

CASI Pharmaceuticals

Evomela sales going strong into 2021

Financial update

Pharma & biotech

19 February 2021

Price **US\$2.8**

Market cap **US\$346m**

Net cash (\$m) at 31 December 2020 57.1

Shares in issue 123.9m

Free float 61.5%

Code CASI

Primary exchange Nasdaq

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (17.7) 41.3 26.8

Rel (local) (20.8) 28.8 9.2

52-week high/low US\$3.6 US\$1.4

Business description

CASI Pharmaceuticals is building a portfolio of drugs it intends to market for Chinese and worldwide markets, including Evomela launched in China, anti-CD19 CAR-T therapy CNCT19 and anti-CD38 drug CID-103, among others. The goal is to seek approval through new pathways that have opened in the quickly changing Chinese regulatory environment.

Next events

B-ALL Phase II initiation Q121

Phase I CAR-T studies complete Q121

CID-103 trial start Q121

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CASI has announced as part of its preliminary results that it sold \$4.8m worth of Evomela in Q420 and approximately \$15m for the year (unaudited), exceeding the company guidance of \$14m and our estimate of \$14.4m. The company stated that it is targeting 50% growth in Evomela sales in 2021. Additionally, in 2021 the company will be jump starting its clinical development engine as it is expected to initiate clinical studies on a majority of its portfolio during the year.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/18	0.0	(20.0)	(0.24)	0.00	N/A	N/A
12/19	4.1	(36.5)	(0.39)	0.00	N/A	N/A
12/20e	15.2	(29.7)	(0.27)	0.00	N/A	N/A
12/21e	25.8	(23.4)	(0.18)	0.00	N/A	N/A

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

Evomela exceeds expectations again

Evomela revenues are continuing to grow at a breakneck pace, 269% year-on-year in FY20. A large part of this is because it is the first melphalan product approved in the country so it is immediately filling a known gap in the treatment of multiple myeloma patients. Further, CASI will be able to realize a bigger portion of the revenue going forward after securing a lower cost source of the product in Q320.

Numerous studies starting in 2021

CASI has significantly increased the size of its portfolio in recent years, with the in-licensing of a range of early-stage products. It plans on initiating a Phase I study of CID-103, its CD38 targeted treatment for multiple myeloma, and its partner Juventas will be initiating the pivotal Phase II study for CNCT19 for acute lymphoblastic leukemia (ALL) (the pivotal study for non-Hodgkin lymphoma, NHL, initiated in 2020). Additionally, registrational studies for octreotide and thiotepa are on deck.

BI-1206 interim results

CASI's partner BioInvent presented interim results from its Phase I study of BI-1206 for the treatment of relapses and refractory indolent NHL. Six of nine patients on the study had a response, two of which were complete responses (CRs), which were maintained for over a year. Also, very importantly, a protocol adjustment regarding a new steroid regimen seems to have reduced the incidence of dose-limiting toxicities. A total of 15 patients are currently enrolled and BioInvent is planning an end of Phase I meeting with the FDA in Q321.

Valuation: Increased to \$431m or \$3.47 per share

We have increased our valuation to \$431m or \$3.47 per share, from \$425m or \$3.43 per share. This increase is driven by rolling forward our NPVs. We have also slightly increased the peak penetration of Evomela (35% from 30%) to reflect the strong launch to date. These factors are offset by removing Marqibo from our models and lower net cash (\$57.1m at the end of 2020, from \$64.4m).

Financial past, present and future

We are very encouraged by the company's preliminary report of revenues for 2020. We previously forecasted sequential sales being down slightly going into Q4 (\$4.1m) from Q3 (\$4.2m) due to seasonality effects and other factors, but the reported revenue of \$4.8m exceeded our expectations. The company is targeting 50% growth in 2021, which we believe is very achievable following the recent pace of growth. We have slightly increased our 2021 revenue projections to \$25.8m from \$25.3m based on the current growth curve for the product, which exceeds the company's 50% growth target. We expect an increased marketing effort with the product (2021 SG&A estimate: \$31.4m) as the company expands its reach within China. At this point in time, we expect most of the hematologists at major treatment centers such as the Institute of Hematology in Tianjin to have integrated the product into their treatment algorithms.

However, the biggest shift we expect on the company P&L will be an increased focus on R&D in 2021. The company has been on a blitz in-licensing new assets over the past two years, and in 2021 most of them will be entering the clinic. In 2020, the company's partner Juventas initiated Phase I clinical trials for the CAR-T therapy CNCT19, and that program has since initiated the first of two pivotal Phase II studies (the first for NHL). The second pivotal study is slated to start in Q121. Additionally, CID-103 is expected to enter the clinic in Q121. The company also expects to initiate registrational studies for octreotide and thiotepa during the year. These products have been previously approved overseas and therefore can go directly into registrational studies. We forecast R&D spending of \$21.0m in 2021 compared to an estimated \$10.9m in 2020 (before accounting for the \$10.8m acquired R&D cost).

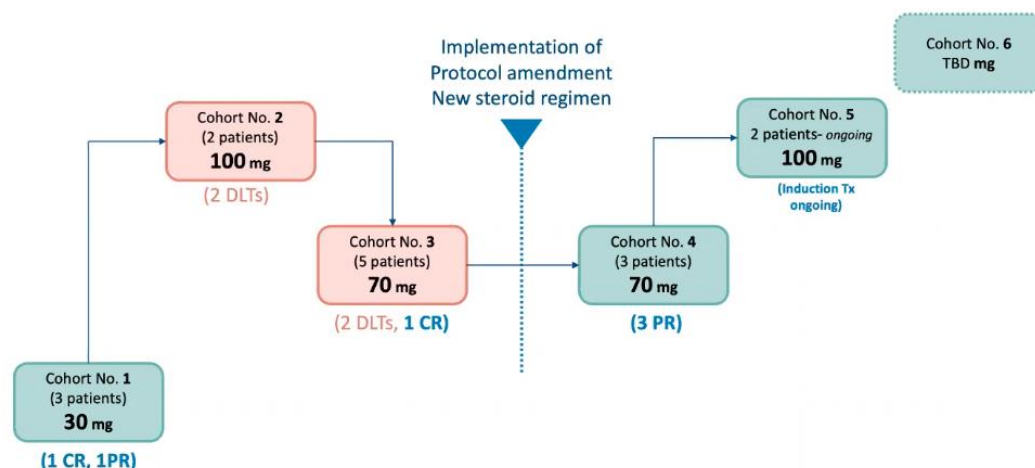
The company reported \$57.1m (unaudited) in cash at the end of 2020. Based on this value we have delayed our forecasts for the expected deployment of the \$10.9m earmarked for Phase I of the company's buildout of the Wuxi facility into 2021. We continue to record \$55m in future financing needs in our models as illustrative debt in 2022. This value is to cover the costs of the company's current programs until profitability (estimated in 2024). However, this is subject to any future in-licensing of new assets, which the company is actively engaged in.

A first look at BI-1206

CASI in licensed the Chinese rights to the novel anti-cancer agent BI-1206 from BioInvent in October 2020. The drug has a novel mechanism of action by targeting FcγRIIB, an antibody receptor on leukocytes with checkpoint-like properties. The product is being developed for hematologic and solid tumors and BioInvent recently reported interim results from its ongoing Phase I dosing study in patients in indolent NHL used in combination with rituximab.

The most important readout from this interim result, by our estimation, is that a recent protocol amendment regarding the administered steroid regimen seems to be addressing some of the safety and tolerability issues seen earlier in the trial (although the specifics of the protocol amendment have not been disclosed). A total of four dose-limiting toxicities (two thrombocytopenias and two AST/ALT elevations) across two dosing cohorts (total of seven patients within these 70mg and 100mg cohorts) were seen before the protocol was changed, and none have been seen in the five patients treated since (Exhibit 1). One takeaway from this is that if these toxicities can be mitigated with steroids, they are likely immunological in nature and associated with the activity of the drug, and this suggests that the drug has some on-target activity.

Exhibit 1: BI-1206 Phase I progress



Source: BioInvent

BioInvent reported that six of nine patients who were evaluable and completed induction had responses to therapy, two of which were CRs. At this stage it is difficult to separate the activity of BI-1206 from the activity of rituximab in these patients. Although they are relapsed, rituximab-based treatments can be used after multiple relapses and retain efficacy, although efficacy diminishes on average. One study reported a response rate for rituximab in the second line after relapse on rituximab of 76% in follicular lymphoma and 65% in mantle cell lymphoma.¹ Of the patients in the BI-1206 study, 12 have follicular lymphoma and three have mantle cell lymphoma, and these patients were more heavily pretreated (on average 3.7 prior lines of therapy), but right now there are too few patients to draw many conclusions regarding efficacy.

Valuation

We have increased our valuation to \$431m or \$3.47 per basic share, from \$425m or \$3.43 per basic share. This increase is driven primarily by rolling forward our NPVs. Additionally, we have increased our expected peak penetration for Evomela from 30% to 35% because it has consistently outperformed our estimates. These changes are offset by lower net cash (\$57.1m from \$64.4m) and because we have removed Marqibo from our models. This product is deprioritized and the company is not expecting to enter the clinic with it in 2021. Other aspects of our valuation may be changed when the company reports its complete 2020 results in March.

¹ Johnston A, et al. (2010) Retreatment with rituximab in 178 patients with relapsed and refractory B-cell lymphomas: a single institution case control study. *Leuk Lymphoma* 51, 399-405.

Exhibit 2: Valuation of CASI

Portfolio	Asset	Region	Peak sales (\$m)	Margins	Clinical risk adjustment	Value (\$m)
Hematology	Evomela	China	39.1	50%	100%	92.11
	Zevalin	China	25.5	64%	90%	44.75
	Thiotepa	China	8.8	39%	90%	4.75
	CID-103	China & US & Europe	766.6	59%	5%	14.92
	CNCT19	China	306.2	up to 50% profit share	10%	26.82
	BI-1206	China	249.9	59%	10%	17.76
Other products	ANDA portfolio	China & US	142.0	47%	100%	180.88
	Octreotide LAI	China	15.7	41%	80%	12.75
Total						394.74
Net cash and equivalents (Q420) (\$m)						57.10
Noncontrolling interest (\$m)						(21.27)
Total firm value (\$m)						430.57
Total shares (m)						123.94
Value per basic share (\$)						3.47
Dilutive warrants and options (m)						15.91
Value per diluted share (\$)						3.39

Source: CASI reports, Edison Investment Research

Exhibit 3: Financial summary

	\$'k	2018	2019	2020e	2021e	2022e
Year end 31 December		US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
INCOME STATEMENT						
Revenue		0.0	4,131.0	15,153.7	25,772.6	28,802.2
Cost of Sales		0.0	(3,935.0)	(9,642.7)	(6,408.5)	(7,165.9)
Gross Profit		0.0	196.0	5,511.0	19,364.1	21,636.3
EBITDA		(19,402.4)	(37,495.0)	(32,358.4)	(23,380.8)	(23,185.9)
Normalised operating profit		(19,767.9)	(38,098.0)	(32,860.4)	(23,437.5)	(23,992.5)
Amortisation of acquired intangibles		(1,305.4)	(1,550.0)	(1,511.9)	(1,511.9)	(1,511.9)
Exceptionals		0.0	0.0	(1,087.0)	0.0	0.0
Share-based payments		(6,118.1)	(7,310.0)	(7,478.0)	(7,478.0)	(7,478.0)
Reported operating profit		(27,191.4)	(46,958.0)	(42,937.3)	(32,427.4)	(32,982.5)
Net Interest		(280.1)	1,062.0	854.0	0.0	0.0
Joint ventures & associates (post tax)		0.0	0.0	0.0	0.0	0.0
Exceptionals		0.0	534.0	2,292.0	0.0	0.0
Profit Before Tax (norm)		(20,048.1)	(36,502.0)	(29,714.4)	(23,437.5)	(23,992.5)
Profit Before Tax (reported)		(27,471.6)	(45,362.0)	(39,791.3)	(32,427.4)	(32,982.5)
Reported tax		0.0	0.0	0.0	6,485.5	6,596.5
Profit After Tax (norm)		(20,048.1)	(36,502.0)	(29,714.4)	(23,437.5)	(23,992.5)
Profit After Tax (reported)		(27,471.6)	(45,362.0)	(39,791.3)	(25,941.9)	(26,386.0)
Minority interests		0.0	(670.0)	(403.0)	0.0	0.0
Discontinued operations		0.0	0.0	0.0	0.0	0.0
Net income (normalised)		(20,048.1)	(37,172.0)	(30,117.4)	(23,437.5)	(23,992.5)
Net income (reported)		(27,471.6)	(46,032.0)	(40,194.3)	(25,941.9)	(26,386.0)
Basic average number of shares outstanding (m)		85	96	110	130	137
EPS - basic normalised (c)		(23.65)	(38.74)	(27.28)	(18.00)	(17.55)
EPS - diluted normalised (c)		(23.65)	(38.74)	(27.28)	(18.00)	(17.55)
EPS - basic reported (c)		(32.41)	(47.98)	(36.41)	(19.92)	(19.30)
Dividend (c)		0.00	0.00	0.00	0.00	0.00
BALANCE SHEET						
Fixed Assets		20,845.4	41,130.0	51,903.0	61,641.2	74,669.6
Intangible Assets		18,784.7	16,895.0	18,015.0	16,503.1	14,991.1
Tangible Assets		1,750.6	985.0	850.0	12,100.2	26,640.5
Investments & other		310.0	23,250.0	33,038.0	33,038.0	33,038.0
Current Assets		92,564.6	61,501.0	64,813.5	36,746.3	60,042.9
Stocks		0.0	4,542.0	3,170.2	2,106.9	2,355.9
Debtors		0.0	1,293.0	2,491.0	4,236.6	4,734.6
Cash & cash equivalents		85,117.0	54,246.0	57,060.3	28,381.8	50,931.4
Other		7,447.6	1,420.0	2,092.0	2,021.0	2,021.0
Current Liabilities		(3,873.9)	(7,947.0)	(6,763.1)	(6,898.0)	(7,131.0)
Creditors		(968.0)	(5,113.0)	(3,905.1)	(4,040.0)	(4,273.0)
Tax and social security		0.0	0.0	0.0	0.0	0.0
Short term borrowings		(1,499.5)	0.0	0.0	0.0	0.0
Other		(1,406.4)	(2,834.0)	(2,858.0)	(2,858.0)	(2,858.0)
Long Term Liabilities		(73.6)	(1,019.0)	(4,962.0)	(4,962.0)	(59,962.0)
Long term borrowings		0.0	0.0	0.0	0.0	(55,000.0)
Other long term liabilities		(73.6)	(1,019.0)	(4,962.0)	(4,962.0)	(4,962.0)
Net Assets		109,462.5	93,665.0	104,991.4	86,527.5	67,619.5
Minority interests		0.0	20,670.0	21,271.0	21,271.0	21,271.0
Shareholders' equity		109,462.5	72,995.0	83,720.4	65,256.5	46,348.5
CASH FLOW						
Op Cash Flow before WC and tax		(19,402.4)	(37,495.0)	(32,358.4)	(23,380.8)	(23,185.9)
Working capital		(9,780.4)	4,452.0	(3,098.1)	(547.4)	(514.0)
Exceptional & other		598.9	9,800.0	10,275.0	6,485.5	6,596.5
Tax		0.0	0.0	0.0	0.0	0.0
Net operating cash flow		(28,583.9)	(23,243.0)	(25,181.5)	(17,442.7)	(17,103.4)
Capex		(1,131.1)	(7,053.0)	(367.0)	(11,306.8)	(15,347.0)
Acquisitions/disposals		(20,642.4)	(21,005.0)	(21,978.0)	0.0	0.0
Net interest		0.0	0.0	0.0	0.0	0.0
Equity financing		92,269.8	3,545.0	45,922.0	0.0	0.0
Dividends		912.0	0.0	0.0	0.0	0.0
Other		0.0	20,000.0	2,195.0	71.0	0.0
Net Cash Flow		42,824.4	(27,756.0)	590.5	(28,678.5)	(32,450.4)
Opening net debt/(cash)		(41,991.7)	(83,617.5)	(54,245.5)	(57,060.0)	(28,381.5)
FX		(1,197.5)	(1,328.0)	587.0	0.0	0.0
Other non-cash movements		(1.0)	(288.0)	1,637.0	0.0	0.0
Closing net debt/(cash)		(83,617.5)	(54,245.5)	(57,060.0)	(28,381.5)	4,068.9

Source: CASI reports, Edison Investment Research

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