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Trimel Pharmaceuticals

Pharma & biotech

21 February 2014

Funding ahead of key drivers in H114

Trimel is raising C$10.5m in equity (C$0.711/share) following an 80% share price gain since the US regulatory pathway for CompleoTRT was resolved and agreement disputes with M&P were settled. Further potential returns in H114 will be geared towards the results of the Tefina Phase II ambulatory trial (Q214) and the FDA's decision (PDUFA date 28 May) on CompleoTRT.

CompleoTRT dose and PDUFA date clarified

Trimel decided, following discussions with FDA officials, to focus its CompleoTRT (a testosterone replacement therapy) regulatory submission on a three-times daily (TID) dosing schedule. FDA officials had raised questions over the drug's ability to normalise testosterone in a Phase III study (n=306) when used twice-daily (BID), whereas the TID data were more robust. This pushed the PDUFA target action date back to 28 May 2014 (from 28 February), but in our view improves the product's likelihood of gaining approval. While a TID label could affect convenience vs current topical TR products (generally dosed once-daily), once CompleoTRT is approved, a process to extend the label to BID dosing could be initiated.

Out-licensing deal likely to hinge on FDA decision

Added clarity on the CompleoTRT approval strategy should improve Trimel's prospects in partnering discussions, although we believe a transaction is more likely to occur after FDA approval (given de-risking benefits for a potential licensee).

Tefina ambulatory study results in late Q214

Trimel recently completed recruitment for the 240-patient, 84-day Tefina ambulatory Phase II study in anorgasmia/female orgasmic disorder (FOD). Positive results in Q214 could lead to partnership discussions and future trials. While there is little clarity on acceptable FDA endpoints for FOD, the FDA's recent guidance to Sprout Pharmaceuticals for a re-submission of a previously rejected FSD drug candidate, flibanserin, signals a potentially more flexible stance by the regulator on FSD drugs.

Valuation: Recovering EV of C$101m

Trimel's shares have now recovered the losses suffered in October 2013 when the FDA queried the CompleoTRT NDA. We estimate that after the capital raise and a US$4.25m payment to M&P Patent to settle their legal disputes, current net cash (pro forma) is ~US$17.5m. This should be sufficient to fund operations into Q414, and provide the flexibility to assess different out-licensing options for CompleoTRT.

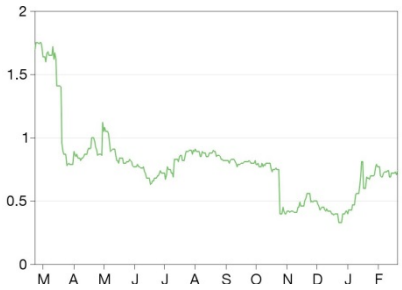
Consensus estimates

Year end	Revenue (US$m)	PBT (US$m)	EPS (US$)*	DPS (US$)	P/E (x)	Yield (%)
12/11	0.0	(26.01)	(0.39)	0.0	N/A	N/A
12/12	0.0	(28.13)	(0.32)	0.0	N/A	N/A
12/13e	0.0	(28.60)	(0.23)	0.0	N/A	N/A
12/14e	5.12	(21.13)	(0.08)	0.0	N/A	N/A

Source: Bloomberg. Note: *Does not reflect February 2014 private placement.

Price	C$0.74
Market cap	C$121m
	C$1.10/US$

Share price graph



Share details

Code	TRL
Listing	TSX
Shares in issue	163.1m (post 14.8m private placement)

Business description

Trimel Pharmaceuticals is a Canadian specialty pharmaceutical firm. Its lead products, CompleoTRT and Tefina, both deliver testosterone through a bio-adhesive intranasal gel drug delivery platform for male hypogonadism and female sexual dysfunction (FSD)/female orgasmic disorder (FOD), respectively.

Bull

- CompleoTRT different from competitors, may avoid a "black box" label warning.
- Tefina targets an area of high unmet need and has positive data from the VTS study.
- CompleoTRT Phase III study met FDA guidance for testosterone replacement (TR) therapy.

Bear

- Uncertainty for CompleoTRT approval and timing given FDA concerns on BID-to-TID titration group and increasing scrutiny on long-term health risks (eg cardiovascular) associated with TR therapy.
- Financing likely required before year end 2014 unless CompleoTRT partnership deal is finalised.
- Uncertainty on acceptable endpoints by regulators for FSD/FOD.

Analysts

Pooya Hemami	+1 646 653 7026
Christian Glennie	+44 (0)20 3077 5727
Robin Davison	+44 (0)20 3077 5737

healthcare@edisongroup.com

QUICKVIEW NOTES USE CONSENSUS EARNINGS ESTIMATES.

EDISON

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 9258 1161
Level 25, Aurora Place
88 Phillip St, Sydney
NSW 2000, Australia

Wellington +64 (0)48 948 555
Level 15, 171 Featherston St
Wellington 6011
New Zealand