

Trimel Pharmaceuticals

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Endo to partner Natesto

Trimel is partnering its Natesto intranasal gel testosterone replacement therapy (TRT) product in the US and Mexico with Endo Pharmaceuticals, receiving US\$25m upfront and a tiered supply price for manufacturing. Endo's marketed portfolio of TRT products makes it an ideal partner, and Trimel expects to be ready for commercial manufacturing in Q115.

US\$25m upfront; up to US\$165m in milestones

Trimel has secured a licensing deal with Endo, granting it commercialisation rights for Natesto in the US and Mexico. Trimel will receive US\$25m upfront (plus US\$5m for prepaid inventory) and is eligible for up to US\$165m in potential milestones (US\$10m payable if Natesto attains twice-daily [bid] dosage approval, and up to US\$155m on reaching sales targets). Trimel will manufacture Natesto and be entitled to a tiered supply price on product sales, which we estimate will be in a range of 20-30% of net selling price. The deal is expected to close in early 2015.

Endo is an experienced TRT partner

Endo already markets Fortesta testosterone gel (and its authorised generic) as well as Aveed, an injectable long-acting testosterone formulation. Natesto would expand Endo's offering in the space, and its familiarity with marketing TRT products and its existing relationships with prescribing physicians should help optimise Natesto's potential sales reach into the US\$2bn US TRT market. Launch timing is unclear, but Trimel expects to have commercial launch quantities available in Q115.

Cash infusion could pave way for future deals

After paying 18% of the upfront to its licensor for Natesto's drug delivery platform (M&P Patent AG) and paying down US\$5m in debt, Trimel will have ~US\$20m in added cash. The firm is looking at product acquisition opportunities (similar to its Estrace purchase), although it may need to spend US\$3-5m for dose titration studies to convince the FDA to permit bid dosing, and it plans to start further Tefina studies.

Valuation: EV of C\$125m; upside hinging on catalysts

Net debt (at 30 September 2014) was US\$17m, and 9m14 cash burn was US\$18m. While Estrace should add ~US\$7m in yearly cash inflows, the 2015 burn rate will depend on the timing and progress of Natesto launch and the firm's future clinical trial costs (for Natesto and Tefina). Progress on a Natesto launch, updates on twice-daily dosing application and FDA guidance on future Tefina development are key potential catalysts to drive the market valuation.

Consensus estimates (pre Endo deal)

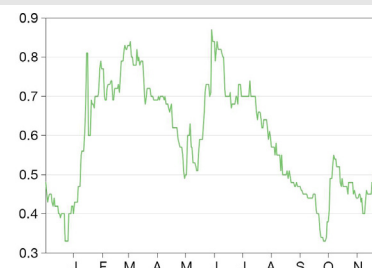
Year end	Revenue (US\$m)	PBT (US\$m)	EPS (US\$)	DPS (US\$)	P/E (x)	Yield (%)
12/13	0	(32.3)	(0.25)	0.0	N/A	N/A
12/14e	3.9	(15.8)	(0.09)	0.0	N/A	N/A
12/15e	16.9	(6.2)	(0.03)	0.0	N/A	N/A

Source: Bloomberg

Price C\$0.53
Market cap C\$106m

C\$1.14/US\$

Share price graph



Share details

Code	TRL
Listing	TSX
Shares in issue	200.9m

Business description

Trimel is a Canadian specialty pharmaceutical company. Natesto and Tefina deliver testosterone through a bio-adhesive nasal gel drug delivery technology platform, for male hypogonadism and female orgasmic disorder (FOD), respectively. Estrace is being marketed for HRT in Canada.

Bull

- Novel nasal delivery platform for Natesto differentiated from competing topical testosterone products by lower transference risk to third parties.
- Tefina targets an area of high unmet need and has encouraging data from Phase II FOD study.
- Sales of Estrace and Natesto should generate revenue and reduce the need for future capital.

Bear

- Possible FDA-directed changes to labelling of testosterone replacement therapy (TRT) products could affect end-user demand.
- Three-times-daily recommended dose is less convenient than once-daily comparators.
- Risk of generic competition for Estrace.

Analysts

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