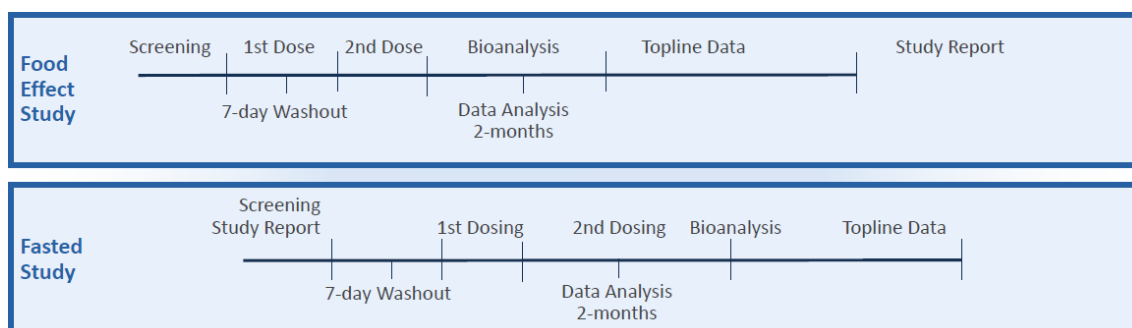
² Source: Alpha Cognition June 2022 Corporate Presentation

Dr. Kay's and other's work has shown that progranulin plays an important role in many neurodegenerative diseases. When the protein is dysregulated, dislocated or absent it can lead to ALS, Parkinson's Disease and other dementias. This has encouraged Alpha Cognition to advance research investigating the varied GEMs components that comprise progranulin. Dr. Kay's research has shown that some of the GEMs are supportive of neuronal survival and others can be toxic. One of the shortcomings of other approaches has been to introduce excessive progranulin which has led to inflammation and other negative side effects, and Alpha Cognition hopes to find the proper balance in the mix of GEMs that will resolve the disease without causing adverse events and negative side effects.

Alpha-1062 Pivotal Bioavailability/Bioequivalence Study

Alpha Cognition launched its pivotal bioavailability and bioequivalence studies in 2Q:22 which will each enroll 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 Design³



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 investigated 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 which is expected to occur in the latter part of 2Q:22. 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.

³ Source: Alpha Cognition June 2022 Corporate Presentation







Alpha-0602 Program Update

In February 2020, Alpha-0602 was granted [orphan drug designation](#) by the FDA for the treatment of amyotrophic lateral sclerosis (ALS). This was followed by other *in vivo* and *in vitro* preclinical work

On March 29, 2022, Alpha Cognition announced positive preclinical data for its progranulin program designated Alpha-0602 for the treatment of ALS. The study evaluating Alpha-0602 demonstrated “abundant” progranulin expression in motor neurons and decreased motor neuron cell death when observed in *in vitro* models. When evaluating *in vivo* models response to Alpha-0602, the candidate reversed the motor neuron toxicity resulting from suboptimal levels of TDP-43 and Fused-In-Sarcoma (FUS). In an ALS mouse model, Alpha-0602 was delivered using an adeno-associated virus (AAV) vector, was successfully transduced into the central nervous system (CNS) cells and was successful in increasing the cerebrospinal fluid (CSF) levels of progranulin. During the treatment period, the mice gained weight throughout the 10-week study in contrast to the untreated animals which did not. Study investigators employ weight gain as a proxy for therapeutic benefit of Alpha-0602.

Additional preclinical work for Alpha-0602 is ongoing and is expected to be complete in 2Q:22, following which, safety studies will be launched in animal models. The goal of this work is to prepare for an IND application to be filed with the FDA in 2H:22. Alpha Cognition expects to run Phase I to Phase III trials for the use of progranulin or its Granulin Epithelin Modules (GEMs) in the treatment of ALS.

Exhibit III - Alpha Cognition Clinical Pipeline⁴

Indication	Preclinical	Phase 1	Phase 2	Phase 3 / Pivotal	Status / Upcoming Milestones
Alzheimer's Dementia (AD)					
ALPHA-1062 Enteric-coated Tablet <i>Indication: mild-to-moderate AD</i>					Pivotal Study Top-line Results Q2/22 NDA filing Q2/23
ALPHA-1062 + Memantine Fixed-Dosed Combination Tablet <i>Indication: moderate-to-severe AD</i>					Formulation development ongoing for 505(b)(2) regulatory pathway Pivotal Trial initiation Q4/23
Mild Traumatic Brain Injury (mTBI)					
ALPHA-1062 Intranasal Formulation					Preclinical Top-line Results Q1/22 Phase 1 studies completed IND Submission Q4/22
Amyotrophic Lateral Sclerosis (ALS)					
ALPHA-0602 Progranulin and Granulin Epithelin Modules					Progranulin Gene therapy approach for ALS Preclinical study2 results Q3/22
Clinical Studies					
AD Patient Tolerability Study					Initiates Q3 2022 Label enabling for dose, tolerability

Management Changes

On April 12, 2022, Alpha Cognition filed a press release stating that it had replaced its contract Chief Financial Officer Jeremy Wright with permanent CFO Don Kalkofen. Mr. Kalkofen was previously CFO of Protagonist Therapeutics (NASDAQ: PTGX). He received his B.A. in accounting from Washington State University and is a CPA and Certified Global Management accountant. The press release went on to announce that Michael McFadden, the company's CEO, was appointed to the Board of Directors.

Initiating Coverage

On March 7th, 2022, we [initiated coverage](#) on Alpha Cognition. In the report we provide a review of AD, its prevalence, death rate relative to other common diseases and economic impact. We then shift towards other aspects of the disease including its etiology, diagnosis and the mechanism behind neurotransmission which are key to understanding galantamine's mechanism of action. A review of other products approved for AD is provided including several in development. Alpha Cognition's 505(b)(2) pathway to approval is also described. Following this background, we introduce Alpha-1062, providing the history behind the drug, its mechanism of action, most common side effects and observed benefits as promulgated in a broad spectrum of clinical research.

⁴ June 2022 Corporate Presentation

Summary

Alpha Cognition reported first quarter 2022 results highlighting new data for Alpha-1062 in TBI, Alpha-0602 preclinical data for ALS, a new CFO and the anticipation on pivotal trial results for the AD program in the near term. Two new candidates were introduced in the GEMs space: Alpha 0702 and Alpha-0802 which may provide treatment for a broad variety of neurodegenerative diseases. Assuming that the AD results meet expectations, we should see an NDA submission in 3Q:22.

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

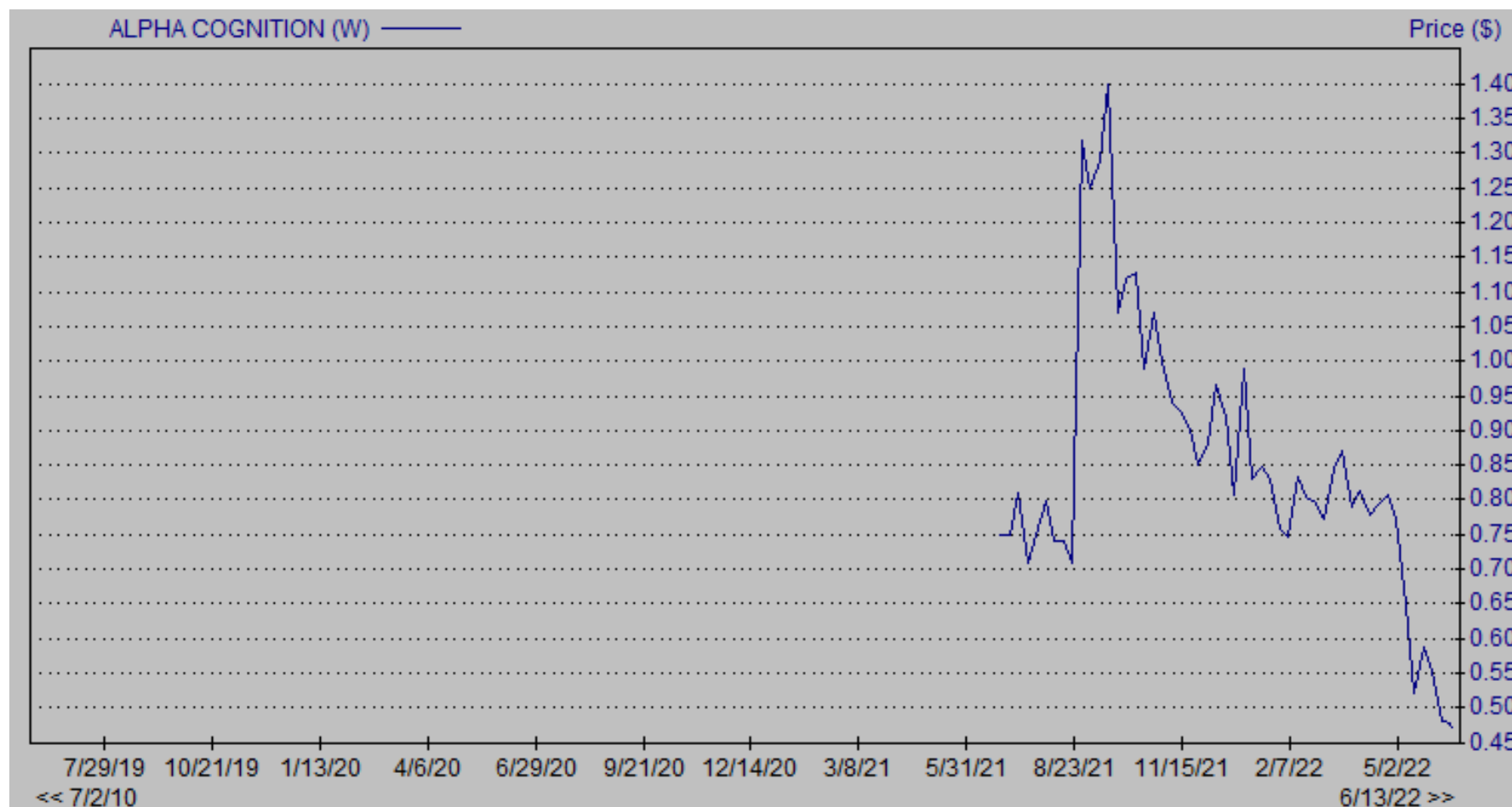
Alpha Cognition Inc. - Income Statement

Alpha Cognition Inc.	2021 A	Q1 E	Q2 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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