EDISON

CASI Pharmaceuticals

Business update

CASI acquires an early stage CD38 mAb

Pharma & biotech

CASI announced on 17 April 2019 that it had in-licensed the novel CD38 monoclonal antibody TSK011010 from Black Belt Therapeutics. The deal includes a €7m upfront (€5m cash and €2m equity investment) and undisclosed milestones and royalties. The drug is in the pre-IND stage but CASI noted that the IND-enabling studies are complete and it expects to submit IND/IMPD applications at the end of 2019 or early 2020.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/17	0.0	(10.1)	(0.16)	0.0	N/A	N/A
12/18	0.0	(20.0)	(0.24)	0.0	N/A	N/A
12/19e	9.0	(16.8)	(0.17)	0.0	N/A	N/A
12/20e	33.5	(2.9)	(0.03)	0.0	N/A	N/A

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

Goal: Improve on Darzalex profile

CD38 has already been established as an active target for the treatment of hematological malignancies. Darzalex (daratumumab, Janssen) is an anti-CD38 monoclonal antibody that was approved in 2015 for the treatment of relapsed multiple myeloma. The drug generated $2.0bn in sales in 2018. However, Darzalex is associated with frequent adverse events such as infections, GI side effects, muscle spasms and infusion reactions. CASI stated that the goal with the TSK011010 is to improve on this profile while retaining activity.

Drug formerly an asset owned by Tusk

The new drug TSK011010 was formerly an asset of Tusk Therapeutics, which was acquired by Roche in 2018 for a €70m upfront payment. The acquisition was focused on Tusk's CD25 antibody and the remaining assets were spun off into Black Belt. In addition to multiple myeloma, Tusk investigated the drug in preclinical studies of solid tumors, although CASI has not guided towards this direction.

A shift toward developing a hematology portfolio

The in-licensing of this drug marks a change from previous strategies that CASI has employed. CASI's primary strategy has been to in-license drugs already approved in the US to expedite its regulatory process in China. However, the company has indicated with this asset that it intends to build on its other hematologic oncology assets from Spectrum to build a fully fledged hematology portfolio for the global market and is willing to undertake start-to-finish clinical development.

Valuation: Increased to $680m or $7.11/basic share

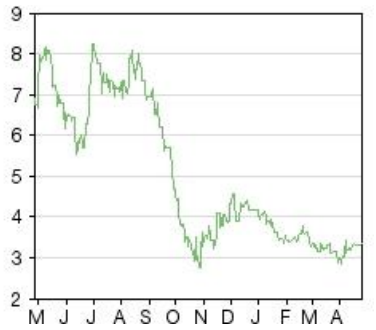
We have increased our valuation to $680m ($7.11 per basic share) from $675m ($7.06 per basic share) due to the inclusion of the new drug in our model, offset by the transaction cost. Our initial probability of success is 5% (our basic assumption for drugs at this stage), but we expect to increase this as TSK011010 progresses in the clinic. We forecast commercialization in 2028 and peak sales of $747m.

26 April 2019

Price	**US$3.34**
Market cap	**US$320m**

Net cash ($m) at YE18 less transaction costs	75.78
Shares in issue	95.7m
Free float	44.83
Code	CASI
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	6.0	(3.7)	(48.3)
Rel (local)	1.4	(12.3)	(53.4)
52-week high/low	US$8.23	US$2.77	

Business description

CASI Pharmaceuticals is a pharmaceutical company that has acquired or licensed a series of drugs that it intends to market in China. These include proprietary drugs licensed from Spectrum Pharmaceuticals and a portfolio of ANDAs. The goal is to seek approval through new pathways that have been opened in the quickly changing Chinese regulatory environment.

Next events

Evomela launch	Mid-2019
TSK011010 IND/IMPD filing	Late 2019/early 2020

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Edison profile page

CASI to expand its clinical development

CASI recently announced that it had in-licensed the rights to the anti-CD38 antibody TSK011010 from Black Belt Therapeutics. Black Belt was recently spun off from Tusk Therapeutics when the latter merged with Roche in September 2018 (for €70m upfront and €585m in milestones) to acquire an unrelated asset (an anti-CD25 antibody). Tusk/Black Belt previously completed preclinical studies of the drug and CASI plans to submit IND and IMPD applications in late 2019 or early 2020. CASI will assume all development responsibility for the asset.

CD38 is a cell-surface protein expressed on a range of white blood cells, including the malignant B-cells present in multiple myeloma. The strategy of targeting CD38 has already been vetted clinically. The drug Darzalex (daratumumab, Janssen) is an anti-CD38 antibody that was approved in 2015 in the US for the treatment of multiple myeloma and had sales of $2.0bn in 2018. Inclusion of the drug in a regimen of lenalidomide and dexamethasone significantly improved progression free survival (HR=0.37, p<0.0001, median not reached at 21 months). However, despite its success Darzalex has been limited in part by its tolerability profile. The drug is associated with high rates of infusion reactions (48% as a monotherapy), fatigue (39%), back pain (23%), nausea (27%), vomiting (17%) and infections (20% upper respiratory, 15% nasopharyngitis, 11% pneumonia). There is ample room to improve on these results, particularly in the area of safety and tolerability.

There are a small number of other CD38 antibodies in clinical development (Exhibit 1), the most advanced of which is isatuximab (Sanofi), which recently reported positive results for its pivotal Phase III study in February 2019 (although the company has not reported detailed data).

Exhibit 1: Other anti-CD38 programs

Drug	Stage	Sponsor
Darzalex	Approved	Janssen
Isatuximab	Phase III complete	Sanofi
MOR202	Phase II	MorphoSys, I-Mab
TAK-079	Phase I	Takeda
TSK011010	Preclinical	CASI

Source: Evaluate Pharma

In addition to the obvious indication of multiple myeloma, TSK011010 has been investigated in preclinical studies for activity in solid tumors. CD38 is expressed in certain solid tumor cells and is believed to play a role in avoiding an anti-tumor immune response. Janssen also explored this possibility in the clinic combining the PD-L1 inhibitor Tecentriq (atezolizumab) with Darzalex for the treatment of non-small cell lung cancer (NSCLC). However, the study was terminated in May 2018 after finding higher mortality in the treatment arm, but there are other combination studies in solid tumors that remain ongoing.

The acquisition of this drug is different from the company's previous strategy to acquire or in-license mature drugs and seek approval in China via new regulatory regimes in that country. However, it is consistent with the company's previous acquisition of hematology drugs from Spectrum. The development and approval of TSK011010 will follow a more traditional route and will require Phase I through III trials. While we expect the company to seek approval for the drug in China, the major markets will be the US and Europe. However, the company will also be able to add the drug to its portfolio of other hematologic malignancy assets it acquired from Spectrum for marketing in China. It recently received approval in China for Evomela and has a launch planned for mid-2019.

Valuation

We have increased our valuation to $680m ($7.11 per basic share) from $675m ($7.06 per basic share) due to the inclusion of TSK011010 in our model at a present value of $12.6m. This is offset by a reduction in cash associated with the acquisition. There are number of unknown factors regarding the license agreement including future royalty and milestone payments, which are estimated at this time (5% royalty and $230m in development and commercial milestones). We assume pricing on par with Darzalex, which we adjust for future price inflation ($150,000 at launch in 2028). We assume a 5% probability of success, which is based on our standard prior assumptions for a drug at this stage, but we expect to increase this when the drug enters the clinic.

Exhibit 2: Valuation of CASI

Portfolio	Asset	Region	Peak sales ($m)	Margin	Clinical risk adjustment	Value ($m)
Spectrum	Evomela	China	15.5	46%	100%	27.69
	Marqibo	China	8.3	58%	90%	8.65
	Zevalin	China	23.9	64%	90%	48.61
Generics		China and US	212.0	49%	100%	504.93
Internal	ENMD-2076	China and US	25.2	51%	20%	1.90
	TSK011010	China, US and Europe	746.8	59%	5%	12.60
Total						604.38
Net cash and equivalents (YE18 - TSK011010 transaction) ($m)						75.78
Total firm value ($m)						680.16
Total shares (m)						95.72
Value per basic share ($)						7.11
Dilutive warrants and options (est.) (m)						30.21
Value per diluted share ($)						6.13

Source: CASI reports, Edison Investment Research

Financials

The addition of TSK011010 has a relatively limited impact on our near-term forecasts, given the lack of activity we expect in 2019 associated with the asset. We have added the transaction to our 2019 estimates and we have increased our 2020 operating costs (by approximately $1.5m) associated with the IND filing and initial clinical studies. Otherwise our forecasts remain unchanged.

Exhibit 3: Financial summary

$000s	2017	2018	2019e	2020e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
INCOME STATEMENT				
Revenue	0.0	0.0	8,964.9	33,546.7
Cost of Sales	0.0	0.0	(2,479.5)	(8,127.2)
Gross Profit	0.0	0.0	6,485.4	25,419.5
EBITDA	(9,983.1)	(19,402.4)	(16,440.4)	1,624.0
Normalised operating profit	(10,100.9)	(19,767.9)	(16,790.5)	(2,932.8)
Amortization of acquired intangibles	0.0	(1,305.4)	(1,388.8)	(1,388.8)
Exceptionals	0.0	0.0	0.0	0.0
Share-based payments	(650.4)	(6,118.1)	(6,118.1)	(6,118.1)
Reported operating profit	(10,751.3)	(27,191.4)	(24,297.5)	(10,439.8)
Net Interest	1.0	(280.1)	0.0	0.0
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0
Exceptionals	(19.9)	0.0	0.0	0.0
Profit Before Tax (norm)	(10,119.8)	(20,048.1)	(16,790.5)	(2,932.8)
Profit Before Tax (reported)	(10,770.2)	(27,471.6)	(24,297.5)	(10,439.8)
Reported tax	0.0	0.0	0.0	0.0
Profit After Tax (norm)	(10,119.8)	(20,048.1)	(16,790.5)	(2,932.8)
Profit After Tax (reported)	(10,770.2)	(27,471.6)	(24,297.5)	(10,439.8)
Minority interests	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0
Net income (normalised)	(10,119.8)	(20,048.1)	(16,790.5)	(2,932.8)
Net income (reported)	(10,770.2)	(27,471.6)	(24,297.5)	(10,439.8)
Basic average number of shares outstanding (m)	62	85	98	103
EPS - basic normalised (c)	(16.45)	(23.65)	(17.20)	(2.86)
EPS - diluted normalised (c)	(16.45)	(23.65)	(17.20)	(2.86)
EPS - basic reported (c)	(17.51)	(32.41)	(24.89)	(10.18)
Dividend (c)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	1,288.5	20,845.4	48,330.2	71,768.4
Intangible Assets	0.0	18,784.7	25,235.9	23,847.0
Tangible Assets	1,046.5	1,750.6	22,784.3	47,611.3
Investments & other	242.0	310.0	310.0	310.0
Current Assets	43,812.4	92,564.6	48,609.1	21,920.7
Stocks	0.0	0.0	611.4	2,004.0
Debtors	0.0	0.0	1,473.7	5,514.5
Cash & cash equivalents	43,489.9	85,117.0	39,076.4	6,954.6
Other	322.5	7,447.6	7,447.6	7,447.6
Current Liabilities	(5,062.1)	(3,873.9)	(5,582.6)	(6,654.0)
Creditors	(4,316.1)	(968.0)	(4,176.2)	(5,247.6)
Tax and social security	0.0	0.0	0.0	0.0
Short term borrowings	0.0	(1,499.5)	0.0	0.0
Other	(746.0)	(1,406.4)	(1,406.4)	(1,406.4)
Long Term Liabilities	(1,498.8)	(73.6)	(73.6)	(73.6)
Long term borrowings	(1,498.8)	0.0	0.0	0.0
Other long term liabilities	0.0	(73.6)	(73.6)	(73.6)
Net Assets	38,540.1	109,462.5	91,283.1	86,961.4
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	38,540.1	109,462.5	91,283.1	86,961.4
CASH FLOW				
Op Cash Flow before WC and tax	(9,983.1)	(19,402.4)	(16,440.4)	1,624.0
Working capital	3,572.4	(9,780.4)	1,123.1	(4,362.1)
Exceptional & other	8.5	598.9	0.0	0.0
Tax	0.0	0.0	0.0	0.0
Net operating cash flow	(6,402.2)	(28,583.9)	(15,317.3)	(2,738.1)
Capex	(934.7)	(1,131.1)	(21,383.8)	(29,383.8)
Acquisitions/disposals	0.0	(20,642.4)	(7,840.0)	0.0
Net interest	0.0	0.0	0.0	0.0
Equity financing	23,733.9	92,269.8	0.0	0.0
Dividends	0.0	912.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Net Cash Flow	16,397.0	42,824.4	(44,541.1)	(32,121.9)
Opening net debt/(cash)	(25,601.7)	(41,991.7)	(83,617.5)	(39,076.4)
FX	0.0	(1,197.5)	0.0	0.0
Other non-cash movements	(7.0)	(1.0)	0.0	0.0
Closing net debt/(cash)	(41,991.7)	(83,617.5)	(39,076.4)	(6,954.6)

Source: CASI Pharmaceuticals reports, Edison Investment Research

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