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Bioasis Technologies Inc.

(BIOAF: OTCQB)

FY 2022 Results and Valuation Update

Based on our DCF model and a 15% discount rate, Bioasis is valued at approximately \$0.70 per share. Our model applies a weighted 9% probability of ultimate approval and commercialization for CRES101, xB³-004, xB³-007 and other partnered compounds in a variety of indications including Guillain-Barré Syndrome, Gaucher Disease and others. The model includes contributions from global sources.

Current Price (7/27/2022) \$0.10
Valuation (\$USD) \$0.70

OUTLOOK

Bioasis' most advanced program comes from the June 2022 acquisition of Cresence's Phase II ready assets with targets in several neurological disorders. Bioasis' legacy xB³ platform enables therapeutics to cross the BBB. These preclinical programs target treatment of Gaucher & other brain disease. xB³-007 is in combination with Cerezyme and is undergoing proof of concept studies. Other candidates are also in development internally & with partners.

Bioasis' xB³ technology transports molecules using receptor-mediated endocytosis via the LRP1 receptor. The transport molecule is the xB³ peptide, which is derived from the iron-binding human protein melatonintransferrin found in the blood. LRP1 is widely expressed in critical brain regions and is over-expressed in many disease states.

The company has forged several partnerships with Janssen, Chiesi Group, Prothena, Neuramedy and other pharmaceutical companies. The partners provide external validation of the platform, upfront funding, candidate development and the opportunity for future royalty revenues.

Our valuation assumes a 2026 approval and launch CRES101 in GBS and later for other candidates globally through collaboration efforts.

SUMMARY DATA

52-Week High 0.28
52-Week Low 0.10
One-Year Return (%) -54.5
Beta 0.37
Average Daily Volume (sh) 11,196

Shares Outstanding (mil) 79.4
Market Capitalization (\$mil) 7.9
Short Interest Ratio (days) 0.1
Institutional Ownership (%) 0.0
Insider Ownership (%) 2.1

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 CAD)

	Q1 (May)	Q2 (Aug)	Q3 (Nov)	Q4 (Feb)	Year (Feb)
2021	\$0.0 A	\$4.1 A	\$0.0 A	\$0.0 A	\$4.1 A
2022	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A
2023					\$1.8 E
2024					\$1.8 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2021	-\$0.02 A	\$0.03 A	\$0.01 A	-\$0.02 A	\$0.01 A
2022	-\$0.01 A	-\$0.01 A	-\$0.02 A	-\$0.01 A	-\$0.04 A
2023					-\$0.07 E
2024					-\$0.05 E

WHAT'S NEW

Fiscal Year 2022 Operational & Financial Results

Bioasis Technologies Inc. (OTC: BIOAF) filed fiscal year 2022 operational and financial reports with SEDAR on June 14, 2022 for the twelve-month period ending February 28, 2022. The most impactful event for Bioasis occurred after the end of the reporting period where the company acquired the Norway-based Cresence in a transformational acquisition that catapults the company into the clinic with multiple indications in remyelination-related diseases.

During the 2022 fiscal year, Bioasis' material events include:

- Presented at Sachs 21st Annual Biotech in Europe Forum *Digital* Conference - October 2021
- Japanese p97-IDS fusion protein patent application granted - October 2021
- Attended BIO-Europe *Digital* - October 2021
- Annual General Meeting (AGM) - December 2021
- Planned divestiture of xB³-001 program – December 2021
- HCW BIOCONNECT Virtual - January 2022

In the financial realm, Bioasis reported FY:22 revenues of CAD\$38,000 and total operating expenses of CAD\$3.6 million¹ resulting in net loss of (\$3.0) million or (\$0.04) per share.

For the fiscal year ending February 28, 2022 and versus the same ending February 28, 2021:

- Research revenue totaled \$38,000 versus \$4.1 million, as revenues in the prior year included contributions from a research collaboration and license agreement with Chiesi Group that were not recognized in the most recent year. Revenues of \$38,000 represent funds attributable to a material transfer agreement with a global pharmaceutical company;
- General and administrative expenses totaled \$1.2 million, essentially even with prior year levels as increases in investor relations, marketing and travel, and share based compensation were mostly offset by lower salaries, consulting, office, insurance and legal expense;
- Research and development expenses totaled \$2.4 million, falling 6% from \$2.6 million on lower patent maintenance, legal and filing fees, offset by increases in office, rent, preclinical and share based compensation;
- Total other income was \$1.3 million vs. \$463,000. Increase in value of warrant liability due to changes in stock price compare with a variety of other financial related expenses in the prior year;
- Interest expense was (\$654,000) vs. (\$145,000) increasing due to the amortization of discount and issuance expense on the convertible debentures;
- Net loss was (\$3.0) million, or (\$0.04) per share, compared to \$0.7 million or \$0.01 per share.

As of February 28, 2022, cash and equivalents on the balance sheet totaled \$1.7 million. Cash burn for FY:22 was approximately (\$3.6) million, while cash flows from financing were a net \$2.6 million from convertible debenture proceeds partially offset by debt issuance costs.

Acquisition of Cresence Clinical Stage Assets

Bioasis [announced](#) the acquisition of several Phase II-ready rare disease assets in a June 16th press release. The asset purchase agreement was consummated with [Cresence AS](#) of Oslo, Norway and includes candidates with indications in Chronic Inflammatory Degenerative Polyneuropathy, Guillain-Barre Syndrome, and Multiple Sclerosis related Optic Neuritis. The most advanced asset is designated EGF1-48² (alternatively designated CRES101) and comes with a cleared Investigational New Drug (IND) package and clinical data demonstrating safety. EGF1-48 has demonstrated the ability to stimulate myelination and downregulate neuroinflammation and offering potential benefits to patients with Guillain-Barre Syndrome, Chronic Inflammatory Degenerative Polyneuropathy and certain

¹ Subsequent financial results and comparison in Canadian Dollars (CAD\$)

² EGF: Epidermal Growth Factors. [Cresence background on EGF relationship here.](#)

clinical manifestations related to onset and/or progression of multiple sclerosis including optic neuritis and relapses of the disease.

Bioasis will issue 6.5 million common shares to the sellers, which was valued at approximately \$1.0 million based on the company's closing share price the prior day. An additional 6.0 million common shares may be issued to the sellers upon achieving further milestones including the start of a pivotal clinical trial in the US and approval for the first product. Additional milestones payments of \$1.0 million may be made for the second and later FDA approval for related assets. A royalty of 1% of net sales will also be due Cresence. A two-year lockup for shares issued is in place for the sellers.

Targeted Indications

Bioasis highlighted three indications that will be prioritized for development using CRES101, two of which have targeted Phase II initiation dates.

- Guillain-Barré Syndrome (GBS) – 4Q:22
- Optic Neuritis associated with multiple sclerosis (MS) – 2Q:23
- Chronic Inflammatory Demyelinating Polyneuritis (CIDP) - TBD

Our model forecasts development of GBS and will layer on valuations for the other two programs when launched.

Guillain-Barré Syndrome

Guillain-Barré Syndrome or GBS is a rare neurological disease that affects 1 to 2 people out of 100,000. When GBS presents itself, the body's immune system attacks peripheral nerves resulting in weakness and tingling in extremities. The sensations can spread throughout the body resulting in paralysis. The symptoms can last weeks and can cause breathing difficulties that require a breathing machine. Approximately 70% of those with GBS recover from the syndrome, while others suffer from persisting weakness and a minority of the remainder suffer death.

There are three types of GBS. The most common is acute inflammatory demyelinating polyradiculoneuropathy (AIDP) which starts in the lower body and spreads upward. Other types include Miller-Fisher syndrome (MFS) which starts in the eyes and acute motor axonal neuropathy (AMAN) and acute motor-sensory axonal neuropathy (AMSAN) which is characterized by acute onset of distal weakness, loss of deep tendon reflexes and sensory symptoms.



³ Source: Shutterstock: [Image 1454292620](https://www.shutterstock.com/image-vector/1454292620)

History

While first described by Jean-Baptiste Octave Landry in 1859, the disease was named after army physicians Guillain, Barré and Strohl who submitted a paper in 1916 explaining the condition. Two cases were reported of acute self-limited motor weakness with reduced tendon reflex and good prognosis. For unknown reasons, Strohl's name was dropped and it was known as Guillain-Barré Syndrome after 1927 when it was used in a presentation by a group of physicians including Barré. In the 1960s, diagnostic criteria were proposed for GBS by researchers Osler and Sidell with additional refinements made in the mid-1970s. The latter were made in response to the rise in GBS cases that followed the 1976 swine flu vaccinations.

In the 1990s progress was made against GBS on several fronts including work identifying the effectiveness of IVIg in a Dutch study, and further understanding of the role of campylobacter jejuni and mycoplasma pneumoniae infection in the disease.

Cause

While the precise cause is not known, the syndrome usually occurs after a respiratory or digestive tract infection. It has also been associated with a vaccine, the Zika virus and the bacteria campylobacter jejuni. It is hypothesized that GBS is a nonspecific reaction to certain infective agents and may be attributable to abnormal antigen-antibody response. COVID-19 has also been implicated in GBS.⁴ Risk factors that may trigger the disease are fairly broad including the aforementioned factors and additionally the flu, cytomegalovirus, Epstein-Barr virus, HIV, surgery, trauma, Hodgkin's lymphoma and other less common viruses.

Incidence and prevalence:

Incidence of GBS is approximately one or two per 100,000, which is approximately 3,000 to 6,000 persons in the United States per year.⁵ Weakness for those with GBS lasts from three to six months for most and from 60% to 80% recover within a year.

Symptoms

Patients first notice a tingling or sensation of pain in the extremities, followed by weakness that manifests itself in the inability to walk or climb stairs. Nerves associated with the muscles in the arms, diaphragm and the face can also be affected. The sensation of weakness peaks within the first two weeks after initial symptoms and by the third week, 90% of the affected individuals are at their weakest. Other less common symptoms include breathing and swallowing difficulty, heart rate and blood pressure problems.

Diagnosis

While the symptoms of GBS may be confused with other neuropathies, several tests including lumbar puncture (spinal tap) to draw central nervous system (CNS) fluid and electromyograms (EMGs) may be performed to narrow the diagnosis. EMGs in particular are very important for determining nerve conduction and blockade. Nerve conduction studies may also be performed. Blood tests and relation of any recent infections, vaccinations, toxin exposure and other exogenous factors are addressed.

Treatment

There are several treatments for GBS including plasma exchange (PE) and high-dose immunoglobulin (IVIg) therapy. Plasmapheresis requires that a patient be connected to a machine that removes blood from the body, filters it and returns it after removing harmful antibodies. IVIg essentially dilutes the harmful antibodies that have emerged in the immune system with healthy donated antibodies. Physical therapy is also used to maintain muscle flexibility and strength. Anti-inflammatory steroid hormones called corticosteroids have been tried to reduce the severity of GBS with inconsistent benefit observed.⁶

Other treatments in development including interferon beta-1a, brain-derived neurotrophic factor, and CSF filtration, have been tried, but did not show efficacy.⁷

While there are treatments for GBS, about 10% will relapse after receiving it. Approved treatments will not reverse the disease although they may lessen the severity. Results for IVIg are inconsistent, highlighting the unmet need in

⁴ Khan, F. *et al.* COVID-19-associated Guillain-Barre syndrome: Postinfectious alone or neuroinvasive too? J Med Virol. 2021 Oct;93(10):6045-6049. doi: 10.1002/jmv.27159. Epub 2021 Jul 6.

⁵ CDC.gov. [General Questions and Answers on Guillain-Barré syndrome \(GBS\)](#). December 2009.

⁶ Lin, J. *et al.* Efficacy of therapies in the treatment of Guillain-Barre syndrome. Medicine (Baltimore). 2021 Oct 15; 100(41): e27351. Published online 2021 Oct 15. doi: 10.1097/MD.00000000000027351

⁷ Pritchard J, Hughes RA, Hadden RD, Brassington R. Pharmacological treatment other than corticosteroids, intravenous immunoglobulin and plasma exchange for Guillain-Barré syndrome. Cochrane Database Syst Rev 2016; 11: Cd008630

the disease. A meta-analysis by Lin *et al.*⁸ noted that only plasma exchange and IVIg were consistently better than placebo and corticosteroids showed no considerable impact.

For patients treated with PE or IVIg, about 5% die due to complications related to muscle weakness and up to 20% cannot walk a year after the start of the disease.⁹ Recovery can be slow and difficult. Existing treatments only slow and potentially stop the demyelination process and reduce inflammation rather than remyelinating the neuronal axons.

Updating Our Valuation

Since our previous valuation update, Bioasis has put the xB³-001 program on hold and allocated resources to other active programs including the newly acquired CRES101. We remove the valuation associated with the xB³-001 program and replace it with the pursuit of GBS with CRES101. Other programs for xB³-007, xB³-008, xB³-004 and xB³-009 remain in the pipeline at a preclinical stage and with our original estimates.

The GBS program is expected to start with a Phase II study in 2023 and traverse the clinical trial development process relatively quickly to registrational trials due to its status as a rare disease and the expedited treatment that regulatory agencies frequently grant to such indications. A biologics license application (BLA) is modeled to be submitted in 2026 and approval is assumed in 2027. Our approach assumes that Bioasis will find a partner for commercialization and will receive a royalty of 33% of net sales.

Guillain-Barré syndrome has an incidence of 1 to 2 cases per 100,000 per year. In the United States this is about 5,000 patients per year and in the developed world approximately 15,000. Since this is a debilitating rare disease with only a few modestly effective treatments, we anticipate a relatively high penetration rate. Our estimates for both the US and the developed world are penetration of 15% in the first full year of commercialization rising to a terminal penetration rate of 50% by year six.

We estimate based on today's environment that \$120,000 per course of therapy is appropriate pricing in the United States and \$48,000 is a reasonable average in the developed world. Annual inflation of 3% from today to the first year of commercialization supports a 2027 price of \$143,000 in the US and \$57,000 in the ex-US developed world. In the first year of US commercialization, we estimate approximately 764 patients using the therapy generating \$143,000 of revenue per patient producing \$109 million in revenues and \$36 million in royalties at a 33% royalty rate. In the first year of developed world commercialization, we estimate approximately 2,400 patients using the therapy generating \$57,000 of revenue per patient producing \$137 million in revenues and \$45 million in royalties using a 33% royalty rate. We apply a 10% probability of success for the GBS program based on its stage of development as a post Phase I and ready to start Phase II asset.

Following the hand off of the GBS program to a partner for commercialization, Bioasis will continue to advance its other programs in Gaucher Disease, Frontotemporal Lobe Dementia, multiple sclerosis, amyotrophic lateral sclerosis among that rely on xB³ to cross the blood brain barrier. We estimate the value of these programs by assuming potential average global revenue of \$435 million for the duration of the intellectual property protection, royalties ranging from 10% to 33% and apply a 7% probability of success. Our success rate will rise for all programs as they advance through clinical development stages.

Expense estimates increase with the new clinical programs in development and are dependent on a successful capital raise sufficient to support 18 to 24 months of operations. We assume operating expenditures of \$6.0 million in 2023 and \$7.2 million in 2024 reflecting the increase in research and development expenditures required to advance the pipeline. We expect to see annual inflation in expenses as the pipeline matures until approval of the GBS program, after which we anticipate a drop as earlier stage programs take the baton. Our model does not include estimates for other indications for CRES101; however, if funding is raised and programs launched in these indications, we will layer on the appropriate discounted cash flow (DCF) valuation.

As in our initiation, we use a DCF model using a 15% discount rate, terminal growth of -10% and shares used to calculate target price of 135 million. This consists of 80 million shares outstanding, 22 million warrant and option shares, 80 million newly issued shares to fund the program, and 13 million related to the Cresence transaction. The product of our valuation work generates a target price of \$0.70 per share.

⁸ Lin, J. *et al.* Efficacy of therapies in the treatment of Guillain-Barre syndrome. *Medicine* (Baltimore). 2021 Oct 15; 100(41): e27351. Published online 2021 Oct 15. doi: 10.1097/MD.00000000000027351

⁹ Misawa, S., *et al.* Safety and efficacy of eculizumab in Guillain-Barré syndrome: a multicentre, double-blind, randomised phase 2 trial. *The Lancet, Neurology*. Vol. 17 June 2018

Research Collaboration with Neuramedy

On May 10th, Bioasis [announced](#) its entry into a research collaboration and license agreement with Neuramedy. [Neuramedy](#) is a Seoul, Korea-based neurodegenerative disease company founded in 2019 with a focus on Parkinson's Disease (PD) and other α -synuclein related disorders. Neuramedy will use Bioasis' xB³ technology in its research, development and commercialization of Tomaralimab, its toll-like receptor 2 targeted antibody for PD. Bioasis has granted Neuramedy global rights to xB³ for use with Tomaralimab that will provide the former with an upfront payment and up to \$72 million in milestone payments. Royalties on net sales will also be owed.

Collaboration Arrangement with Janssen

On April 11th, Bioasis Technologies Inc. (OTCQB: BIOAF) [announced](#) a research collaboration with Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson (NYSE: JNJ). As part of the deal, Bioasis will provide access to its xB³ platform to Janssen in order for the latter to research, develop and commercialize new products. Few details were provided regarding the arrangement; however, any intellectual property generated from the work will be available to Bioasis. Representatives from both companies will have the opportunity for regular project team meetings to remain aligned with the research plan negotiated as part the agreement. The financial structure is a cost reimbursement plus margin arrangement with timing of the work to follow the research plan.

Exhibit I – Bioasis' Pipeline¹⁰

Asset	Indication	Drug Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3
Epidermal Growth Factor Platform						
CRES101	Optic Neuritis associated with MS				Phase 2 initiation Q2, 2023	
CRES101	Guillain-Barre Syndrome (GBS)				Phase 2 initiation Q4, 2022	
CRES101	Chronic Inflammatory Demylinating Polyneuritis (CIDP)					
CRES202	Alzheimers Disease					
xB ³ Platform						
xB ³ -008	Hunter Syndrome				Initiation Phase 1 Q4 2023	
xB ³ -007	Gaucher Disease, PD, Lewy Body Dementia					
xB ³ -004	Multiple Sclerosis, Epilepsy, Autoinflammatory Diseases					
xB3-009	CLN, Frontotemporal Dementia ALS					

¹⁰ Source: June 2022 Corporate Slide Deck / Cresence Acquisition

Upcoming Milestones

Below are recent and anticipated milestones:

- \$200,000 non-brokered private placement – February 2022
- [Attendance](#) at the 5th Annual Neuroscience Innovation Forum – March 2022
- Research collaboration with Janssen – April 2022
- Research collaboration with Neuramedy – May 2022
- Acquisition of Cresence – June 2022
- xB³-007 glucocerebrosidase enzyme replacement therapy (ERT), BBB data – 2022
- xB³-009 (Progranulin) BBB data – 2022
- IND preparation for xB³-007 – 2022
- IND preparation for xB³-003 – 2022
- Additional research agreements with partners related to signed MTA – 2022

Additional Capital Raised

On February 17, 2022 Bioasis [announced](#) that it had raised \$200,000 in a non-brokered private placement, issuing 770,000 common shares to an arm's length investor for \$0.26 per share. The common shares issued pursuant to the private placement are subject to a four month hold period in accordance with applicable securities laws.

Summary

Bioasis entered into several agreements over the last several months including collaborations with Janssen and Neuramedy and the acquisition of Cresence, which transforms Bioasis into a clinical stage company with multiple Phase II ready assets. Next up for Bioasis management is to secure the funding to support the advance of lead asset CRES101 that has potential in multiple remyelination diseases including Guillain-Barré and Multiple Sclerosis.

Bioasis offers a broad portfolio built on both its epidermal growth factor platform and its xB³ technology platform that can be developed both internally and with partners for many therapies demonstrating brain activity. While transportation, COVID and material availability related issues have delayed work, we anticipate a slowdown to the company's timeline and one dependent on partner capacity. We anticipate a near term capital raise to acquire sufficient funds to develop CRES101 and catapult Bioasis into a new valuation paradigm. Based on the opportunity and further development of the company's new lead asset, we increase our valuation of \$0.70 per share.

PROJECTED FINANCIALS

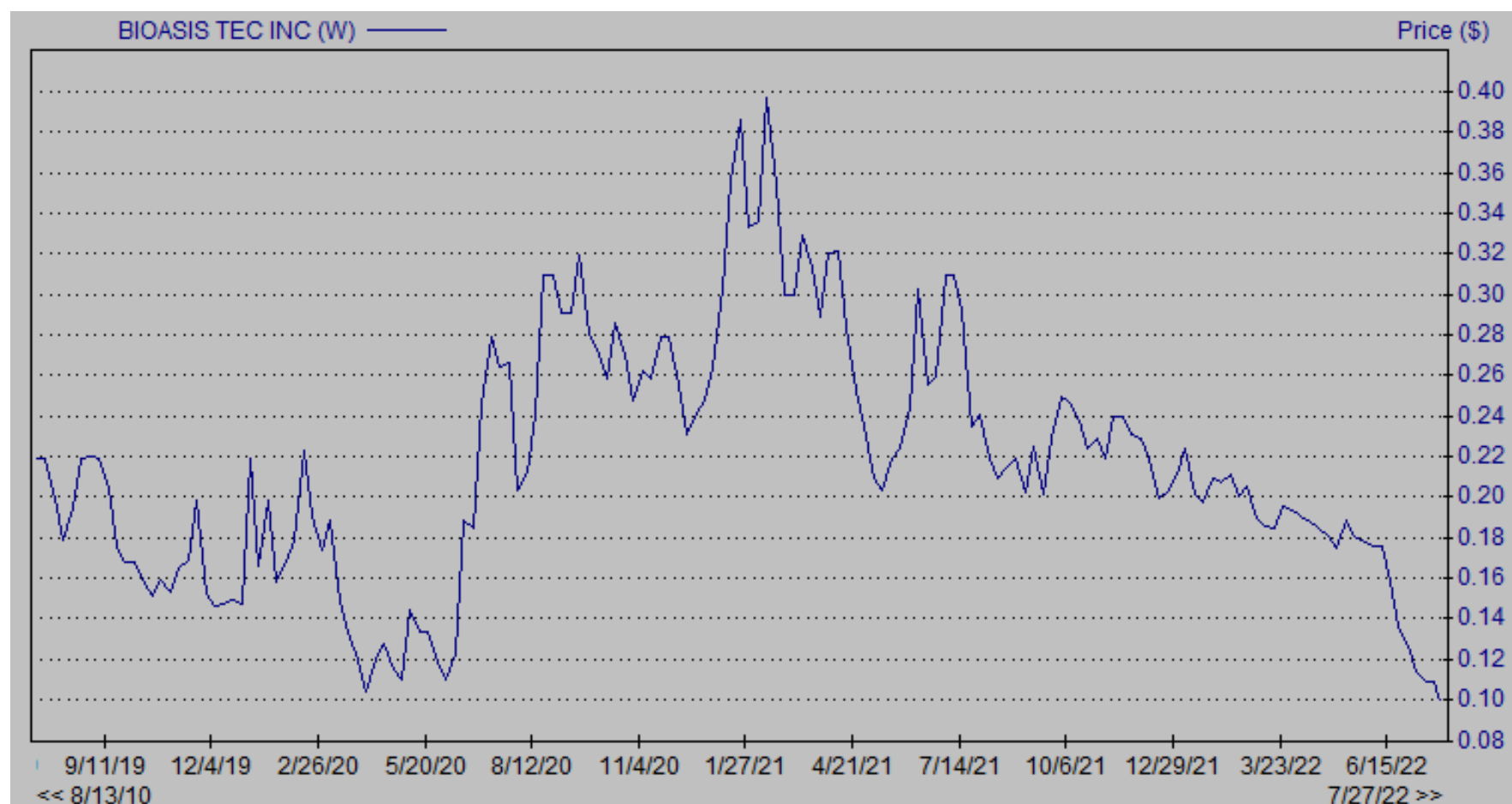
Bioasis Technologies Inc. - Income Statement

Bioasis Technologies Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 A	2022 A	2023 E	2024 E
Total Revenues ('000 \$CAD)	\$4,078	\$0	\$0	\$38	\$0	\$38	\$1,750	\$1,800
General & Administrative	\$2,569	\$589	\$782	\$512	\$525	\$2,408	\$2,420	\$2,550
Research & Development	\$1,238	\$200	\$404	\$302	\$321	\$1,226	\$3,568	\$4,640
Income from operations	\$271	(\$789)	(\$1,186)	(\$776)	(\$846)	(\$3,597)	(\$4,238)	(\$5,390)
Other Income	\$463	\$248	\$760	(\$253)	\$535	\$1,291	\$0	\$0
Interest Income	(\$36)	\$0	(\$155)	(\$243)	(\$256)	(\$654)	(\$1,500)	\$0
Pre-Tax Income	\$698	(\$541)	(\$580)	(\$1,272)	(\$567)	(\$2,960)	(\$5,738)	(\$5,390)
Provision for Income Tax	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>100.0%</i>
Net Income	\$698	(\$541)	(\$580)	(\$1,272)	(\$567)	(\$2,960)	(\$5,738)	(\$5,390)
<i>Net Margin</i>								
Reported EPS	\$0.01	(\$0.01)	(\$0.01)	(\$0.02)	(\$0.01)	(\$0.04)	(\$0.07)	(\$0.05)
<i>YOY Growth</i>								
Basic Shares Outstanding	68,115	72,144	72,144	72,144	72,500	72,167	84,625	102,000

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

HISTORICAL STOCK PRICE

Bioasis Technologies Inc. – Share Price Chart



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