

Capstone Therapeutics

Pharma & biotech

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First human lipid biomarker trends

Early data in healthy volunteers have demonstrated trends in favour of AEM-28 on a number of lipid biomarkers, even at low doses. These are the first-in-man data, which hint at potential future efficacy. AEM-28 continues to be investigated in a Phase Ib/IIa trial, with data anticipated by YE14/Q115. These could pave the way for future development in an orphan cardiovascular indication, although additional funds will likely be needed if data are positive.

Dose dependent lipid biomarker trends in Phase Ia

Full data from the six doses examined in the AEM-28 Phase Ia study have confirmed the acceptable safety profile observed previously. Moreover, biomarker measurements have shown dose dependent trends favouring AEM-28 on a number of lipid parameters, even at low AEM-28 doses. These include total cholesterol, non-HDL cholesterol, VLDL and triglycerides, amongst others. Whilst these are early biomarker data in healthy volunteers, rather than in potential patients, these do offer the first-in-man glimpse into AEM-28's potential efficacy.

Data from ongoing Phase Ib/IIa in Q414/Q115

The Phase Ia trial progressed to the [Phase Ib/IIa](#) multiple ascending dose trial in June following safety data from the first five doses. The protocol was recently expanded to include healthy volunteers with both high cholesterol and BMI (body mass index) in addition to patients with refractory hypercholesterolemia to expedite recruitment. Data from this trial are now anticipated by end Q414/early Q115.

A new class of cardiovascular drug

AEM-28 is a mimetic of Apolipoprotein E, a protein involved in lipid and cholesterol metabolism. AEM-28 is initially being developed for HoFH (homozygous familial hypercholesterolemia), an inherited orphan indication, which Capstone believes could be a \$200m market. Furthermore, AEM-28 has shown more rapid cholesterol clearance than typical cholesterol-lowering drug classes in preclinical models, in addition to atherosclerosis reduction. Earlier-stage AEM-28 analogs with potentially better safety, combined with this profile, could have a role in significant indications such as acute coronary syndrome, peripheral artery disease and diabetes.

Valuation: Undemanding EV for CV

Capstone had \$4.2m net cash at end-June, suggesting an EV of c \$10m, relatively undemanding for a company with a cardiovascular (CV) focus. \$0.8m cash is allocated to Lipimetix Development, a joint venture for AEM-28 in which Capstone has 60% ownership. Positive AEM-28 clinical data could trigger a re-rating.

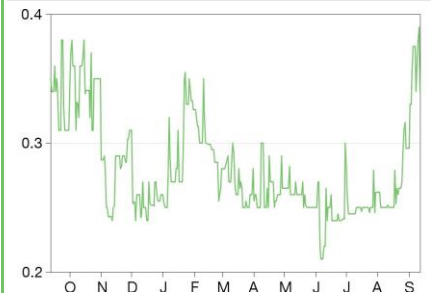
Historic financials

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 **\$0.34**
Market cap **\$14m**

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 and early stage data in healthy volunteers 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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