

CASI Pharmaceuticals

Continuing to execute

Earnings update

Pharma & biotech

CASI continues to execute on multiple fronts and demonstrates that it has become a multifaceted company. It is expanding the sales of Evomela, its proprietary formulation of melphalan for multiple myeloma in China. Simultaneously, it is adding to its pipeline with new licensing deals and is executing on its development strategy, with four drug candidates currently in the clinic.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/19	4.1	(36.5)	(0.39)	0.00	N/A	N/A
12/20	15.1	(37.9)	(0.35)	0.00	N/A	N/A
12/21e	25.8	(23.2)	(0.17)	0.00	N/A	N/A
12/22e	28.8	(23.8)	(0.17)	0.00	N/A	N/A

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

Evomela growth strong again

Evomela growth continues unabated as the company has reported \$5.7m in sales for Q121. This is up from \$3.4m in Q120 and \$4.8m in Q420. CASI's margins have improved substantially given its new supplier as costs of revenue have reduced to \$2.4m in Q121 from \$3.2m in Q120. The company continues to guide towards 50% growth in product sales (~\$22.5m) for 2021, which we expect it to exceed.

Sourcing new treatments for hematologic disease

CASI continues to execute on its strategy of in-licensing new assets. It recently acquired the rights to CB-5339 in mainland China (as well as Taiwan, Hong Kong and Macau) from Cleave Therapeutics, a private pharma company based in San Francisco, for \$5.5m upfront, \$74m in milestones and mid-single to mid-double-digit royalties. The drug is an inhibitor of valosin-containing protein (VCP)/p97 and is being tested in a Phase I dosing study in acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) patients.

Pipeline continues to progress

The company currently has four assets being tested in clinical studies, including CB-5339. The majority of these assets, like CB-5339, are being developed primarily by partners at this time. These include the other recent acquisition BI-1206 from BioInvent, in Phase I for non-Hodgkin lymphoma (NHL), and CNCT19, the CAR-T therapy in pivotal trials run by partner Juventas. But CASI has also started Phase I studies in March 2021 on its proprietary drug for multiple myeloma CID-103, which will enroll its first patient in May 2021.

Valuation: \$498m or \$3.56 per share

Our valuation is largely flat: down slightly on the whole to \$498m from \$500m, but up on a per share basis, at \$3.56 from \$3.54. Rolling forward our net present values (NPVs) was offset by lower net cash (\$77.1m from \$90.8m). We include \$20m as an additional financing requirement in 2022 for the company prior to profitability in 2024.

18 May 2021

Price

US\$1.5

Market cap

US\$203m

Net cash (\$m) at 31 March 2021	77.13
Shares in issue	139.8m
Free float	72%
Code	CASI
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance



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

Phase I CAR-T studies complete	Imminent
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A multifaceted strategy

What sets CASI apart from many other small to medium sized drug developers is that it is advancing a large number of independent programs at the same time. These include commercial operations, such as the growing sales of Evomela in China, as well as the company's development activities with four ongoing clinical studies. Finally, the company also continues to expand its pipeline with the identification of new assets to license.

A major operational focus of the company is the continued expansion of its sales footprint in China. CASI currently markets Evomela in China. The drug is a proprietary formulation of melphalan developed by Spectrum Pharmaceuticals that is used as a conditioning treatment for patients undergoing hematopoietic stem cell transplantation (HSCT), predominantly for multiple myeloma. It is the only melphalan product currently approved in China. CASI reported with its Q121 results that the drug had \$5.7m in sales during the period, which shows a strong growth trend. This is up from \$3.2m in Q120 and \$4.8m in Q420. The company reiterated its guidance that it expects 50% growth in Evomela sales in 2021 (~\$22.5m from \$15.0m in 2020), which we think should be achievable even if further growth slows. We currently forecast \$25.6m in 2021 sales. The company's margins are also substantially improved over prior periods: costs of revenue were \$2.4m in Q121 from \$3.2m in Q120. This is predominantly because CASI was using a short-term supplier previously, but has transitioned to a dedicated manufacturer.

During Q121, CASI in-licensed the Chinese rights to investigational drug CB-5339 from Cleave Therapeutics. CB-5339 is an anti-cancer drug with potential applicability to both solid tumors and hematologic neoplasms. It is an inhibitor of VCP/p97, a protein involved in the maintenance and degradation of other proteins in the cell. Its inhibition can induce DNA damage, to which cancer cells are sensitive. The protein's primary function is to isolate certain proteins and traffic them to degradation in the proteasome. We therefore expect the profile of the drug (if it is active) to resemble that of proteasome inhibitors such as Velcade (bortezomib, Takeda). Drugs of the proteasome inhibitor class are used in the treatment of multiple myeloma and indolent N, such as mantle cell lymphoma. These drugs as a class have significant adverse effect profiles that include cytopenias, gastrointestinal upset and peripheral neuropathy, among others. A drug such as CB-5339 may be a viable alternative to proteasome inhibitors if it can improve on this adverse effect profile.

CB-5339 marks the fourth product the company has licensed that is currently in the clinic. These include the other recent acquisition BI-1206 from BioInvent, in Phase I for NHL, and CNCT19, a CAR-T therapy run by partner Juventas. CNCT19 is the most advanced-stage development asset and is in pivotal studies. Additionally, the company has stated that it intends to release data from the earlier Phase I studies of CNCT19 in 2021, as these studies were slated to complete in Q121. The company also initiated a Phase I study of its wholly owned asset CID-103 in March 2021, and it expects to enroll the first patient in May 2021. R&D spending for Q121 was reported as \$5.3m, up from \$3.0m in Q120. We expect these expenses to continue at approximately this level through 2021 (estimated 2021 R&D \$20.4m). This would be up from \$11.5m in 2020.

CASI ended the period with \$77.1m in net cash. This follows the company's earlier 24 March offering of \$32.5m gross (at \$2.05 per share for 15.85m new shares), as well as the \$11m cost of the transaction with Cleave Therapeutics (which included \$5.5m upfront and a \$5.5m investment in Cleave through a convertible note). We continue to include \$20m as an additional financing requirement in 2022 for the company prior to profitability in 2024 (recorded as illustrative debt), although the company may want to raise additional capital for the execution of additional licensing deals.

Valuation

Our valuation is largely flat: down slightly on the whole to \$498m from \$500m previously, but up on a per share basis to \$3.56 from \$3.54. Our share count is slightly lower (140m from 141m previously) following the final share count after the offering was complete (as reported in the Q121 financials). The valuations for the company's individual programs are up on rolling forward our NPVs, and this is offset by lower net cash (\$77.1m at the end of Q121, which includes liquid investments, from \$90.8m previously). Our valuation assumptions remain unchanged otherwise.

Exhibit 1: Valuation of CASI

Portfolio	Asset	Region	Peak sales (\$m)	Margins	Clinical risk adjustment	Value (\$m)
Hematology	Evomela	China	39.1	50%	100%	94.31
	Zevalin	China	25.5	64%	90%	45.83
	Thiotepa	China	8.8	39%	90%	4.86
	CID-103	China, US & Europe	766.6	59%	10%	42.26
	CNCT19	China	306.2	up to 50% profit share	10%	27.62
	BI-1206	China	249.9	59%	10%	18.29
	CB-5339	China	77.3	52%	10%	10.20
Other products	ANDA portfolio	China & US	142.0	47%	100%	186.29
	Octreotide LAI	China	15.7	41%	80%	13.05
Total						442.72
Net cash and equivalents (Q121) (\$m)						77.13
Noncontrolling interest (\$m)						(22.16)
Total firm value (\$m)						497.69
Total shares (m)						139.80
Value per basic share (\$)						3.56
Dilutive warrants and options (m)						16.75
Value per diluted share (\$)						3.47

Source: CASI reports, Edison Investment Research

Exhibit 2: Financial summary

	\$'000s	2019	2020	2021e	2022e
Year end 31 December		US GAAP	US GAAP	US GAAP	US GAAP
INCOME STATEMENT					
Revenue		4,131.0	15,141.0	25,750.0	28,791.2
Cost of Sales		(3,935.0)	(9,508.0)	(6,402.5)	(7,162.8)
Gross Profit		196.0	5,633.0	19,347.5	21,628.4
EBITDA		(37,495.0)	(41,361.0)	(23,086.1)	(22,838.4)
Normalised operating profit		(38,098.0)	(41,923.0)	(23,223.6)	(23,771.2)
Amortization of acquired intangibles		(1,550.0)	(1,397.0)	(1,397.0)	(1,397.0)
Exceptionals		0.0	(385.0)	0.0	0.0
Share-based payments		(7,310.0)	(7,821.0)	(7,821.0)	(7,821.0)
Reported operating profit		(46,958.0)	(51,526.0)	(32,441.6)	(32,989.2)
Net Interest		1,062.0	866.0	0.0	0.0
Joint ventures & associates (post tax)		0.0	0.0	0.0	0.0
Exceptionals		534.0	3,149.0	0.0	0.0
Profit Before Tax (norm)		(36,502.0)	(37,908.0)	(23,223.6)	(23,771.2)
Profit Before Tax (reported)		(45,362.0)	(47,511.0)	(32,441.6)	(32,989.2)
Reported tax		0.0	0.0	6,488.3	6,597.8
Profit After Tax (norm)		(36,502.0)	(37,908.0)	(23,223.6)	(23,771.2)
Profit After Tax (reported)		(45,362.0)	(47,511.0)	(25,953.3)	(26,391.4)
Minority interests		(670.0)	(776.0)	0.0	0.0
Discontinued operations		0.0	0.0	0.0	0.0
Net income (normalised)		(37,172.0)	(38,684.0)	(23,223.6)	(23,771.2)
Net income (reported)		(46,032.0)	(48,287.0)	(25,953.3)	(26,391.4)
Basic average number of shares outstanding (m)		96	110	137	144
EPS - basic normalised (c)		(38.74)	(35.04)	(16.96)	(16.54)
EPS - diluted normalised (c)		(38.74)	(35.04)	(16.96)	(16.54)
EPS - basic reported (c)		(47.98)	(43.73)	(18.96)	(18.36)
Dividend (c)		0.00	0.00	0.00	0.00
BALANCE SHEET					
Fixed Assets		41,130.0	53,709.0	71,674.5	84,824.2
Intangible Assets		16,895.0	13,210.0	22,813.0	21,416.0
Tangible Assets		985.0	2,062.0	13,991.5	28,538.2
Investments & other		23,250.0	38,437.0	34,870.0	34,870.0
Current Assets		61,501.0	74,025.0	65,894.9	54,404.5
Stocks		4,542.0	1,356.0	2,104.9	2,354.9
Debtors		1,293.0	4,645.0	4,232.9	4,732.8
Cash & cash equivalents		54,246.0	66,373.0	57,977.1	45,736.8
Other		1,420.0	1,651.0	1,580.0	1,580.0
Current Liabilities		(7,947.0)	(7,976.0)	(8,320.9)	(8,550.5)
Creditors		(5,113.0)	(3,669.0)	(4,013.9)	(4,243.5)
Tax and social security		0.0	0.0	0.0	0.0
Short term borrowings		0.0	0.0	0.0	0.0
Other		(2,834.0)	(4,307.0)	(4,307.0)	(4,307.0)
Long Term Liabilities		(1,019.0)	(16,185.0)	(16,894.0)	(36,894.0)
Long term borrowings		0.0	0.0	(709.0)	(20,709.0)
Other long term liabilities		(1,019.0)	(16,185.0)	(16,185.0)	(16,185.0)
Net Assets		93,665.0	103,573.0	112,354.5	93,784.2
Minority interests		20,670.0	22,033.0	22,164.0	22,164.0
Shareholders' equity		72,995.0	81,540.0	90,190.5	71,620.2
CASH FLOW					
Op Cash Flow before WC and tax		(37,495.0)	(41,361.0)	(23,086.1)	(22,838.4)
Working capital		4,452.0	(3,318.0)	8.1	(520.3)
Exceptional & other		9,800.0	18,793.0	6,488.3	6,597.8
Tax		0.0	0.0	0.0	0.0
Net operating cash flow		(23,243.0)	(25,886.0)	(16,589.7)	(16,760.9)
Capex		(7,053.0)	(1,499.0)	(12,067.0)	(15,479.4)
Acquisitions/disposals		(21,005.0)	(21,529.0)	(11,000.0)	0.0
Net interest		0.0	0.0	0.0	0.0
Equity financing		3,545.0	45,904.0	30,481.0	0.0
Dividends		0.0	0.0	0.0	0.0
Other		20,000.0	2,309.0	71.0	0.0
Net Cash Flow		(27,756.0)	(701.0)	(9,104.7)	(32,240.3)
Opening net debt/(cash)		(83,617.5)	(54,245.5)	(66,372.5)	(57,267.8)
FX		(1,328.0)	2,895.0	0.0	0.0
Other non-cash movements		(288.0)	9,933.0	0.0	0.0
Closing net debt/(cash)		(54,245.5)	(66,372.5)	(57,267.8)	(25,027.6)

Source: CASI reports, Edison Investment Research

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