

Biotech Daily

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MARC SINATRA'S BIOGUIDE ACRUX HEADING FOR SALES

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Overview: Acrux's shares have spent two years in the doghouse after an initial public offering in late 2004 that was generally viewed as overpriced. Since February 1 2007, however, Acrux's share price has made tremendous gains, moving from 77 cents to a high of \$1.76 last month. The price has since fallen a little, but it is still a healthy \$1.55.

The rise in Acrux's share price seems to have been triggered by a number of significant events, but none more so than the FDA approval of the first product incorporating Acrux's technology, Evamist. Although FDA approval is an important achievement, it does not guarantee commercial success. Biota's Relenza, Cellestis' original Quantiferon-TB and Sirtex's Sir-Spheres are testament to that. Ultimately, cash flows from sales determine success.

This begs the question, what factors will influence Acrux's success post regulatory approval of its first product?

Financials: Market cap: \$234 million; cash: approx \$39 million; last half cash burn: \$3.5 million.

Directors & Management: non-executive chairman, Ross Dobinson; non-executive deputy chairman, Ken Windle; CEO & MD, Dr Richard Treagus; non-executive director, Professor Barrie Finnin; non-executive director, Peter Gillooly.

Acrux has a solid board with skills suited to the company's stage of development.

Technology: Acrux's technologies create a reservoir of a drug within the skin, generally via the application of a fast drying spray. The drug is then absorbed into the blood stream from the reservoir. Acrux's technology consists of:

- 1) Across - enhancers which enable the drug to pass into the skin;
- 2) MDTs (metered dose transdermal spray) Applicator - delivery device that directs the drug on to the skin;
- 3) Patchless Patch - a liquid formulation enabling the formation of the drug reservoir within the skin.

Products in Development: The following are Acrux's main products in development, the indication they target and their current or next developmental stage.

- 1) Evamist - menopausal symptoms - product launch end of 2007;
- 2) Testosterone MDTs - decreased libido in women - phase III starting mid-2008;
- 3) Testosterone MD Lotion - hypogonadism - phase III starting by mid-2008;
- 4) Fentanyl MDTs - chronic pain - phase I starting by the end of 2007;
- 5) Contraceptives - phase I next trials starting by the end of 2007;
- 6) Animal Health Products - lead product starting phase III by the end of 2007;
- 7) Women's Health Product - phase I starting late 2008.

Estradiol MDTs (Evamist) is licenced to KV Pharmaceutical and Testosterone MDTs to Vivus for US markets. Worldwide rights to Acrux's technology are licenced to Organon for selected contraceptives and the women's health product, and to Eli Lilly for the animal health products.

Product Markets: In general, the worldwide target markets for Acrux's products are large. The estrogen market is worth \$3 billion, with the value of transdermals put at \$US500 million. Analysts put the women's libido market between \$US500 million and \$US1 billion. The hypogonadism market is \$US550 million, while the transdermal fentanyl market is \$US2-3 billion. The market for companion animals in 2005 was \$US6.8 billion according to Animal Pharm Reports.

There isn't a great deal of product development in Acrux's target markets. Most development is centred on minor changes to existing product formats. One notable exception is Wyeth's contraceptive Lybrel, which attempts to stop menstruation. One reason for the lower level of new product development is the presence of generics in many of these markets. This crowds the market place and reduces margins.

Verdict: Acrux is a good, solid company. It has unique, well-protected and now proven technologies applicable to a variety of drugs. Combine this with first-rate management and you have a formidable combination.

The big questions are: will people buy products using Acrux's technology and what sort of returns will this generate for Acrux?

Acrux's technology will be competing with various combinations of pills, patches and/or gels and, while its technology may provide some safety and efficacy advantages, sales will ultimately be determined by consumer preference. After comparing Acrux's delivery system with the other delivery methods and evaluation of analogous product markets, I expect Acrux's technology to garner significant sales. Experts in many areas think this is probable, given Acrux's impressive list of licencees.

Competition with well-established products and methods of delivery will slow the uptake of products using Acrux's technology. Competition with generics will also limit the ability of licencees to achieve premium prices for their products in most markets. This is likely to impact the amount Acrux has and can charge its licencees. These issues have been factored into my valuation of Acrux.

In the near term, Acrux's share price may weaken as those focused on Evamist's recent regulatory approval exit the stock. I believe this will provide a good buying opportunity before the stock begins to appreciate in anticipation of Evamist's launch and, more importantly, subsequent initial sales. In the not-too distant future, I see Acrux's share price approaching my discounted cash flow valuation of \$2.12. Acrux closed down seven cents or 4.7 percent to \$1.42.

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Marc Sinatra owns shares in Acrux.