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Bioasis Technologies Inc. (BIOAF - OTC)

Hunter Success Lights Path for xB^3

Based on our DCF model and a 15% discount rate, Bioasis is valued at approximately $0.60 per share. Our model applies a weighted 8% probability of ultimate approval and commercialization for xB^3-001 and xB^3-007 and partnered compounds in a variety of indications including HER2+ metastatic breast cancer and Gaucher Disease. The model includes contributions from global sources.

Current Price (11/19/2020)	$0.28
Valuation ($USD)	**$0.60**

OUTLOOK

Bioasis is developing a platform that enables therapeutics to cross the BBB designated xB^3. The most advanced preclinical programs underway target HER2+ breast cancer metastases and treatment of Gaucher Disease. The first, xB^3-001, combines the xB^3 platform with trastuzumab and may be awarded accelerated approval. The second, xB^3-007, is in combination with Cerezyme and is undergoing proof of concept studies. Other candidates are also in development internally and with partners.

Bioasis' technology transports molecules using receptor-mediated endocytosis via the LRP1 receptor. The transport molecule is the xB^3 peptide, which is derived from the iron-binding human protein melanotransferrin found in the blood. LRP1 is widely expressed in critical brain regions and is over-expressed in many disease states. We expect clinical trials to begin in 2021 for both candidates.

The company has forged several partnerships with the Chiesi Group, Prothena 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 2030 approval and launch of xB^3-001, xB^3-007 and later for other candidates globally through collaborator efforts.

SUMMARY DATA

52-Week High	**0.38**
52-Week Low	**0.09**
One-Year Return (%)	**71.8**
Beta	**0.73**
Average Daily Volume (sh)	**14,673**
Shares Outstanding (mil)	**68.0**
Market Capitalization ($mil)	**19.0**
Short Interest Ratio (days)	**0.8**
Institutional Ownership (%)	**0.0**
Insider Ownership (%)	**2.4**
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 2020 Estimate	**N/A**
P/E using 2021 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)
2019	$0.2 A	$0.2 A	$0.2 A	$0.0 A	$0.6 A
2020	$0.0 A	$4.1 A	$0.3 E	$0.3 E	$4.6 E
2021					$1.6 E
2022					$1.8 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-$0.02 A	-$0.02 A	-$0.01 A	-$0.02 A	-$0.07 A
2020	-$0.02 A	$0.03 A	-$0.01 E	-$0.01 E	-$0.01 E
2021					-$0.04 E
2022					-$0.04 E

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WHAT'S NEW

Second Quarter Operational & Financial Results

Bioasis Technologies Inc. (OTC: BIOAF) filed fiscal year 2021 second quarter operational and financial results on October 29, 2020. Since our initiation on October 19th, the company announced the issuance of a US patent related to the p97 peptides and the sale of royalty interest in the Chiesi assets to Xoma Corporation (Xoma).

Revenue of $4.1 million[1] represents upfront amounts from the Chiesi deal (US$3.0 million) after converting to reporting currency. General and administrative expense was $904,000, up a modest 8% on increases in stock based compensation, investor relations, marketing and travel costs. This was partially offset by decreases in salaries as well as contractions in consulting, legal, professional and regulatory expenses. Research and development contracted to $115,000, receding a substantial 82%. Decreases in pre-clinical expenses, salaries, consulting fees, benefits and share based compensation led to the change. This was partially offset by increases in patent maintenance, legal and filing fees.

Free cash flow of $3.0 million compares to cash burn of ($0.9) million in 2Q:20. Cash and equivalents were $1.9 million on August 31, 2020, up from $576,000 million at the end of FY:20. The positive cash flow in the quarter was attributable to the upfront paid by Chiesi. Following the end of the quarter, Bioasis received a US$1.2 million upfront payment from Xoma.

Advances in Hunter Syndrome

On November 10th, Denali Therapeutics (NASDAQ: DNLI) posted a press release highlighting success in DNL310. The company's technology uses a transferrin receptor-based enzyme transport vehicle (ETV) to cross the blood brain barrier and has a broad portfolio of candidates in many brain diseases including Parkinson's, frontotemporal dementia and mucopolysaccharidosis type II (MPS II), or Hunter Syndrome. Hunter syndrome is a rare genetic disorder where glycosaminoglycans (GAGs) build up in body tissues and is a type of lysosomal storage disease. The body lacks sufficient natural production of the enzyme iduronate-2-sulfatase (I2S) to break down the complex sugars. As a result, two GAGs, heparan sulfate and dermatan sulfate, accumulate in body tissues. The buildup of GAGs leads to a wide range of symptoms from physical manifestations (large head, abdominal hernias, distinct facial features) to hearing loss, decline in cardiac functions, enlargement of liver and spleen and obstructive airway disease. Hunter syndrome can also impact the central nervous system with nearly two-thirds of patients having psychomotor retardation, behavioral issues and neurological regression/dysfunction. The severe cases of the disease result in death at an early age.[2] Enzyme replacement therapy with idursulfase (Elaprase) is standard treatment for the disease, which is a purified form[3] of the affected enzyme. The drug, however, cannot cross the blood brain barrier, it is not able to address the neurological aspects of the disease[4] and has motivated researchers to find mechanisms to transport the enzyme into the brain.

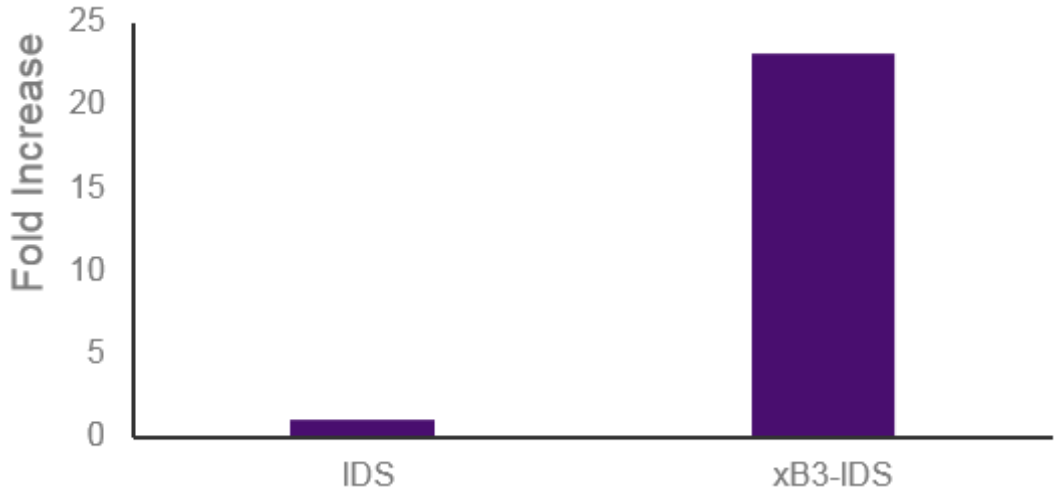
Denali has made an effort to solve the enzyme deficiency in the brain and is in early stage clinical trials using its ETV to transport idursulfase into the brain. In a Phase I/II study of DNL310 in Hunter Syndrome, the therapy was able to achieve a 76% mean reduction in cerebrospinal fluid (CSF) GAG. Patients on idursulfase ERT were switched to DNL310, which was administered for four weeks. The study was able to achieve normal healthy levels of GAG as measured in the CSF for four of the five enrolled patients. Summarized findings from the study include:

- Total urine GAG levels maintained in same range as prior to shift to DNL310
- CSF levels of heparan sulfate were reduced by 76% on average
- Four of five patients were able to reduce heparan sulfate in excess of 80%
- CSF levels of dermatan sulfate were reduced by 53%

[1] Note that financial statement items are denominated in $CAD in contrast to our target price which is in $USD.
[2] Giugliani R, Villarreal ML, Valdez CA, et al. Guidelines for diagnosis and treatment of Hunter Syndrome for clinicians in Latin America. Genet Mol Biol. 2014;37(2):315-329. doi:10.1590/s1415-47572014000300003
[3] Recombinant human idursulfase (rhIDS)
[4] There are many aspects of the disease such as neurotoxic and inflammatory disease mechanisms, secondary neurological conditions such as cervical stenosis, carpal tunnel compression, hydrocephalus.

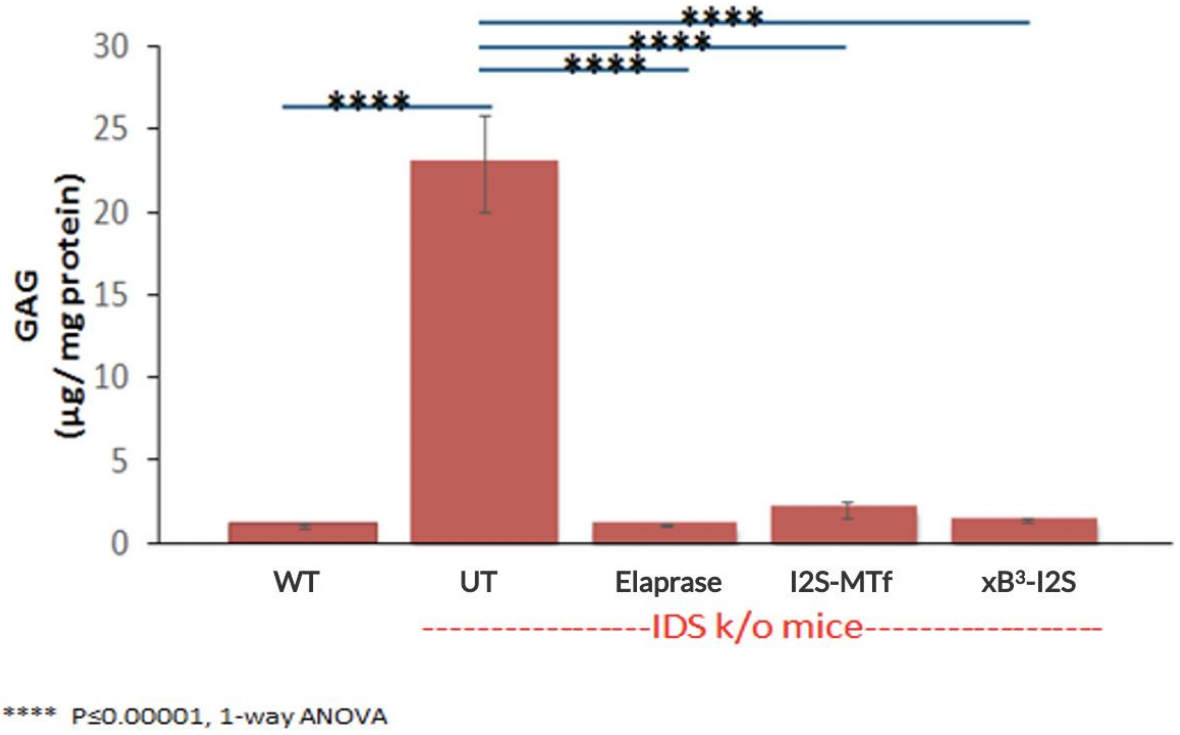
The favorable results from Denali's I2S study also illuminate the potential of Bioasis' technology. xB^3 has shown the ability to transfer a high proportion of idursulfase past the BBB. Bioasis has performed preclinical studies in Hunter syndrome, demonstrating favorable uptake of idursulfase in mouse brains. The *in vivo* studies employ the xB^3-linked idursulfase compared to the native IDS enzyme and measured an over 20-fold superior delivery of the enzyme using the platform.

Exhibit I – Enzyme Uptake in Brain Parenchyma[5]



High levels of GAGs in the urine and liver is an indication that there is a deficiency of the IDS enzyme. Bioasis measured both liver and urine levels of GAG, finding that reduction of the unwanted complex sugar was reduced to similar levels between the xB^3-I2S fusion protein and Elaprase treated mice. Suggesting, unlike Denali, that xB^3-I2S is effective in the periphery while providing significant brain uptake. In another experiment, xB^3-I2S treatment of IDS knockout mice reduced liver GAG levels to those found in wild type mice.

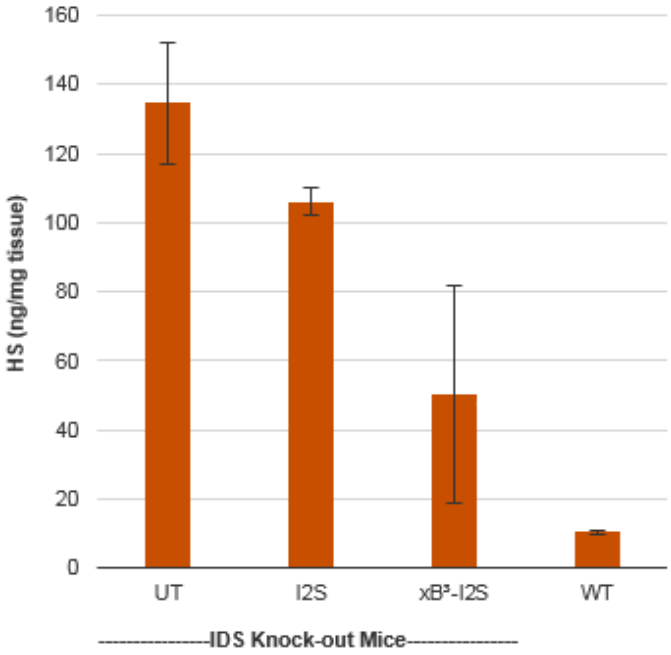
Exhibit II – Reduced Liver GAG in xB^3-I2S Conjugate vs. Elaprase[6]



[5] Source: Bioasis corporate presentation for Hunter Syndrome, Fall 2020
[6] Source: Bioasis corporate presentation for Hunter Syndrome, Fall 2020

While not directly comparable to Denali's CSF measurement of GAG level decline, Bioasis examined the reduction in brain heparan sulfate levels in a mouse model of MPS-II/Hunter's Syndrome. Untreated IDS knock-out mice presented heparan sulfate levels of over 130 ng/mg in brain tissue while xB^3-IDS treated mice were able to demonstrate significantly reduced levels, about 50 ng/mg, in excess of a 60% decrement in concentration.

Exhibit III – Reduction in Brain Heparan Sulfate Accumulation[7]



XOMA Transaction

Bioasis entered into an arrangement with royalty aggregator XOMA, LLC, in February 2019 where XOMA paid US$300,000 for the rights to future royalties and milestones related to the Prothena agreement. On November 3rd, Bioasis announced another agreement with XOMA selling rights to future milestone and royalty revenues related to the assets being developed by Chiesi Group which leverage the xB^3 platform. XOMA has paid its agreed upon US$1.2 million upfront payment to Bioasis in return for the rights to a low single digit royalty on net sales of the xB^3 enzymes. The cash from this transaction will be used to advance unpartnered assets in the Bioasis pipeline, including Parkinson's disease, Lewy Body Dementia and frontotemporal lobe dementia.

Expiring Warrants

Bioasis has 3,480,759 warrants that will expire on December 23, 2020, related to the 7.5% debentures issued December 2019. The principal of the debentures was paid down; however, the associated warrants remain active with an exercise price of CAD$0.20. The warrants are now in the money and can be exercised. If successfully exercised, they can raise almost CAD$700,000 which would provide additional capital to support development projects.

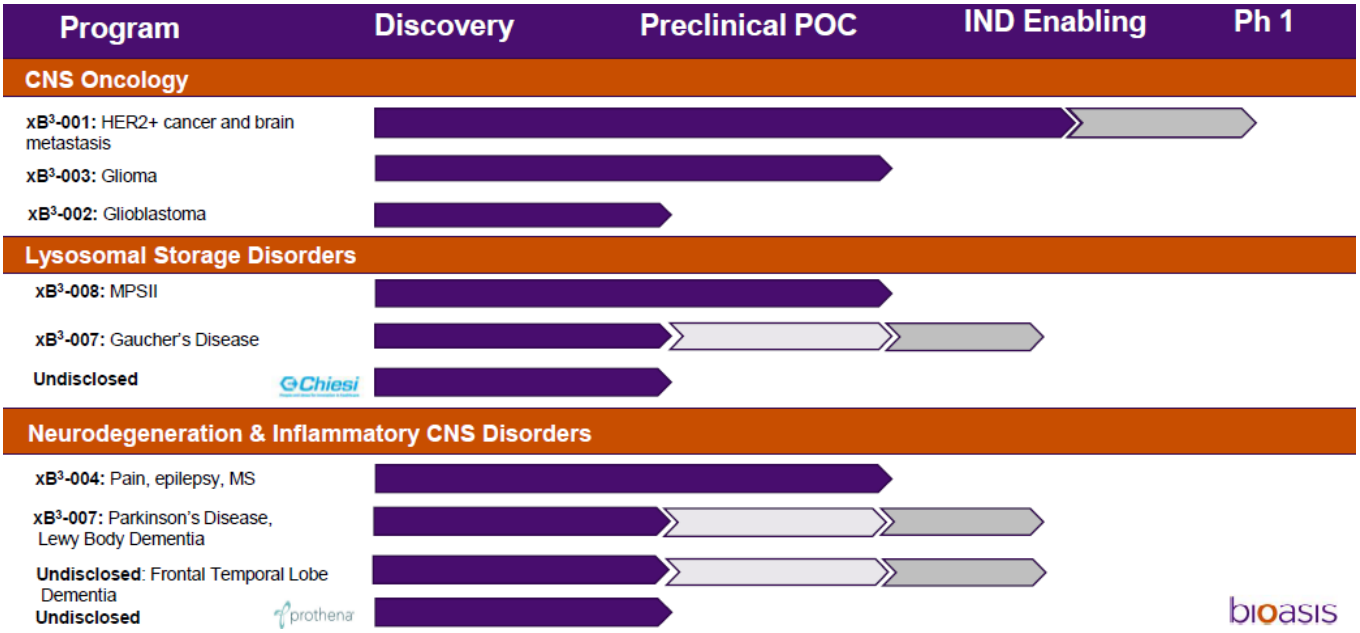
Corporate Milestones

Select milestones over the recent past and near term future are included below.

- xB^3 platform technology licensing agreement with Prothena – October 2018
- Agreement with leading pharmaceutical company for xB^3 preclinical research – January 2019
- Appointment of Christine Antalik as CFO – January 2019
- Appointment of Dr. Deborah Rathjen as President and CEO – March 2019
- Rare diseases strategic alliance with Chiesi Group – June 2020
- Royalty purchase agreement with XOMA for Chiesi assets – November 2020

[7] Source: Bioasis corporate presentation for Hunter Syndrome, Fall 2020

Exhibit IV – Bioasis' Pipeline[8]



Summary

Bioasis has developed an important carrier platform able to ferry several types of molecules across the blood brain barrier where they can treat diseases of the brain. The xB^3 platform consists of a twelve amino acid peptide based on the iron-binding human protein melanotransferrin. It binds to the LRP1 receptor, which enables transcytosis of the peptide and linked therapy carrying them across the BBB and into the brain parenchyma. xB^3 can bind to antibodies, enzymes, siRNA and small molecules and may serve an important unmet need to deliver in-development and existing medicines into the brain which otherwise could not cross.

Substantial preclinical research has been conducted demonstrating xB^3's superiority to transferrin and other competing platforms in both the quantity of dose and types of drugs that can be transported into the brain. Additional *in vivo* work has shown xB^3's ability to shuttle Herceptin into the brains of mice with HER2+ breast cancer brain metastases and significantly reduce both the tumor number and size in the organ. Similar work has been conducted transporting enzymes across the BBB, also in mice, as indicated above in an MPS-II disease model.

Bioasis offers several candidates being developed in house and by partners. The two leading internal compounds are xB^3-001 and xB^3-007. xB^3-001 is a fusion protein containing Herceptin and is indicated for HER2+ cancer and HER2+ brain metastases while xB^3-007 is combined with Cerezyme and intended to treat neuropathic forms of Gaucher Disease, as well as GBA-associated Parkinson's Disease and Lewy Body Dementia. These two candidates are expected to enter the clinic in fiscal year 2022. Bioasis' partnerships are with the rare diseases division of Chiesi Group, Prothena Corporation and an unidentified leading pharmaceutical company. These partnerships are focused on lysosomal storage disorders and neurodegenerative diseases.

[8] Source: July 2020 Corporate Slide Deck

Key reasons to own Bioasis shares:

- **Best in class xB^3 blood brain barrier penetrating technology**
  - **Non-transferrin based transcytotic pathway**
- **Addresses a major hurdle to CNS therapy**
- **High selectivity for BBB and CNS parenchyma**
- **Preserves payload function and pharmacodynamics**
- **Can deliver antibodies, enzymes, siRNA and small molecules**
- **Lead indications in HER2+ metastatic breast cancer and Gaucher Disease**
- **Broad licensing and funding opportunities with partners**
  - **Chiesi Group**
  - **Prothena Corporation**
  - **Leading pharma company**
- **Diversified preclinical portfolio able to address multiple CNS disorders**
- **120+ patents and pending applications across 10+ patent families**

Bioasis has a broad portfolio and a technology platform that can be developed both internally and externally for many therapies demonstrating brain activity. The blood brain barrier is effective at keeping out both the bad and the good; however, when there is disease in the brain, the xB^3 peptide can help shuttle needed medicines into this protected space. We anticipate parallel development of several xB^3 compounds that will enter the clinic over the next several years. Our valuation work assumes median drug revenue for each of the programs underway and applies a discount related to the anticipated 8% weighted probability of success. We maintain our valuation of $0.60 per share. Please refer to our initiation here for detail on the company and our thesis.

PROJECTED FINANCIALS

Bioasis Technologies Inc. - Income Statement

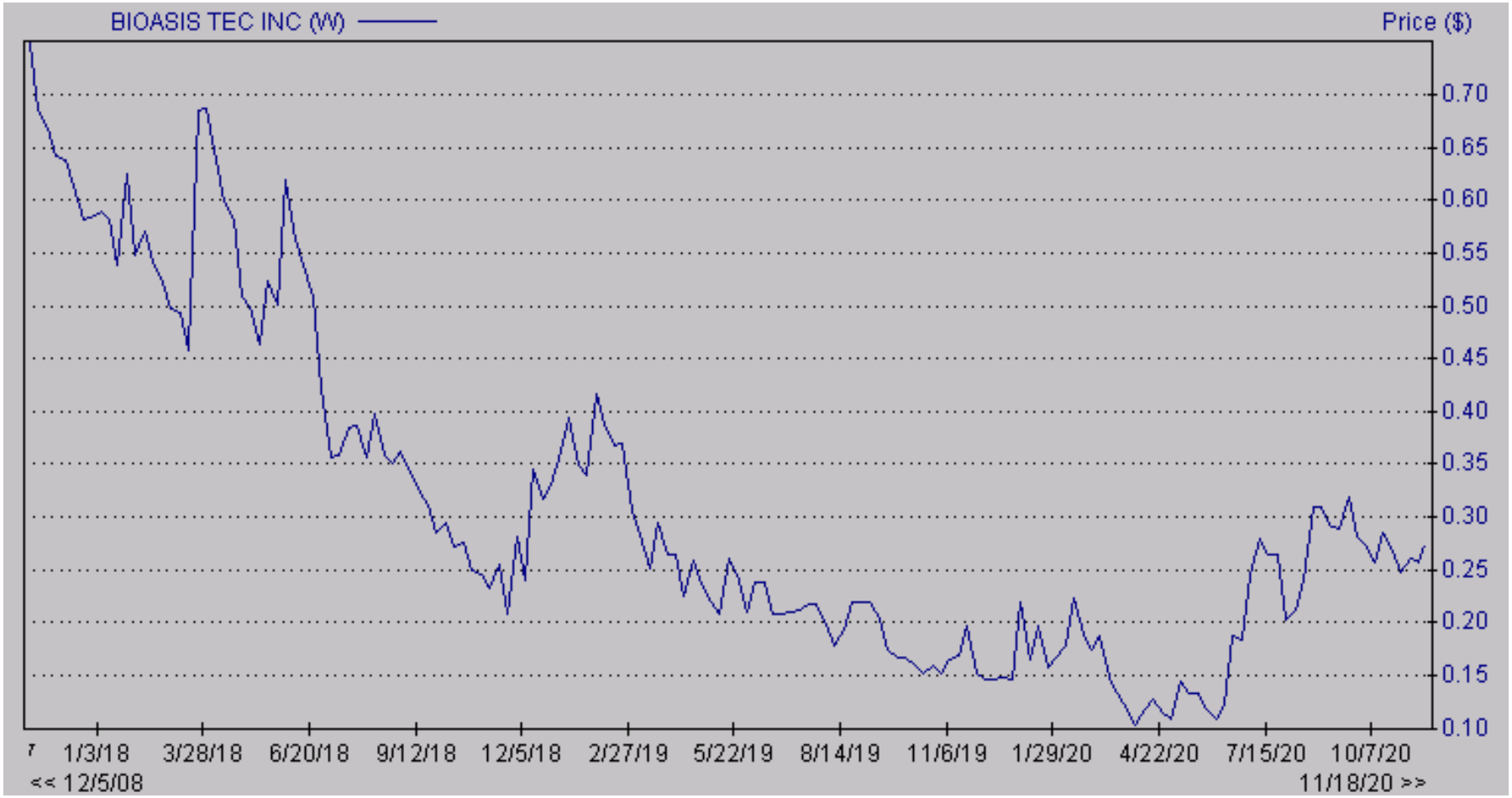
Bioasis Technologies Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($CAD)	**$606**	**$0**	**$4,078**	**$275**	**$300**	**$4,653**	**$1,600**	**$1,750**
General & Administrative	$3,174	$579	$904	$490	$502	$2,474	$2,117	$2,420
Research & Development	$2,034	$445	$115	$510	$556	$1,626	$2,490	$2,568
Income from operations	($4,602)	($1,024)	$3,060	($725)	($758)	$553	($3,007)	($3,238)
Other Income	$592	($7)	($1,103)	$0	$0	($1,110)	$0	$0
Interest Income	($47)	($25)	($10)	$0	$0	($34)	$0	$0
Pre-Tax Income	($4,056)	($1,055)	$1,947	($725)	($758)	($591)	($3,007)	($3,238)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($4,056)**	**($1,055)**	**$1,947**	**($725)**	**($758)**	**($591)**	**($3,007)**	**($3,238)**
Net Margin	*-669%*							
Reported EPS	**($0.07)**	**($0.02)**	**$0.03**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.04)**
YOY Growth								
Basic Shares Outstanding	62,271	64,824	64,937	68,200	68,320	66,570	69,025	88,125

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

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HISTORICAL STOCK PRICE

Bioasis Technologies Inc. – Share Price Chart



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