EDISON

Bioasis Technologies

Business update

Platform licensed to Chiesi

Pharma & biotech

Bioasis announced on 29 June 2020 that it had entered into an agreement with Chiesi, in which it would license its technology to bypass the blood brain barrier (BBB), the xB^3 platform, for the development of drugs targeting lysosomal storage disorders. Chiesi will use the platform to develop drugs for four disorders, and in return Bioasis will receive US$3m upfront, up to US$138m in additional milestones and undisclosed royalties. We see this as a major validation of the platform and for additional future licensing potential.

Year end	Revenue (C$m)	PBT* (C$m)	EPS* (C$)	DPS (C$)	P/E (x)	Yield (%)
02/19	1.4	(2.4)	(0.04)	0.00	N/A	N/A
02/20	0.6	(3.4)	(0.06)	0.00	N/A	N/A
02/21e	4.6	(6.5)	(0.09)	0.00	N/A	N/A
02/22e	4.6	(8.7)	(0.12)	0.00	N/A	N/A

Note: *PBT and EPS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments.

Platform well suited for lysosomal storage disorders

Neither company has released the details of which lysosomal storage disorders will be targeted as part of the agreement. However, these diseases are very well suited for use with the xB^3 platform. Lysosomal storage disorders are characterized by an accumulation of various substances in the body that cannot be broken down due to the genetic lack of the appropriate enzymes. A common treatment paradigm is enzyme replacement where these proteins are exogenously provided, but they are unable to pass the BBB and therefore unable to address neurologic symptoms of these diseases.

xB^3 provides a plug-and-play solution

The xB^3 platform may offer an attractive solution to the issue of improving central nervous system (CNS) drug activity because it is entirely modular. Enzyme replacement therapies have already been developed for a range of lysosomal storage disorders, and the development of a brain penetrant derivative of these drugs could be as simple as producing a conjugate to the xB^3 peptide developed by the company. There is little risk that this will interfere with the normal activity of the enzyme, allowing the programs to quickly bypass early drug development and progress to animal studies, which will verify the potential to penetrate the BBB.

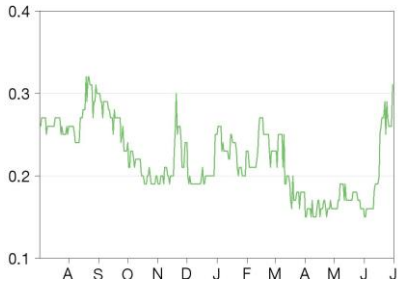
Valuation: Increased to C$60.1m or C$0.89/share

We increased our valuation to C$60.1m or C$0.89 per basic share, from C$47.8m or C$0.71 per basic share, driven by the addition of the Chiesi partnership to our model. We provide a provisional valuation of the agreement of C$11.6m: C$4.1m from the upfront payment and the remainder from a placeholder model that assumes peak revenue potential of US$400m, 8–12% royalty rates and a 2.5% probability of success. We reduced our expected financing requirement to C$110m (from C$130m previously) after inclusion of future Chiesi milestone revenue in our model, and we expect the company will need additional financing in FY21.

2 July 2020

Price	**C$0.31**
Market cap	**C$21m**
	C$1.36/US$
Net cash (C$m) at February 2020 - debenture conv. + Chiesi upfront	4.0
Shares in issue	67.9m
Free float	99%
Code	BTI
Primary exchange	TSX Venture
Secondary exchange	OTCQB

Share price performance



%	1m	3m	12m
Abs	106.7	100	19.2
Rel (local)	103.0	66	25.9
52-week high/low	C$0.32	C$0.15	

Business description

Bioasis Technologies is a biopharma company developing the xB^3 platform to aid in the delivery of molecules to the brain using receptor mediated transcytosis. The company's lead program is xB^3-001, which is in preclinical development for brain metastases in HER2+ metastatic breast cancer patients. The company has additional preclinical programs in pain, neurodegenerative diseases, and rare diseases.

Next events

xB^3-001 IND	2021

Analyst

Nathaniel Calloway +1 646 653 7036

healthcare@edisongroup.com

Edison profile page

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An attractive partnership

The development agreement with Chiesi is an attractive deal for all parties involved. Bioasis will receive US$3m upfront and US$138m in development, regulatory and commercial milestones, we assume spread between the four indications to be targeted as part of the collaboration. Chiesi will assume all development responsibility, and there are no major future commitments on the part of Bioasis. We expect these types of deals to become an increasingly important aspect of Bioasis's business strategy, because it will allow Bioasis to capitalize on the broad potential of the platform outside of what the firm can reasonably achieve alone. The xB^3 peptide is designed to solve a major current limitation of CNS drug development, which could have wide reaching implications outside of the company's internal pipeline (and indeed outside of lysosomal storage disorders as well). And the technology's modular nature allows it to be coupled with existing, well understood and vetted drugs. Collaboration deals with established pharmaceutical companies like Chiesi could provide access to drugs that have already undergone significant investment. This would substantially simplify the development process, by allowing the companies to skip the lead generation phase and there can be increased confidence in its clinical relevance if activity has already been demonstrated in humans. Moreover, if the XB^3 technology is coupled with previously approved drugs, we expect this to at least partially simplify the regulatory process (albeit we expect the xB^3 conjugates to be classified as new chemical entities).

Chiesi is a very good partner for these programs. Chiesi has successfully navigated the clinical and regulatory process multiple times and has approved drugs across a range of indications, including in rare disease. It also recently established the US business unit Chiesi Global Rare Diseases in February 2020 to advance the company's rare disease pipeline. The company has European approval for Lamzede (velmanase alfa), an enzyme replacement therapy for the lysosomal storage disorder alpha-mannosidosis (AM), and it is the only approved drug for this indication. AM is characterized by immunodeficiency, skeletal abnormalities, mental retardation and motor defects. This drug is an obvious candidate for pairing with xB^3, given the potential to address the disease's symptoms of CNS origin. Additionally, Chiesi's lead development program is pegunigalsidase alfa, an enzyme replacement therapy for the treatment of Fabry disease, a lysosomal storage disorder. The drug was developed in a partnership with Protalix BioTherapeutics, and a BLA was submitted for approval in May 2020. This drug could also be a candidate for initial testing in combination with xB^3, because Fabry disease has some CNS effects (although they are generally considered mild). We should note that pairing these programs with xB^3 is speculative, and Chiesi may have other plans, but it has already demonstrated considerable interest and committed substantial resources to developing and expanding its rare disease franchise, and xB^3 may become a part of executing on that strategy.

The development of brain penetrating enzyme replacement therapies for lysosomal storage disorders is an obvious application of transcytosis technology like xB^3, and there are other companies currently investigating the same strategy. The most prominent company is Denali Therapeutics, which is developing a transferrin-based approach to delivering enzymes to the brain. This company is investigating the technology for a range of lysosomal storage disorders and is preparing to enter the clinic with its treatment for Hunter syndrome (mucopolysaccharidosis type II, MPS II) in 2020. JCR Pharmaceuticals in Japan has a treatment for Hunter syndrome that has completed pivotal Phase III clinical studies in that country, and it is planning on submitting a marketing application in September 2020.

Valuation

We have increased our valuation to C$60.1m or C$0.89 per basic share, from C$47.8m or C$0.71 per basic share, driven by the addition of the Chiesi partnership in our model. This included the US$3m upfront payment (included in cash) and a provisional model to account for future revenue streams from the agreement. Aside from the size of the potential milestones associated with the agreement, we have little information on its terms or the target indications. We therefore model US$400m peak sales from the agreement as a placeholder. Other assumptions include royalties in the rage of 8–12% and 12 years' exclusivity (assuming at a minimum any products from the collaboration will receive biologic exclusivity of 12 years in the US). Given our lack of knowledge surrounding the programs and the general high risk of early stage development products, we assign a probability of success of 2.5%, consistent with Bioasis's other undisclosed development program partnered with Prothena. The majority of the value associated with Chiesi agreement is from early stage milestones, which we model as US$5m for successful Phase I results, US$10m for Phase II, and US$20m for Phase III. We expect to update our assumptions following the release of more details regarding these programs. In addition to this adjustment, we have rolled forward our NPVs.

Exhibit 1: Valuation of Bioasis

Development Program	Indication	Clinical stage	Geography	Prob. of success	Launch year	Launch pricing ($/month)	Peak sales (US$m)	Patent/ exclusivity protection	Royalty/ margin	rNPV (C$m)
xB^3-001	Treatment of mBC BMs	IND	US	10%	2027	11,500	125	2039	52%	16.44
			Europe	10%	2027	7,500	115	2039	52%	15.26
			R&D	10%						(11.05)
	1st line, prevention of mBC BMs	Planned	US	5%	2032	12,700	397	2039	57%	13.24
			Europe	5%	2032	8,200	437	2039	57%	14.88
			R&D	5%	2032					(3.52)
Prothena milestones	Undisclosed	Discovery		2.5%	2028					3.39
Chiesi partnership	Four lysosomal storage disorders	Discovery		2.5%	2029		*400	2041	*8–12%	7.43
Total										56.1
Net cash and equivalents (FY20 – debenture conversions + Chiesi upfront pro-forma) (C$m)										4.0
Total firm value (C$m)										60.1
Total basic shares (m)										67.9
Value per basic share (C$)										0.89
Dilutive warrants and options (m)										26.6
Total diluted shares (m)										94.5
Value per diluted share (C$)										0.75

Source: Bioasis reports, Edison Investment Research. Note: *Peak sales are a placeholder, royalty rates estimated. mBC BMs = metastatic breast cancer brain metastases.

Financials

The company reported a net loss of C$4.1m for FY20 ending in February 2020. We expect this loss to increase in FY21 (C$7.1m) as the company prepares to enter clinical trials in FY22. We also include provisional milestone payments from Prothena in FY21 and FY22 of US$3m (before 10% payable to Xoma), and our expected loss for FY21 may increase if this program does not advance in that timeframe. Additionally, we have added the US$3m Chiesi upfront payment to our model in FY21 and amortize the revenue over five years. The company ended FY20 with C$576,000 in cash and had a C$1.4m (carrying value C$1.0m) in debt associated with convertible debenture bridge loans. In April 2020, C$751,000 of these loans were subsequently converted, and we expect the recent licensing deal with Chiesi to trigger a repayment covenant on the remaining C$696,000 in principal.

The company faces a significant future financing requirement to develop its internal programs, which we expect it to address at least in part through continued licensing and business

development similar to the recent Chiesi deal. If the company were to develop xB^3-001 without any financial support (ie no milestone payments from its partnership agreements), we would expect this to require as much as C$160m in additional capital to reach commercialization. However, we expect the company to continue to seek similar agreements to offset these costs, including potentially out-licensing xB^3-001. As our model now includes the Chiesi milestones stated above (as well as the Prothena milestones already assumed in our model as discussed in our Outlook report), this reduces the financing requirement for the company to C$110m (from C$130m previously), which we include as illustrative debt. This is modelled as C$20m in FY21, C$50m in FY23 and C$40m in FY26 (down from C$60m previously).

At current cash levels, we expect the company to need additional financing in FY21, and although we expect the company to attempt to offset these needs through licensing activity, it may need to seek additional cash on the capital markets to bring its internal pipeline to the clinic if these deals do not materialize quickly.

Exhibit 2: Financial summary

C$m	2019	2020	2021e	2022e
Year end 28 February	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Revenue	1,422.0	606.4	4,554.0	4,554.0
Cost of Sales	(10.4)	0.0	0.0	0.0
Gross Profit	1,411.6	606.4	4,554.0	4,554.0
R&D	(1,954.3)	(2,033.6)	(6,581.5)	(8,492.3)
SG&A	(4,314.5)	(3,174.4)	(5,095.4)	(5,350.2)
EBITDA	(3,805.0)	(3,965.4)	(6,494.4)	(8,660.7)
Normalised operating profit	(3,815.8)	(3,977.4)	(6,498.6)	(8,664.1)
Amortization of acquired intangibles	(61.1)	(58.8)	(58.8)	(58.8)
Exceptionals	0.0	0.0	0.0	0.0
Share-based payments	(980.2)	(565.6)	(565.6)	(565.6)
Reported operating profit	(4,857.2)	(4,601.7)	(7,122.9)	(9,288.5)
Net Interest	1.8	(46.9)	0.0	0.0
Other income	986.9	592.2	0.0	0.0
Exceptionals	395.1	0.0	0.0	0.0
Profit Before Tax (norm)	(2,432.1)	(3,432.1)	(6,498.6)	(8,664.1)
Profit Before Tax (reported)	(3,473.4)	(4,056.4)	(7,122.9)	(9,288.5)
Reported tax	0.0	0.0	0.0	0.0
Profit After Tax (norm)	(2,432.1)	(3,432.1)	(6,498.6)	(8,664.1)
Profit After Tax (reported)	(3,473.4)	(4,056.4)	(7,122.9)	(9,288.5)
Minority interests	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0
Net income (normalised)	(2,432.1)	(3,427.1)	(6,492.6)	(8,657.1)
Net income (reported)	(3,473.4)	(4,056.4)	(7,122.9)	(9,288.5)
Basic average number of shares outstanding (m)	56,675	62,271	69,886	73,380
EPS - basic normalised ($)	(0.04)	(0.06)	(0.09)	(0.12)
EPS - diluted normalised ($)	(0.04)	(0.06)	(0.09)	(0.12)
EPS - basic reported ($)	(0.06)	(0.07)	(0.10)	(0.13)
Dividend ($)	0.00	0.00	0.00	0.00
Revenue growth (%)	141.1	0.0	0.0	0.0
Gross Margin (%)	99.3	100.0	100.0	100.0
BALANCE SHEET				
Fixed Assets	360.9	290.2	227.1	165.0
Intangible Assets	327.8	269.0	210.2	151.4
Tangible Assets	33.1	21.1	16.9	13.5
Investments & other	0.0	0.0	0.0	0.0
Current Assets	1,382.3	651.6	19,010.2	10,339.0
Stocks	0.0	0.0	0.0	0.0
Debtors	9.7	13.4	0.0	0.0
Cash & cash equivalents	1,360.0	576.4	18,948.3	10,277.1
Other	12.6	61.9	61.9	61.9
Current Liabilities	(1,262.9)	(2,476.7)	(7,481.2)	(7,470.7)
Creditors	(998.5)	(1,991.1)	(4,169.2)	(4,986.7)
Tax and social security	0.0	0.0	0.0	0.0
Short term borrowings	0.0	(485.6)	0.0	0.0
Other	(264.4)	0.0	(3,312.0)	(2,484.0)
Long Term Liabilities	(1,027.0)	(951.3)	(19,947.8)	(19,947.8)
Long term borrowings	0.0	(517.9)	(19,514.4)	(19,514.4)
Other long term liabilities	(1,027.0)	(433.4)	(433.4)	(433.4)
Net Assets	(546.7)	(2,486.3)	(8,191.6)	(16,914.5)
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	(546.7)	(2,486.3)	(8,191.6)	(16,914.5)
CASH FLOW				
Op Cash Flow before WC and tax	(3,805.0)	(3,965.4)	(6,494.4)	(8,660.7)
Working capital	568.4	691.5	5,503.5	(10.5)
Exceptional & other	6.9	(24.8)	0.0	0.0
Tax	0.0	0.0	0.0	0.0
Net operating cash flow	(3,229.7)	(3,298.7)	(990.9)	(8,671.2)
Capex	(2.1)	0.0	0.0	0.0
Acquisitions/disposals	395.1	0.0	0.0	0.0
Net interest	0.0	0.0	0.0	0.0
Equity financing	3,526.7	1,205.0	852.0	0.0
Dividends	0.0	0.0	0.0	0.0
Other	0.0	0.0	(485.6)	0.0
Net Cash Flow	690.0	(2,093.6)	(624.5)	(8,671.2)
Opening net debt/(cash)	(678.0)	(1,360.0)	427.4	565.9
FX	(7.9)	22.2	0.0	0.0
Other non-cash movements	0.0	284.0	486.0	0.0
Closing net debt/(cash)	(1,360.0)	427.4	565.9	9,237.1

Source: Bioasis reports, Edison Investment Research.

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