EDISON

CASI Pharmaceuticals

Earnings update

Continuing to advance and expand the pipeline

Pharma & biotech

The year 2020 was one of challenges for CASI, as it was for the rest of the world, but the company was able to continue to advance the commercialization of Evomela and jumpstart its clinical development engine. CASI is continuing to execute on its strategy of opportunistically in-licensing assets and the recent trend has been to earlier-stage assets such as its latest acquisition, the Chinese rights to the Phase I broad spectrum anti-cancer drug CB-5339, announced in March.

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.

CB-5339: A novel drug for a range of tumors

CASI 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. Additionally, CASI made a $5.5m investment in Cleave through a convertible note. The drug is an inhibitor of valosin-containing protein (VCP)/p97 and has the potential for activity in hematologic and solid tumors. It is in a Phase I dosing study in acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) patients (sponsored by Cleave) and an NCI-sponsored study in hematologic and solid tumors.

Continued focus on early-stage assets

CASI has described its business-development strategy as opportunistic and the products it has licensed for the Chinese and worldwide markets are from a range of classes, from market-ready products such as Evomela, to generics. However, the recent trend has been to license early-stage assets. CASI has four assets being tested in Phase I, including CID-103, which entered the clinic in March 2021.

More money to support increased development

CASI ended 2020 with $57.1m, recently bolstered with a $32.5m (gross) offering (at $2.05 per share for 15.85m new shares). This has significantly offset our expected future financing for the company (reduced to $20m from $55m). However, we expect CASI to continue to deploy this cash in strategic ways to advance its pipeline through the in-licensing of assets.

Valuation: Increased to $500m from $431m

We have increased our valuation to $500m or $3.54 per share, from $431m or $3.47 per share, previously, driven by increased cash, increased probability of success for CIB-103 (to 10% from 5%) and the addition of CB-5339. The per share amount is only slightly changed given the increased shares outstanding.

6 April 2021

Price	**US$2.15**
Market cap	**US$301m**

Net cash ($m) at 31 December 2020	57.1
Shares in issue	139.8m
Free float	70.5
Code	CASI
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(5.3)	(22.9)	15.0
Rel (local)	(10.8)	(29.6)	(29.8)

52-week high/low	US$3.6	US$1.5

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

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Edison profile page

The new drug

On 8 March 2021, CASI announced it has in-licensed the Chinese rights to the 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 non-Hodgkin lymphomas, 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 is being evaluated in a Phase I dosing study in patients with AML and MDS sponsored by Cleave Therapeutics. Additionally, it is in a Phase I study sponsored by the National Cancer Institute, investigating it for lymphomas and solid tumors. CASI will be obligated to perform the clinical studies necessary for approval in China, but we expect this to be relatively limited in scope, such as a relatively small bridging study (eg, n=30). The company intends to file for clinical trial authorization in China sometime in the next year.

This drug continues the recent trend of the company to in license early-stage assets. The economics of such deals can be much more attractive that later-stage assets (which typically command much higher up-front costs), albeit with higher development risk. Moreover, in the case of CB-5339 and the company's other most recent acquisition, BI-1206, CASI has a relatively limited clinical commitment. In both cases, the pivotal studies will be supported primarily by the company's partners, and although we expect CASI to enroll patients for these studies in China, the cost will be much smaller than if it were itself running the entire clinical program. Through these early-stage licensing agreements, the company has been able to assemble a relatively large pipeline of programs. We expect CASI to continue to use this strategy to deploy some of the capital from its recent offering (described below) to support the continued pipeline development.

Valuation

We have increased our valuation to $500m or $3.54 per basic share, from $431m or $3.47 per basic share, previously. A major factor driving this valuation is the increase in net cash ($90.8m pro forma, compared to $57.1m previously) following the offering announced on 24 March. We assume the underwriters of the offering will use the full greenshoe (underwriters' options to purchase 2.38m shares for up to 30 days), which is still available at the time of this report (resulting in $35.4m total net proceeds). The pro-forma net cash value also includes the cost of the Cleave transaction ($11m total) and the company's liquid investments ($9.3m at the end of 2020). Another major factor driving the increased valuation is that we have increased the probability of success for CID-103 to 10% from 5%, as this product has now entered clinical trials. This increased the valuation for this asset to $41.0m from $14.9m previously.

We have added CB-5339 to our model, with an initial valuation of $10.1m. We assume for the initial indication the drug will be approved for AML. We assume the drug will be launched in 2028 with a price of US$37,000 per patient. This is a significant discount to the pricing for similar agents in

Western countries. For instance, Venclexta (venetoclax, AbbVie) has an estimated price of $122,000 in the US (Evaluate Pharma). We model a 30% peak penetration into the AML market if the drug is successful. We estimate a probability of success of 15%, which is average for drugs in Phase I dosing studies. Our model includes royalties payable to Cleave (10% on average) and $40m of the $74m in planned milestones ($20m clinical/regulatory and $20m sales based). We assume CASI will be responsible for development activity in China and this will be supported with a small (30-patient) bridging study run concurrently with the pivotal Phase III study (supported by Cleave). In addition, our line item for CB-5339 includes the convertible note issued to Cleave ($5.5m), valued at cost.

Exhibit 1: Valuation of CASI

Portfolio	Asset	Region	Peak sales ($m)	Margins	Clinical risk adjustment	Value ($m)
Hematology	Evomela	China	39.1	50%	100%	92.09
	Zevalin	China	25.5	64%	90%	44.75
	Thiotepa	China	8.8	39%	90%	4.75
	CID-103	China, US & Europe	766.6	59%	10%	41.03
	CNCT19	China	306.2	up to 50% profit share	10%	26.82
	BI-1206	China	249.9	59%	10%	17.76
	CB-5339	China	77.3	52%	10%	10.07
Other products	ANDA portfolio	China & US	142.0	47%	100%	180.88
	Octreotide LAI	China	15.7	41%	80%	12.75
Total						430.90
Net cash and equivalents (Q420 unaudited) ($m) pro-forma of Q121 financing and Cleave transaction						90.81
Noncontrolling interest ($m)						(22.03)
Total firm value ($m)						499.68
Total shares (m) assuming underwriters exercise full greenshoe						141.23
Value per basic share ($)						3.54
Dilutive warrants and options (m)						16.75
Value per diluted share ($)						3.45

Source: CASI reports, Edison Investment Research

Financials

As mentioned above, CASI performed an offering in March 2021 that raised $32.5m gross (at $2.05 per share for 15.8m new shares). This substantially reduces our expected financing requirement for the company to $20m from $55m (which we include in 2022 as illustrative debt). We expect CASI to deploy at least a portion of this capital through the continued expansion of its pipeline, so the company may raise additional capital beyond this, but we expect these deals to be accretive.

Other changes to our model are largely to align it with the company's recently published annual report, and these changes have little impact on our forecasts. For a more detailed breakdown of our revenue forecasts, see our previous report on the company's preliminary earnings. The company reported an operating loss of $51.5m, but $17.8m of this amount was payments associated with its licensed programs. We expect recurring operating expenses to expand in 2021 (to $51.8m), but to be offset by increased gross profit from Evomela ($19.3m) for an expected FY21 operating loss of $32.4m. This increase in expenses is associated with its ongoing development programs, which we expect will now be less hindered by COVID-19.

Exhibit 2: Financial summary

$'k	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)	(22,889.1)
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	74,481.4	87,628.5
Intangible Assets	16,895.0	13,210.0	17,313.0	15,916.0
Tangible Assets	985.0	2,062.0	13,231.4	27,775.5
Investments & other	23,250.0	38,437.0	43,937.0	43,937.0
Current Assets	61,501.0	74,025.0	70,905.1	59,421.4
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	62,987.3	50,753.7
Other	1,420.0	1,651.0	1,580.0	1,580.0
Current Liabilities	(7,947.0)	(7,976.0)	(8,320.9)	(8,554.7)
Creditors	(5,113.0)	(3,669.0)	(4,013.9)	(4,247.7)
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)	(16,185.0)	(36,185.0)
Long term borrowings	0.0	0.0	0.0	(20,000.0)
Other long term liabilities	(1,019.0)	(16,185.0)	(16,185.0)	(16,185.0)
Net Assets	93,665.0	103,573.0	120,880.5	102,310.2
Minority interests	20,670.0	22,033.0	22,033.0	22,033.0
Shareholders' equity	72,995.0	81,540.0	98,847.5	80,277.2
CASH FLOW				
Op Cash Flow before WC and tax	(37,495.0)	(41,361.0)	(23,086.1)	(22,889.1)
Working capital	4,452.0	(3,318.0)	8.1	(516.1)
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)	(16,807.4)
Capex	(7,053.0)	(1,499.0)	(11,306.8)	(15,426.2)
Acquisitions/disposals	(21,005.0)	(21,529.0)	(5,500.0)	0.0
Net interest	0.0	0.0	0.0	0.0
Equity financing	3,545.0	45,904.0	35,440.0	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)	2,114.5	(32,233.6)
Opening net debt/(cash)	(83,617.5)	(54,245.5)	(66,372.5)	(62,987.0)
FX	(1,328.0)	2,895.0	0.0	0.0
Other non-cash movements	(288.0)	9,933.0	(5,500.0)	0.0
Closing net debt/(cash)	(54,245.5)	(66,372.5)	(62,987.0)	(30,753.4)

Source: CASI reports, Edison Investment Research

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