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Capstone Therapeutics

Pharma & biotech

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A new class of cardiovascular drug

First clinical data for AEM-28, an Apo-E mimetic, is expected during H214, which could pave the way for continued development in an orphan cardiovascular (CV) indication, although additional funds will likely be needed if data are positive. Preclinical data suggest AEM-28 can lower cholesterol and protect the artery wall; this profile could have utility in broader CV indications, although development is still at an early stage.

A cholesterol buster with protective effects

AEM-28 is a mimetic of Apolipoprotein E (Apo-E), a protein involved in lipid and cholesterol metabolism, which clears postprandial (after eating) lipoproteins. AEM-28 could enhance and increase the ability of the liver to clear these lipoproteins, reducing cholesterol and therefore potentially cardiovascular (CV) risk. In addition it could have a protective effect on the artery wall.

A stone's throw from key AEM-28 catalysts

AEM-28 has completed a Phase Ia study with full data expected in Q314. Safety was observed in the first five escalating doses with the sixth dose still under evaluation. According to the protocol, these safety findings allowed progression to the Phase Ib/IIa multiple ascending dose trial in patients with refractory hypercholesterolemia; data are expected in Q414. AEM-28 is initially being developed for homozygous familial hypercholesterolemia (HoFH), an inherited genetic orphan indication, where both Juxtapid (US approval December 2012; EU approval July 2013; 2013 US sales $48.5m) and Kynamro (US approval January 2013; EU negative opinion; sales undisclosed) were approved based on small, single Phase III trials using a cholesterol reduction endpoint. Capstone believes HoFH could be a $200m market.

Broader potential in significant indications

In preclinical models, AEM-28 has shown more rapid cholesterol clearance than typical cholesterol-lowering drug classes in addition to a reduction in atherosclerosis. This unique profile could have a role in larger indications, potentially including acute coronary syndrome (ACS), peripheral artery disease (PAD) and diabetes.

Valuation: Undemanding EV for CV

Capstone had $5.5m net cash at end-March, suggesting an EV of c $7m, relatively undemanding for a company with a cardiovascular (CV) focus. $1.7m cash is allocated to LipimetiX Development, a joint venture for AEM-28 in which Capstone has 60% ownership. Positive AEM-28 clinical data expected during H214 could trigger a re-rating. However, further funds will be needed for future development.

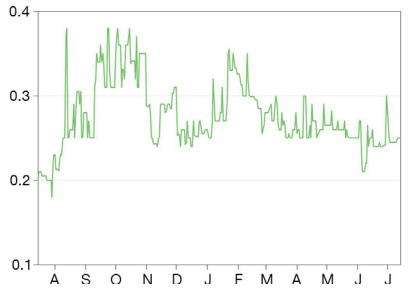
Historic financials

Year end	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E ($)	Yield (%)
12/11	0.0	(9.9)	(0.24)	0.0	N/A	N/A
12/12	0.0	(4.1)	(0.09)	0.0	N/A	N/A
12/13	0.0	(4.1)	(0.10)	0.0	N/A	N/A

Source: Capstone Therapeutics

Price	$0.3
Market cap	$12m

Share price graph



Share details

Code	CAPS
Listing	OTCQB
Shares in issue	40.89m

Business description

Capstone Therapeutics' lead candidate AEM-28 is currently in a Phase I/II clinical trial for orphan disease homozygous familial hypercholesterolemia. AEM-28 also has potential in broader CV indications. Capstone owns 60% of AEM-28 through a JV with LipimetiX Development.

Bull

- Initial target indication could allow for shorter and smaller trials than typical CV development.
- Broader CV disorders and lipid lowering could be significant future markets.
- Upcoming clinical catalysts in H214.

Bear

- Only preclinical data available to date.
- Limited cash to pursue further trials.
- Lawsuit uncertainty relating to bone growth stimulation business, exited in 2003.

Analysts

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